The Revised International Health Regulations and Restraint of National Health Measures

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I. Introduction

Occurring against the backdrop of severe acute respiratory syndrome (SARS), avian influenza and fears of a global influenza pandemic, the revision of the International Health Regulations (IHR or Regulations) is one of the most significant developments in international health law in recent years. The previous Regulations, outdated and notoriously ineffective, have been comprehensively revised, providing a new legal framework for global infectious disease surveillance and control. In May 2005, the World Health Assembly adopted the revised IHR, which will be binding on WHO member states when they come into force in 2007. With major changes to the Regulations’ scope, states’ obligations, and the powers and duties of the World Health Organization (WHO), the revised IHR represent a landmark in the international legal framework relating to health. It has even been suggested that the revision can be seen as part of a transition to a new era in global health governance.1

One important change involves the way in which the revised IHR purport to govern or limit public health measures taken by individual states. The previous Regulations prescribed specific measures to be taken in response to diseases within their scope, and prohibited additional or “excessive” measures. The aim of this restriction was to achieve the main purpose of the IHR, “to ensure the maximum security against the international spread of diseases with a minimum interference with world traffic.”2 This objective remains important, but the means of achieving it have been dramatically changed. This difference and its implications are the main focus of this article. After reviewing the IHR and their revision, it will discuss the old and new approaches to restricting states’ public health measures and balancing maximum security against minimum interference. The revisions to the relevant articles themselves will be examined, but these must also be considered in light of changes to other parts of the Regulations and the evolving global context, and in terms of the change they represent for the role of the IHR and their relationship with the rest of international law.

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1 See David P. Fidler, SARS, Governance and the Globalization of Disease (New York: Palgrave Macmillan, 2004) at 60-67 [Fidler, SARS].

II. The International Health Regulations and their revision

A. The International Health Regulations (1969)

The IHR have long been, and remain, the only binding international legal instrument on global disease surveillance and control. They were adopted under the authority of the WHO Constitution, Article 21 of which provides that the World Health Assembly, the highest decision-making body of the WHO, may adopt regulations on matters including "sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease". According to Article 22 of the same instrument, such regulations are binding on WHO member states unless they advise the Director-General of their rejection or reservation. The IHR (1969) had earlier precursors: a series of International Sanitary Conventions adopted in the second half of the 19th century, later consolidated into the 1951 International Sanitary Regulations, renamed the International Health Regulations in 1969. These Regulations, with only a few minor changes, have remained in place despite widespread and profound changes in the global environment relating to infectious diseases.

Like the earlier conventions upon which they were based, the IHR (1969) deal only with a limited set of specific diseases: plague, cholera and yellow fever. In respect of those diseases, they require states to notify the WHO of any case of the disease within their territory (Article 3). The WHO must also be provided with further information during an epidemic (Article 6) and must be notified of measures taken by each state with respect to arrivals from infected areas and vaccination requirements (Article 8). This information is then to be shared by the WHO with the health administrations of all other member states (Article 11). With respect to each of the three diseases, the Regulations set out measures to be taken by states to prevent the spread of the disease (Part V, Chapters I, II, and III). Part III prescribes minimum standards for sanitation and public health facilities at air and sea ports. Other provisions prescribe mandatory and permitted health measures, including restrictions to be imposed on inbound and outbound international travel or movement of goods (Part IV) and health certificate requirements (Part VI). Article 23 provides that the permitted measures are the maximum measures to be applied, and


5 IHR (1969), supra note 2 at Article 1. The Regulations originally covered six diseases: the current three as well as smallpox, relapsing fever and typhus.

6 Article 22 provides that where “the volume of international traffic is sufficiently important and whenever epidemiological conditions so require” these facilities must also be available at road and railway crossings as well as on inland waterways. Ibid. at Article 22.
the application of certain measures or of measures in certain circumstances is specifically prohibited.

Although they were considered to be a “significant advance” at the time of their adoption, the IHR proved to be of limited effectiveness. Several key weaknesses were perceived, as much within the WHO itself as by external critics. First, the limited scope of the Regulations means that they have been of little or no relevance in most of the major contemporary global public health crises: responses to the HIV/AIDS pandemic, the SARS epidemic and the threat of an influenza pandemic have all fallen outside the scope of the IHR provisions. Second, the record of states’ compliance with the IHR has been poor, both with respect to notifying the WHO of cases of diseases subject to the Regulations and in their application of excessive health measures beyond those permitted by the IHR. This is particularly worrying in conjunction with the third major weakness, which is that the WHO is required, under the existing IHR, to rely on official state notifications, despite the increasing amount of information now available from other sources. This not only limits the Organization’s ability to respond in a timely and effective manner to new outbreaks, but is out of step with recent developments in global surveillance capacity.

