

Revision of the World Health Organization's International Health Regulations

By David P. Fidler

April 2004

Recent global infectious disease crises, particularly the 2003 outbreak of Severe Acute Respiratory Syndrome (SARS) [1] and the 2004 epidemic of avian influenza A (H5N1), [2] have elevated the importance of international public health cooperation. Heightened efforts in this area involve reform of the existing international legal framework for infectious disease control. In January 2004, the World Health Organization (WHO) released an interim draft of the revised International Health Regulations (Interim IHR Draft). [3] This Insight describes the Interim IHR Draft and the changes proposed in it for international law on infectious disease control.

Background on the International Health Regulations

WHO originally adopted the International Health Regulations (IHR or Regulations) as the International Sanitary Regulations in 1951. Article 21 of the WHO Constitution (1948) empowers the World Health Assembly (the main policy-making organ of WHO) to adopt "regulations" concerning, among other things, infectious disease control; and the World Health Assembly adopted the International Sanitary Regulations under this authority in order to consolidate in one instrument the many international sanitary conventions negotiated since the late nineteenth century. [4] WHO changed the name of the Regulations to the IHR in 1969 and last revised them in 1983 when it removed smallpox from the IHR's list of diseases. Under Article 22 of the WHO Constitution, Assembly-adopted regulations are binding on all WHO member states except those that notify the Director-General of rejection or reservations within a specified time.

The IHR's purpose is to ensure maximum security against the international spread of disease with minimum interference with world traffic (IHR, Foreword). To achieve maximum security against international disease spread, the IHR requires, among other things, WHO members to (1) notify WHO of outbreaks of specific diseases subject to the Regulations (originally six diseases, reduced to three by 1983); and (2) maintain certain public health capabilities at points of international entry and exit (e.g., the capability to de-rat ships or disinfect aircraft).

To ensure minimum interference with world traffic, the IHR impose maximum measures that WHO members can apply to travelers and trade coming from other WHO members affected by outbreaks of diseases subject to the Regulations. These measures are based on the best available scientific evidence and are designed to justify rational and effective responses from WHO members to outbreaks in other countries.

Revision of the IHR

In 1995, the World Health Assembly instructed the WHO Secretariat to begin the process of revising the IHR. [5] The first half of the 1990s had seen increasing public health concern about “emerging and re-emerging infectious diseases,” [6] and this alarm included the realization that the IHR no longer provided an adequate international legal framework to deal with the mounting microbial threats. Identified weaknesses of the IHR included (1) their application to only three infectious diseases (cholera, plague and yellow fever); (2) the failure of WHO members to notify outbreaks of the diseases subject to the Regulations; (3) WHO’s inability to use information about outbreaks it received from non-governmental sources; and (4) the frequency with which WHO members applied excessive and irrational measures to the trade and travel of other WHO members suffering from outbreaks.

In February 1998, WHO released a provisional draft of revised Regulations, but this draft did not meet with widespread approval among WHO members. [7] Between 1998 and 2003, the IHR revision process continued but was obscured by other developments in international law and public health, such as the battle concerning the effect of pharmaceutical patent protection under the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights on access to essential medicines, especially access to antiretrovirals for AIDS treatment in developing countries.

The SARS outbreak of 2003 accelerated the IHR revision process because the outbreak underscored the need for a new international legal framework for infectious disease control. In May 2003, the World Health Assembly instructed the WHO Secretariat to complete the revision of the IHR and to present the World Health Assembly with the final draft for approval at its 2005 annual meeting. [8] Six months later the WHO released the Interim IHR Draft for governmental and non-governmental review and comments.

The Interim IHR Draft

The Interim IHR Draft is composed of a Foreword and nine parts containing 55 articles. In addition, the Interim IHR Draft has ten annexes that form an integral part of Draft’s rules. This Insight will only describe key substantive changes being proposed in the Interim IHR Draft and will not engage in detailed analysis of the text. More detailed analyses of the Interim IHR Draft are available in other documents. [9]

A revolutionary proposal

The existing IHR follow an international legal approach to infectious disease control that can be traced back to the mid-nineteenth century origins of diplomacy on infectious disease threats. The Interim IHR Draft breaks radically with the traditional approach in a number of respects, and these radical breaks illustrate the extent to which the WHO is responding to the nature of infectious disease threats in the globalized world of the twenty-first century.

Scope of the proposed regime: From specific infectious diseases to public health risks

The traditional approach, embodied in the IHR, has been to address specific infectious disease threats, such as cholera, plague and yellow fever. The Interim IHR Draft proposes instead an approach that differs significantly from the IHR in two respects.

First, the IHR (and the international sanitary conventions that preceded them) addressed only infectious diseases. The Interim IHR Draft defines, by contrast, “disease” to mean “an illness that presents a risk of significant harm to humans caused by biological, chemical or radiological sources” (Article 1.1). This definition reflects the impact of the threat posed by weapons of mass destruction and expands the IHR’s scope to cover areas never before incorporated in this regime.