B. Revision of the International Health Regulations

The process to revise the IHR formally began in 1995 with a resolution of the World Health Assembly requesting the preparation of revised and updated IHR. Discussion and consultation progressed over the following years, during which various possible concepts and approaches were explored. The experience

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7 Fidler, “Fourth Horseman”, supra note 4 at 836.
9 The WHO’s Global Outbreak Alert and Response Network (GOARN), formally launched in 2000, links over a hundred institutions, organizations and networks from around the world to enable rapid identification of and response to outbreaks. One of the partners in GOARN is the Global Public Health Intelligence Network (GPHIN), a Canadian initiative which continually scans the internet for news of possible outbreaks. Both GOARN and GPHIN gather information from both official and informal, nongovernmental sources. WHO, Global defence against the infectious disease threat, Doc. WHO/CDS/2003.15 (2003) at 58; David L. Heymann & Guénaël Rodier, “Global Surveillance, National Surveillance, and SARS” (2004) 10:2 Emerging Infectious Diseases 173 at 173. However, the WHO’s legal authority to use nongovernmental sources, prior to the revised IHR, is questionable, see discussion in Fidler, SARS, supra note 1 at 63-68.
10 WHO, Revision and updating of the International Health Regulations, WHA Res. 48.7 (12 May 1995).
of the SARS epidemic in 2003 and growing fears of avian influenza and the next influenza pandemic provided the catalyst for renewed efforts. Although the death toll from SARS was low relative to other global health threats, it highlighted both the strengths and weaknesses of global infectious disease surveillance and control. As the “first severe and readily transmissible new disease to emerge in the 21st century”, with an incubation period long enough to allow “spread via air travel between any two cities in the world”, it illustrated the challenges posed by one aspect of globalization: the increase in speed and volume of international travel that can result in a faster and more unpredictable spread of infectious disease. The significance of increased global interconnectedness through information and communications technology was also demonstrated, however, as mobile phones, text messaging, email and the internet played key roles in sharing information about the disease. The importance of unofficial sources of information became clear as the WHO struggled to obtain the cooperation of the Chinese government.

SARS “demonstrate[d] dramatically the global havoc that can be wreaked by a newly emerging infectious disease” but also the importance of effective national and international surveillance and response to the ultimate impact of a global health threat. Although the response to SARS was generally considered to be a success story for the WHO and the international community, the epidemic once again drew attention to the inadequacy of the IHR, which were essentially irrelevant in the case of SARS as they have been for other major health threats. Against this backdrop and with a renewed sense of urgency, work continued on the revisions in 2003 and 2004. Drafts were released for comment in January 2004, September 2004 and January 2005, each being revised in response to consultations and submissions by member states and other international organizations. After meetings of the Intergovernmental Working Group in November 2004 and February 2005, agreement was reached on a text of the revised IHR which was subsequently adopted by the World Health Assembly in May 2005.

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13 See e.g. Fidler, SARS, supra note 1 at 73-74.
14 See ibid., c. 5-6.
15 WHO, Severe acute respiratory syndrome, supra note 12 at 2.
16 Heymann & Rodier, supra note 9.
17 See e.g. WHO, Revision of the International Health Regulations, WHA Res. 56.28 (28 May 2003) at preamble.
19 WHO, Review and approval of proposed amendments to the International Health Regulations: draft revision, WHO Doc. A/IHR/IGWG/3 (30 September 2004) [September 2004 Draft].
20 WHO, Review and approval of proposed amendments to the International Health Regulations (Proposal by the Chair), WHO Doc. A/IHR/IGWG/2/2 (24 January 2005) [January 2005 Draft].
21 Revision of the International Health Regulations, WHA Res. 58.3 (23 May 2005). The revised IHR as adopted, attached to this resolution, are to be referred to as the International Health Regulations (2005) [IHR (2005)].
The stated objective of the revised IHR (2005) is very similar to that of the IHR (1969), with some subtle changes in its expression: “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” (Article 2). However, the means of achieving this objective have changed significantly in a number of respects.

The scope of the revised IHR is much broader and is defined differently. As seen above, the IHR (1969) apply to a short and closed list of three diseases, and this was one of the key weaknesses perceived in the IHR. Early in the revision process it was proposed that the Regulations should require reporting of “a number of defined clinical syndromes”, followed by reports of specific diseases once the diagnosis was confirmed. After this approach was field tested, it was concluded that it “was not appropriate for use in the context of a regulatory framework.” Efforts then shifted to developing “criteria to define what constitutes a health emergency of international concern” (PHEIC), a concept which ultimately was adopted as the main approach to defining the scope of the IHR (2005).

The central notification requirement in Article 6 requires states to notify the WHO of “all events which may constitute a public health emergency of international concern within their territory”. The determination of whether such an event has occurred is to be undertaken using the “decision instrument” set out in Annex 2 of the IHR (2005). Annex 2 contains an “algorithm” (flow-chart diagram) with a series of questions. For any event detected by national surveillance that is of “potential” international concern, it must be asked: (1) whether its public health impact is serious; (2) whether it is unusual or unexpected; (3) whether there is a significant risk of international spread; and (4) whether there is a significant risk of international travel or trade restrictions. If any two of these questions receive an affirmative answer, the event must be notified to WHO. The second part of Annex 2 contains a series of examples to be used in application of each of the algorithm’s four criteria. In addition, the Annex contains a list of diseases to which the algorithm must always be applied, presuming that they are always potentially of international concern. It also contains a further list of diseases that must always be notified, presuming that any occurrence is both unusual or unexpected and serious, and thus a PHEIC.

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22 Compare the IHR (1969), supra note 2 at foreword: “to ensure the maximum security against the international spread of diseases with a minimum of interference with world traffic.”
24 WHO. Revision of the International Health Regulations (Report by the Secretariat), WHO Doc. EB111/34 (15 December 2002).
26 IHR (2005), supra note 21 at Annex 2. The diseases in this list are: cholera, pneumonic plague, yellow fever, viral hemorrhagic fevers, West Nile fever and “diseases that are of special national or regional concern, e.g. dengue fever, Rift Valley fever, and meningococcal disease.”
27 Ibid. The diseases in this list are: smallpox, polio myelitis due to wild-type poliovirus, human influenza caused by a new subtype and SARS.
In cases where notification is not required, states “may nevertheless keep WHO advised”, consult with it “on appropriate health measures”, and request assistance in assessing epidemiological evidence (Article 8). Such consultation and prompt notification are encouraged by making all information received by WHO under Articles 6 and 8 confidential in the first instance, that is, it will not be shared with other member states until a PHEIC is confirmed or unless the risk is too great.\(^{28}\) This is in contrast to the IHR (1969), which require all notifications and other relevant communications automatically to be shared with other states (Article 11).

Allowing for confidential provisional notification and consultation is the first of two key changes to deal with the problem of lack of compliance with notification obligations. The second is the provision of authority for the WHO to take into account “reports from sources other than notifications or consultations” in Article 9. As noted above, a variety of unofficial sources of information have become available with developments in information and communications technology, and are of growing importance in global surveillance, but the WHO’s authority to use this information has been uncertain.\(^{29}\) Article 9 allows the WHO to take account of, assess, and share information received from non-governmental sources. Where such information is received, it will consult with the state concerned and attempt to obtain verification before taking any action, but the information will be shared with other states in accordance with Article 11. States have an obligation under Article 10 to verify reports from other sources of an event potentially constituting a PHEIC by sharing certain information with WHO. Where reports of a potential PHEIC are received, the WHO will offer its assistance and collaboration, and if this offer is refused will share available information with other states. These provisions are designed to decrease the risk of non-compliance with notification obligations and deal with uncooperative governments, since governments know that information reaching the WHO from other sources can be used and disseminated. In addition, the WHO is authorized to release information directly to the public, rather to governments, in some cases.\(^{30}\)

Although governments must use the decision instrument to determine whether to notify the WHO of disease events, the existence of a PHEIC is ultimately determined by the Director-General, in consultation with the state concerned and in the case of disagreement, on the advice of a new body called the Emergency Committee (Article 12). The Emergency Committee’s role is to give its views to the Director-General on the existence and termination of a PHEIC and on any proposed temporary recommendations (Article 48), although the final determina-

\(^{28}\) IHR (2005), supra note 21 at Article 11(2). Information will not be made generally available until the WHO Director-General has determined that a PHEIC exists, international spread of the disease has been confirmed, control measures are unlikely to succeed or cannot be carried out, or immediate international control measures are required.

\(^{29}\) See Fidler, SARS, supra note 1 at 64-65.

\(^{30}\) IHR (2005), supra note 21 at Article 11(4). This applies notifications, consultations, and information provided by other states under Article 9(2), where some information about the event has already become public and “there is a need for the dissemination of authoritative and independent information.”
tion on these matters is made by the Director-General (Article 49(5)). Once a PHEIC has been determined to exist, the Director-General will issue temporary recommendations which may include measures to be taken by the state in which the event is occurring and/or other states “to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic” (Article 15(2)). Standing recommendations may also be issued (Article 16), after taking the advice of a Review Committee (established and governed by Part IX, Chapter III). Articles 17 and 18 set out criteria for recommendations and a (non-exhaustive) range of possible recommendations.

Another major change in the IHR (2005) is the substantial expansion of the requirements for national public health capacities. The IHR (1969) contain a limited set of prescriptions for organization, equipment, facilities, and services required at national ports and airports (Part III). The public health capacities demanded of member states in the IHR (2005) are much more ambitious, reflecting the realization that effective surveillance and response at the national level are ultimately the key to containing outbreaks. States must designate a “National IHR Focal Point” for communication with the WHO and authorities responsible for implementation of health measures (Article 4). Article 5 requires states to “develop, strengthen and maintain” surveillance capacities as set out in Annex 1. Each state party must first assess its capacity and then meet the Annex 1 requirements within five years (with a possibility of extension), with the WHO’s assistance if requested. Article 13 sets out similar requirements in respect of public health response capacities. The WHO is to publish guidelines to support the development of public health response capacities, and will offer additional assistance and collaboration in response to public health risks and any PHEIC. Requirements for authorities and capacities at points of entry are set out in Part IV. Annex 1 contains a list of “core capacity requirements for surveillance and response” and “core capacity requirements for designated airports, ports and ground crossings”.

Like the IHR (1969), the revised Regulations also set out a series of health measures that states may apply to travellers and goods, such as inspection or examination, vaccination, and documentation requirements (Parts V and VI). Part VIII contains general provisions which also deal with limits on health measures and their implementation. These provisions will be the focus of discussion below.