Second, the Interim IHR Draft abandons a disease-specific approach for a more flexible strategy based on “public health risks,” defined as events “posing a serious and direct threat to the health of human populations” (Article 1.1). The emergence of new infectious disease threats, such as SARS, makes a disease-specific approach too inflexible, as illustrated by the legal irrelevance of the IHR to the SARS and avian influenza outbreaks. By gearing the regime for new public health risks that might appear, WHO hopes to make the legal framework relevant and responsive to whatever public health threats may emerge in the future.

Same end, radically new means

The Interim IHR Draft adopts essentially the same purpose as the existing IHR, but seeks to achieve this purpose through radically different rules. To achieve the purpose of providing security against the international spread of disease while avoiding unnecessary interference with world traffic, [10] the Interim IHR Draft proposes five significant changes.

First, the Interim IHR Draft obliges WHO members to develop and maintain the capacity to detect, report and respond effectively to public health risks and events potentially constituting public health emergencies of international concern (Articles 4.1 and 10.1). Annex 1 of the Interim IHR Draft lays out the core capacities WHO members should develop and maintain for surveillance and response. No such intrusive duties appeared in the traditional international law on infectious disease control.

Second, the Interim IHR Draft requires WHO members to notify WHO of all “events potentially constituting a public health emergency of international concern” (Article 5.1). The traditional approach only required that WHO members notify WHO of outbreaks of specific infectious diseases listed in the Regulations. The Interim IHR Draft proposes, thus, a significant expansion in the scope of surveillance and notification duties for WHO members.

The concept of “events potentially constituting a public health emergency of international concern” is not defined, [11] but the Interim IHR Draft contains a “decision instrument” to guide WHO members (Annex 2). A “yes” answer to any two of the following four questions means that an event potentially constitutes a public health emergency of international concern that the WHO member must notify to WHO: (1) Is the public health impact of the event serious? (2) Is the event unusual or unexpected? (3) Is there a significant risk of international spread? (4) Is there a risk of restrictions on international travel or trade?

Third, the Interim IHR Draft allows WHO “to take into account reports from sources other than notifications or consultations and validate these reports” (Article 7.1). This provision also represents a radical break from the traditional approach under which WHO’s surveillance efforts were restricted to information provided only by governments. WHO’s ability to collect and use non-governmental sources of epidemiological information is a powerful public health tool, as illustrated in the SARS outbreak. [12]

Fourth, the Interim IHR Draft empowers WHO to determine, independently, whether an event constitutes a public health emergency of international concern (Article 9.1). This proposal increases WHO’s power vis-à-vis its members because it authorizes WHO to make judgments about events transpiring in the territories of its members. [13] Again, nothing approaching this proposal appeared in the IHR or the earlier international sanitary conventions.

Fifth, the Interim IHR Draft authorizes WHO to prevent or reduce the international spread of disease and minimize interference with world traffic by making (1) temporary recommendations, in the event WHO determines that a public health emergency of international concern is occurring (Article 11); and (2) standing recommendations with respect to specific, ongoing public health risks (Article 12). [14] The Interim IHR Draft’s abandonment of the disease-specific approach means that the disease-specific “maximum measures” strategy used in the IHR cannot continue in a regime with an expanded scope. The Interim IHR Draft creates, thus, new legal powers for WHO to issue recommendations on how WHO members should handle public health risks and public health emergencies of international concern.

Other provisions in the Interim IHR Draft attempt to bolster the importance of WHO temporary and standing recommendations by prohibiting measures taken against world traffic that are not recommended by WHO or authorized by other applicable international agreements. [15] The Interim IHR Draft also empowers WHO to request “the cessation of measures applied by States in excess of the measures it has recommended, or of inappropriate measures” and the full implementation of recommended measures (Article 35).

Other new proposed provisions

National IHR Focal Point. The Interim IHR Draft requires each WHO member to designate a National IHR Focal Point that “shall remain accessible at all times by WHO

for urgent communications” (Article 3.1). According to the Interim IHR Draft, the National IHR Focal Point “will play a central role in the notification of potential public health emergencies of international concern and in communications with WHO including, when required, the implementation of event-specific temporary recommendations issued by the Organization” (Foreword).

Human Rights. The Interim IHR Draft contains a new provision, Article 36, on human rights the likes of which never appeared in the traditional approach. Article 36.1 provides that the Regulations shall not prejudice rights persons have under applicable international agreements which provide for, or protect, the rights of persons. Article 36.2 states that “[n]o invasive medical examination, vaccination or prophylaxis under these Regulations shall be carried out on travelers without their prior express informed consent.”

Process of Amending Annexes. The Interim IHR Draft proposes that WHO’s Executive Board may approve amendments to annexes by consensus, and such amendments become binding on WHO members pursuant to Articles 21 and 22 of the WHO Constitution (Article 46.2). The Executive Board is composed of 32 individuals selected from the member states who are technically qualified in the field of health. The Board’s main functions are to advise the World Health Assembly and give effect to Assembly decisions. This provision potentially clashes with Article 21 of the WHO Constitution, which provides that the World Health Assembly (not the Executive Board) shall adopt regulations.