III. Restraining “excessive” or “additional” health measures

A. Why the concern with restraining measures?

As noted above, the IHR (1969) purport to limit the measures taken to prevent the spread of disease. This is one of the crucial aspects of the regime, although it has been largely ineffective. As expressed by the WHO:

The rationale for listing the maximum measures permissible is simple: if a template is not given for protective measures to be taken by other countries in an outbreak situation, then there is great risk of overreaction, which could be damaging to the affected country. Trade, travel
and tourism might well suffer, with economic consequences that extend far beyond the measures necessary from a public health point of view.\footnote{WHO, \textit{Global Crises – Global Solutions}, supra note 4 at 3.}

It is widely recognized that the risk of such disproportionate responses and the resulting economic harm provides a strong disincentive for states to notify outbreaks and cooperate with the WHO. From this perspective, restraining excessive measures is essential to achieving the IHR objective of “maximum security against the international spread of diseases with a minimum interference with world traffic”. The two principles of “maximum security” and “minimum interference” are complementary, “[i]n theory ... integrated to form the overall international legal regime on infectious disease control”.\footnote{Fidler, “Fourth Horseman”, supra note 4 at 843.}

Concern with the economic impact of health measures is far from new. During the “Black Death” plague epidemics in medieval Europe, when quarantine measures began to be systematically applied to travellers and goods, “[o]nce cases of plague began to appear, local health authorities went to great lengths to play down its significance as long as possible to prevent the economic disaster that emergency health measures inflicted on a community” – this despite explicit recognition of “the reciprocal value of the free exchange of information”.\footnote{Dorothy Porter, \textit{Health, Civilization and the State: A history of public health from ancient to modern times} (London: Routledge, 1999) at 39. On the development of quarantine practices, see ibid. at 34ff.} Later, the nineteenth-century efforts to create an international regime dealing with infectious diseases are said to have been motivated primarily by concerns about the impact of quarantine measures on international trade.\footnote{See e.g. Fidler, \textit{SARS}, supra note 1 at 35; Johan Giesecke, “International health regulations and epidemic control” in Richard D. Smith et al., eds., \textit{Global public goods for health: Health economic and public health perspectives} (Oxford: Oxford University Press, 2003) 196 at 204 [Giesecke, “International health regulations”]; Michelle Forrest, “Using the Power of the World Health Organization: The International Health Regulations and the Future of International Health Law” (2000) 33 Colum. J. L. & Soc. Probs. 153 at 166.} In the transition from these precursor sanitary conventions to the IHR, the desire to minimize interference with trade continued to be a key objective.

The IHR (1969) attempt to restrain states’ health measures, but they have generally failed to do so, due in part to a pattern of widespread non-compliance with the restrictions.\footnote{Fidler, “Fourth Horseman”, supra note 4 at 835 (text and n. 308).} There have been many examples of measures being imposed and maintained despite being disproportionate to the risk or even entirely lacking scientific justification.\footnote{A new public health world order,” Editorial, (2004) 4:8 Lancet Infectious Diseases 475 at 475; Fidler, “Fourth Horseman”, supra note 4 at 846; Gostin, “International Infectious Disease Law”, supra note 4 at 2624.}
no basis for travel or trade restrictions, the European Community (EC) and others began imposing import bans on fish and other perishable foods within weeks of the outbreak. Inspection requirements and other measures well in excess of WHO guidelines were also imposed; travellers from Peru were restricted or refused entry in some countries. Peru estimated trade losses for 1991 at over US$770 million.37 Similarly, during a later cholera outbreak in East Africa, imports of fish from affected countries were banned by the EC, again despite WHO statements that this was not an appropriate response.38 In 1994, a suspected outbreak of plague in Surat, India, was reported (formally to the WHO as well as in media reports). Local measures were immediately taken, there was no evidence of transmission to nor any confirmed cases in other cities, and the outbreak was declared over in a little more than a month. However, other countries responded with cancellation of flights, closing of borders to both goods and people, travel advisories, and even in some cases restrictions on Indian nationals residing abroad. Again in this case the WHO had advised that no travel or trade restrictions were appropriate, and in the same year other countries had reported larger numbers of plague cases without any measures being imposed. The estimated cost to the Indian economy was over US$2 billion.39 Many other examples of disproportionate responses could be cited, including some trade bans based on risks of bovine spongiform encephalopathy (BSE)40 or more recently avian influenza,41 and entry restrictions imposed on individuals with HIV/AIDS.42

39 Cash & Narasimhan, supra note 37 at 1360-62.
40 Although bans on beef and cattle imports have been commonly used in response to cases of BSE and are likely legitimate in many instances, others have been controversial. For example, in the case of the recent United States ban on Canadian imports, it has been noted that Canadian control and testing measures are no less stringent than those of the United States, and that strong – though conflicting – economic incentives have played an important part in the trade ban: see e.g. Brian Bergman, “It’s a Mad World” Maclean’s (24 January 2005) 28; Jeremy Grant, “Mad Canadian cow puts divided US beef industry in the spotlight” Financial Times (3 May 2005) 12. An earlier Canadian ban on Brazilian beef was accused of being “a shameless ruse prompted by the ongoing trade dispute between the two countries over [aircraft subsidies]”, Wayne Kondro, “Canada silences scientists that spoke out about BSE” (2001) 357:9256 Lancet 618. For a recent discussion see Laura J. Loppacher & William A. Kerr, “The Efficacy of World Trade Organization Rules on Sanitary Barriers: Bovine Spongiform Encephalopathy in North America” (2005) 39 Journal of World Trade 427.
41 See e.g. “United States bans B.C. poultry” CBC News (21 November 2005), online: CBC News <http://www.cbc.ca/news> (regarding restrictions imposed by the United States in response to a low pathogenic strain of avian influenza which is “not viewed as a public health threat”).
Although it is clear that excessive measures have been a major concern historically, one might ask whether this concern is still relevant in the current context and whether it is one that should be directly addressed by the revised IHR. There appear to be two main arguments to the contrary. The first is that the issue of compliance with notification obligations can be addressed in other ways, so we need not worry about restrictive measures as a disincentive to notification. Developments in global communications have made it possible to disseminate information about disease events more quickly and widely, decreasing reliance on official notification. Experiences during the 2003 SARS outbreak demonstrated the difficulty of concealing information, and witnessed an encouraging pattern of openness on the part of almost all affected states. Fidler argues that this openness was a direct result of the “realization that hiding SARS cases would be futile and counter-productive in an age in which non-state actors can globally disseminate disease information.” Others have echoed this assessment, suggesting that attempting to hide information in the current environment is “a short term stop-gap measure that carries a very high price” or even that it is “no longer an option”. According to Fidler, the incentives to conceal information have “disappear[ed]” or at least “shifted”. If governments do occasionally try to suppress information, the lack of formal notification will not prevent information from getting to the WHO and other states. The revisions to the IHR have reinforced this shift, notably by enabling the WHO to rely on information from unofficial sources. Also, to the extent that governments may still be nervous about sharing information, the new provisions for confidential reporting will further tip the balance in favour of disclosure.

It is very tempting to believe that concealment of disease events is a thing of the past, and there is no doubt that developments in global communications are extremely significant in this context. There are, however, several reasons to be cautious. Though Fidler argues that the combination of non-governmental sources of information and the potential for WHO travel advisories acts as a “pincer” to pressure governments into compliance, it has equally been noted that the economic impact of travel advisories or restrictions creates an even greater incentive to avoid disclosure. Even if it is true that information will inevitably become available through unofficial channels if the relevant authorities try to suppress it, the delay in transmission of reliable information may result in needless harm and loss of life. In addition, official cooperation is important, not just disclosure of informa-

43 See Fidler, SARS, supra note 1 at 116 ff, 128, 134-35.
44 Ibid. at 135.
45 WHO, cited in ibid. at 118.
46 Hardiman, supra note 8 at 210. See also Fidler, SARS, supra note 1 at 118 (suggesting that attempts to cover up outbreaks are “doomed to rapid, embarrassing, and damaging failure”).
47 Fidler, SARS, ibid. at 118, 134.
48 Ibid. at 144.
tion. Unofficial reports must be verified, and WHO collaboration in assessment is subject to state consent. 

Early notification and cooperation are essential prerequisites to an effective response, for which there is no adequate substitute. It is not clear, either, that the SARS experience is representative. It may well have set the pattern for high-profile events where there is intense international interest and scrutiny, but in cases that are less newsworthy states may be more likely to withhold information – and get away with it for longer. The broader criteria for notification under the IHR (2005) leave more room for interpretation and thus for authorities to decide that events need not be notified, and surveillance systems may be (deliberately or not) designed in such a way that relevant events are not detected in the first place or reported in a timely manner. In short, although there is much truth to the insights about how the context for notification has changed, it is unlikely that the risk of concealment has disappeared. As a result, we should not be too quick to disregard the impact of restrictive measures as a barrier to compliance.

A second argument suggests that while excessively harsh trade or travel restrictions may occur, they are not the proper concern of the WHO and preventing them should not be a primary objective of the IHR. This seems to be implied in Gostin’s statement that:

Certainly, international commerce is a social good, and overreaction without scientific evidence can cause economic harm by diminishing trade, travel, and tourism. However, the international community cannot have it both ways – unimpeded travel and trade, with full public health protection. ... The WHO’s mission should unequivocally be expressed as global health protection and promotion. ... That is the vision of the WHO Constitution. Neither the preamble nor article 21 mentions commerce protection, let alone minimization of barriers to commercial intercourse.


51See IHR (2005), supra note 21 at Articles 9-10.

52For example, it has been noted more recently that “[m]ost countries have also been open about avian influenza”, Angus Nicoll et al., “Proposed new International Health Regulations: Agreement must be reached to protect the global village from pandemic influenza” (2005) 330:7487 BMJ 321 at 322.

53In relation to BSE, for example, critics have suggested that the U.S. surveillance and testing regime is designed not to detect incidences of the disease, presumably because of the economic damage that would result. See e.g. Tara Parker-Pope, “Why Blaming Canada Isn’t Enough: U.S. Mad Cow Inspections Lack Teeth” Wall Street Journal (30 December 2003) D1; Donald G. McNeil Jr. & Alexei Barrionuevo, “For Months, Agriculture Department Delayed Announcing Result of Mad Cow Test” The New York Times (26 June 2005) 1.16. The North American approach to BSE has been described as a “don’t look, don’t find” surveillance system”, Andrew Nikiforuk, “Modern plagues” Canadian Business 76:19 (14 October 2003) 50. In a recent BSE case in the U.S. it was revealed that a positive test result was not disclosed until it was confirmed seven months later because the earlier test was classified as “experimental” (McNeil and Barrionuevo, ibid).