Dispute Settlement. The Interim IHR Draft eliminates the option that WHO members can submit disputes concerning the IHR’s interpretation or application to the International Court of Justice. It replaces that procedure with the option to submit disputes to arbitration in accordance with the Permanent Court of Arbitration Optional Rules for Arbitrating Disputes Between States (Article 47.3).

The Interim IHR Draft’s Future

Currently, the Interim IHR Draft is being reviewed by WHO members, which are providing comments to the WHO Secretariat. Based on these comments, the WHO Secretariat will revise the Interim IHR Draft for consideration at formal intergovernmental negotiations to take place in the fall of 2004. The hope is that the intergovernmental negotiations can produce a final draft of the revised IHR that may be presented to the World Health Assembly for adoption in May 2005.

About the Author:

David P. Fidler is Professor of Law and Ira C. Batman Faculty Fellow, Indiana University School of Law, and Senior Faculty, Center for the Law and the Public’s Health, Georgetown and Johns Hopkins Universities. He is currently a Visiting Senior Research Scholar at the Centre for International Studies, University of Oxford.

- [1] For previous Insights on SARS, see David P. Fidler, *SARS and International Law*, April 2003, at www.asil.org/insights/insigh101.htm; and David P. Fidler, *Developments Involving SARS, International Law, and Infectious Disease Control at the Fifty-Sixth Meeting of the World Health Assembly*, June 2003, at www.asil.org/insights/insigh108.htm.
- [2] For a previous Insight on avian influenza, see David P. Fidler, *Global Outbreak of Avian Influenza A (H5N1) and International Law*, January 2004, at www.asil.org/insights/insigh125.htm.
- [3] See World Health Organization, *International Health Regulations: Working Paper for Regional Consultations*, IGWG/IHR/Working Paper/12.2003, Jan. 12, 2004, at www.who.int/csr/revisionprocess/working_paper/en/.
- [4] On the history of international law on infectious disease control between 1851 and 1951, see David P. Fidler, *International Law and Infectious Diseases* (1999), Chapter 2.
- [5] World Health Assembly, *Revision and Updating of the International Health Regulations*, WHA48.7, May 12, 1995.
- [6] The WHO's World Health Report for 1996 was, for example, devoted to the "global crisis" of emerging and re-emerging infectious diseases. See World Health Organization, *World Health Report 1996: Fighting Disease, Fostering Development* (1996).
- [7] For analysis of the February 1998 provisional draft, see Fidler, *supra* note 4, at Chapter 3.
- [8] World Health Assembly, *Revision of the International Health Regulations*, WHA56.28, May 28, 2003.
- [9] See, e.g., Initial U.S. Government Comments on the First Draft of the Proposed Revision of the International Health Regulations (IHRs), March 5, 2004, at www.who.int/csr/ihr/revisionprocess/comments/en/; Center for the Law and the Public's Health, *The Draft Revised International Health Regulations*, March 3, 2004, at www.publichealthlaw.net/Reader/ch12/ch12.htm; and David P. Fidler, *Comments on WHO's Interim Draft of the Revised International Health Regulations*, March 9, 2004, available by request at dfidler@indiana.edu.
- [10] Article 2 of the Interim IHR Draft provides: "The purpose of the International Health Regulations (hereinafter the "IHR" or "Regulations") is to provide security against the international spread of disease while avoiding unnecessary interference with international traffic."
- [11] The Interim IHR Draft only defines "event," which "means a manifestation of disease or an occurrence that creates a potential for disease" (Article 1.1).
- [12] The proposal in Article 7.1 of the Interim IHR Draft would, if adopted, embed in international law a policy of approval for WHO use of non-governmental information in global surveillance, which had been provided on two individual occasions by the World Health Assembly. See World Health Assembly, *Global Health Security: Epidemic Alert and Response*, WHA54.14, May 21, 2001; and World Health Assembly, *Revision of the International Health Regulations*, WHA56.28, May 28, 2003.
- [13] Annex 3 details the procedure through which WHO would exercise this power.
- [14] Annex 3 contains the procedure for the issuance of temporary recommendations, and Annex 10 the procedure for standing recommendations.
- [15] See, e.g., Interim IHR Draft, Articles 19.2, 21.1, 21.2, 23.1, 24, 26, 27.2. See also Article 34, which provides that "States should make every effort not to impose measures exceeding those recommended by WHO under these Regulations."
-

The purpose of ASIL Insights is to provide concise and informed background for developments of interest to the international community. The American Society of International Law does not take positions on substantive issues, including the ones discussed in this Insight.

ASIL Insights may be found on the **[ASIL Web Site](#)**.
Educational copying is permitted with due acknowledgement.