One might say then that the WHO should concern itself with the protection of health through public health measures, and if these sometimes have a negative effect on travel and trade, that is outside the WHO’s mandate. Although there is no question that the WHO’s mission is to protect and promote health, there are several difficulties with this view. It seems to assume that stricter measures are always to be preferred from a public health perspective, and that in cases of doubt, the interests of health are always best served by erring on the side of stronger measures. Given the accepted role of excessive measures in discouraging open reporting, it cannot be said that the overall functioning of the global infectious disease regime is best served by more stringent measures. As discussed above, preventing the spread of disease and reducing interference with international traffic are complementary parts of an integrated regime. Unless we either disregard this connection, or are confident that disincentives to reporting are no longer relevant, restraining measures are important from a public health perspective, not just an economic one. Dismissing economic effects also reflects a narrow view of health that is at odds with the definition in the WHO Constitution\textsuperscript{55} and disregards the well-established links between poverty and ill-health. As has been pointed out in the case of cholera in Peru mentioned above, the impact of excessive measures “only added to the poverty that had led to [the] conditions” facilitating the spread of cholera among the poor in that country.\textsuperscript{56} Economic impacts may have particularly severe effects in developing countries, at the same time that their governments are struggling to cope with the local effects of a disease outbreak. In the case of measures imposed on individuals, experiences with HIV/AIDS, among others, have taught us that draconian measures are often counterproductive from a public health perspective, in addition to raising human rights concerns.\textsuperscript{57}

One implication of the above argument is that although travel and trade restrictions and their impact may be important, they should be dealt with by another organization: let the WHO promote vigorous health measures, and if need be they can be restrained by, for example, the World Trade Organization (WTO) and its agreements, which unlike the WHO are concerned with “minimization of barriers to commercial intercourse”. Some have, in fact, suggested that the WTO should take over responsibility for the IHR.\textsuperscript{58} Of course some division of labour between international organizations is necessary, and the insistence that the WHO should give primacy to its mandate for health protection and promotion is perhaps all the more important given recent concerns about commercial influences on the WHO.\textsuperscript{59} The points of intersection between the spheres of different institutions must be

\textsuperscript{55} Constitution of the World Health Organization, supra note 3 at preamble (“Health is a state of complete physical, mental and social well-being”).
\textsuperscript{56} Cash & Narasimhan, supra note 37 at 1363.
\textsuperscript{57} This has been referred to as the “AIDS paradox”, see e.g. Michael Kirby, “The Right to Health Fifty Years On: Still Skeptical?” (1999) 4:1 Health & Hum. Rts. 7 at 17.
carefully managed, however, and it is not clear that leaving concerns about travel and trade restrictions to the WTO would be ultimately beneficial from a health perspective, any more than leaving human rights concerns to human rights agreements and institutions. Rather, it is more important to ensure that the IHR deals with the relationship between relevant instruments and institutions, and the optimal balance between health protection and trade or human rights, in a way that best promotes WHO’s core mandate. To say that health protection must take priority does not fully capture the complexity of this challenge.

Finally, it is not clear why the primary purpose of health protection necessarily means that other values cannot be taken into account, at least to the extent that they do not interfere with this purpose. Health protection measures and restraint of those measures are complementary parts of the regime in the sense that restraint ultimately improves the overall functioning of the regime. One could also argue that basic fairness requires that states should have some assurance of protection from others’ excessive measures if they invest resources and effort into health surveillance and response that will ultimately benefit others as well. Many of the targets of disproportionate measures – especially the worst examples of these measures – have been developing countries, and states with less economic and political power are less able to prevent or respond to such measures being taken against them. Although these same countries are asked to make significant commitments to the global regime, there has been relatively little consideration of the protection that they might be entitled to expect in return:

Protectionist states are reluctant to let an international organization make any decisions on their behalf. It seems very natural for those states to demand that other – often much more economically vulnerable – countries should inform the world about potentially dangerous outbreaks, but much less natural to accept that this demand requires some assurance, for the country hit by an outbreak, that reporting will not be punished by over-reaction from the rest of the world.

Note that in the same article just referred to, Gostin argues strongly for more detailed provisions on human rights in the IHR: Gostin, “International Infectious Disease Law”, supra note 4 at 2626.

See e.g. Giesecke, “International health regulations”, supra note 35 at 202, 208 (regarding the need to coordinate rather than separate trade and health matters).

See the examples of Peru, India, and East African countries discussed above and Obijiofor Aginam, “Between Isolationism and Mutual Vulnerability: A South-North Perspective on Global Governance of Epidemics in an Age of Globalization” (2004) 77 Temp. L. Rev. 297 at 302-303 (Aginam argues that: “Although countries often overreact to outbreaks of epidemics in other countries with trade, travel, and economic embargoes ostensibly to protect their populations, these embargoes are always more severe and isolationist when the disease or health threat emanates from a developing country.” at 302).

Giesecke, “International health regulations”, supra note 35 at 204. See also Obijiofor Aginam, Global Health Governance: International Law and Public Health in a Divided World (Toronto: University of Toronto Press, 2005) at 82 (arguing that the “present negative rewards of notification – trade, travel, and economic embargoes – must give way to positive rewards”).
Therefore, while it can be argued that restraining excessive health measures is no longer necessary or that it should not be the concern of the IHR and the WHO, ultimately such arguments are not persuasive. This is not, however, to suggest that they should simply be dismissed. Quite to the contrary, these arguments point to important issues and contextual factors that need to be taken into account when evaluating how the IHR should deal with the risk of excessive measures. For example, the development of global communications does not make restraint of health measures irrelevant, but it does significantly change the context for surveillance and response. Similarly, the existence of international institutions and agreements dealing with trade barriers does not necessarily mean that all trade issues are best left to their exclusive responsibility. It does highlight how much has changed in the international legal environment since the period in which the IHR and its precursors originated. Negotiating the complex relationships between the IHR and other relevant sources of international law is among the challenges for the revised Regulations.

Since experience has shown that stringent health measures may be effective and necessary, especially in a public health emergency, a concern with excessive measures does not necessarily mean that a very restrictive approach should be taken and that states’ discretion to adopt measures they consider necessary should be eliminated. There is a wide spectrum of approaches between strict prescription and total freedom for states. Insisting that restraint of national health measures is important does not lead automatically to any particular conclusions as to the appropriate source, nature, or degree of restraint, that is: who or what should impose constraints on national measures; what the basis of those constraints should be; and how narrow or strict the constraints should be. The following sections trace the changes made to the relevant IHR provisions during the revision process, and offer a preliminary analysis and assessment of those changes.

B. Changes to the regime for restricting health measures

From the earliest consultations on revising the IHR, the objective of maximizing security against the spread of disease while minimizing interference with international traffic was retained in revised IHR. Provisions regarding limits on national health measures have appeared the precursors to the IHR, the current Regulations, and in every proposed version of the revised Regulations. As outlined above, the IHR (1969) set out a series of specific measures that states may (or in some cases must) take in response to the threat of international spread of infectious disease. Some of these relate to the individual covered diseases (cholera, yellow fever, and plague) and are tailored to the particular characteristics of those diseases, for example modes of transmission and incubation periods; others are of more

64 Fidler, “Fourth Horseman”, supra note 4 at 851.
65 Ibid. at 834.
66 IHR (1969), supra note 2 at pt. V.
The Regulations then limit states’ measures to those authorized in these provisions.

Article 23 of the IHR (1969) is the general limiting provision: “The health measures permitted by these Regulations are the maximum measures applicable to international traffic, which a State may require for the protection of its territory against the diseases subject to the Regulations.” There are also specific restrictions contained in other articles. For example, Article 27(1) states that “[a] person under surveillance shall not be isolated and shall be permitted to move about freely.” Article 28 provides that “[e]xcept in the case of an emergency constituting a grave danger to public health, a ship or an aircraft, which is not infected or suspected with a disease subject to the Regulations, shall not on account of any other epidemic disease be refused free pratique by the health authority for a port or an airport; in particular it shall not be prevented from discharging or loading cargo or stores, or taking on fuel or water.” Article 32(1) prohibits the application of health measures to “any ship which passes through waters within its jurisdiction without calling at a port or on the coast”, and Articles 33 and 34 limit health measures that may be applied to ships and their passengers and crew under defined circumstances. Articles 35 to 45 and 46 to 49 authorize but limit health measures that may be imposed on arriving conveyances and travellers and on international transport of cargo, goods, baggage and mail, respectively. Part VI deals with health documents such as Maritime Declarations of Health or vaccination certificates, and its final Article 81 provides that “[n]o health document, other than those provided for in these Regulations, shall be required in international traffic.”

As has been noted, in practice these provisions were often violated by states. Article 93 of the IHR (1969) provides that questions or disputes concerning their interpretation or application may be referred, in the first instance, to the Director-General and, failing settlement, to the International Court of Justice. Despite the many instances of non-compliance and the resulting damage to member states, this dispute resolution provision appears almost never to have been used.

During the revision process, attention focussed primarily on the scope of the Regulations, provisions on notification and use of information, and prescribed capacities for surveillance and response. Nevertheless, there were also significant revisions to the provisions restraining national health measures. As other aspects of the IHR changed, it was clear that the provisions on prescribed and maximum measures would have to be modified as well. For example, with a broader scope of coverage, detailed prescriptions tailored to specific diseases would no longer be practical. It was also necessary to accommodate changes in the international

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67 Ibid. at pt. IV, in particular c. II-V.
68 “Free pratique” refers to “permission for a ship to enter a port, disembark and commence operation, or for an aircraft, after landing, to disembark and commence operation”, IHR (1969), supra note 2 at Article 1.
69 Fidler, “Fourth Horseman”, supra note 4 at 848 (noting that there appears to have been only one instance of its use).
context, including the development of other instruments and institutions. Furthermore, member states’ reluctance to allow themselves to be bound by prescribed maximum measures became clear as the revision efforts progressed.

In the interim draft of the revised IHR released as a “Working paper for regional consultations” at the beginning of 2004 (January 2004 Draft), one can immediately see a change in approach from the IHR (1969). Where the original general provision (Article 23) purports to give a binding directive that the “health measures permitted by these Regulations are the maximum measures applicable to international traffic, which a State may require for the protection of its territory against the diseases subject to the Regulations”, the corresponding Article 34 of this draft (entitled “Excessive measures”) contains an exhortation that “States should make every effort not to impose measures exceeding those recommended by the WHO under these Regulations”. Under the following Article 35(1) the WHO “may request the cessation” of excessive or inappropriate measures. The combination of this provision and the hortatory language in Article 34 suggests that the restriction is not binding. However, other proposed provisions contain specific prohibitions, in mandatory language, on certain measures or on the application of measures in certain circumstances. Questions were therefore raised in the consultation documents whether the Regulations purported to impose binding restrictions or not; some submissions also suggested that the restrictions should not be binding, as this would unduly interfere with members’ sovereign discretion to decide on appropriate health measures.

Significantly, a number of these provisions contain conditions which did not exist in the equivalent IHR (1969) articles. These would allow measures, otherwise prohibited, to be imposed in one or more of the following circumstances: (1) recommendation by the WHO; (2) existence of a PHEIC; (3) where authorized under “applicable international agreements”; or (4) “based on evidence of a public health risk”. The last two of these conditions are particularly important because they represent the first steps toward coordination with other international agreements and flexibility for national measures conditional on evidence of a risk to public health, respectively. They are retained in later drafts and in the IHR (2005), although the evidence requirement is developed within in a general provision on what are now referred to (more neutrally) as “additional measures”. This general provision also elaborates the role of the WHO in relation to additional measures. References to WHO recommendations were removed from the specific limitations in most places, in response to concerns that these caused confusion as to the legal

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70 January 2004 Draft, supra note 18.
71 These are similar to the equivalent provisions in the IHR (1969), supra note 2.
72 See infra note 93 and accompanying text.
73 See January 2004 Draft, supra note 18 at Articles 19(1), 21(1), 21(2), 23(1), 26, 27(2).
74 See ibid. at Art. 21(2).
75 See ibid. at Articles 19(1), 19(2), 21(1), 21(2), 24, 26. See also Article 17 which makes the authority to impose certain health measures “[s]ubject to applicable international agreements”.
76 See ibid. at Articles 19(1), 19(2), 29(1). See also a similar provision in Article 21(6).
status of recommendations and that recommendations should not have binding effect. Other significant changes included the development of provisions governing how measures should be applied, adding the principle of transparency and most notably respect for human rights.

The resulting scheme in the IHR (2005) is somewhat more complex than the existing one, with a number of crucial differences. Like the IHR (1969), the new Regulations contain provisions that appear to prohibit certain health measures or the taking of measures in certain situations. However, many of these are subject to other “applicable international agreements”, and most are subject to Article 43 on “Additional health measures”. This Article applies to health measures which “achieve the same or greater level of health protection than WHO recommendations” or which are otherwise prohibited by specified limitations in the Regulations. It provides that the Regulations do not preclude states from implementing such measures, provided they fulfill several conditions. They must be “in accordance with their relevant national law and obligations under international law”, “in response to specific public health risks” or to a PHEIC, and “otherwise consistent with these Regulations”. If such measures are taken, they must not be “more restrictive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection.”

Article 43 also sets out the requirements and process for taking such measures and for taking measures under other articles which permit additional measures in specific circumstances. In deciding whether to implement these measures, determinations must be based on scientific principles, “available scientific evidence of

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77 WHO, Review and approval of proposed amendments to the International Health Regulations: explanatory notes, WHO Doc. A/IHR/IGWG/4 (7 October 2004) at para. 10. References to the existence of a PHEIC were also dropped.

78 IHR (2005), supra note 21 at Article 43. The provisions to which Article 43 applies are listed in notes 79 and 80 infra. Note that these do not include a few of the specific restrictions, for example the Article 35 general rule on health documents, which provides that no documents besides those “provided for under these Regulations or in recommendations issued by the WHO” may be required (except where travellers are seeking temporary or permanent residence or where documents requirements are contained in other applicable international agreements), and Article 36(2) which provides that a “traveller in possession of a certificate of vaccination or other prophylaxis....shall not be denied entry as a consequence of the disease to which the certificate refers, even if coming from an affected area, unless the competent authority has verifiable indications and/or evidence that the vaccination or other prophylaxis was not effective.”

79 Ibid. The specific limitations referred to are those in Articles 25 (Ships and aircraft in transit), 26 (Civilian lorries, trains and coaches in transit), 28(1) (Ships and aircraft at points of entry – calling at points of entry), 28(2) (Ships and aircraft at points of entry – free pratique), 30 (Travellers under public health observation), 31(1)(c) (Health measures relating to entry of travellers – measures as condition of entry) and 33 (Goods in transit).

80 Ibid. These are Articles 23(2) (Health measures on arrival and departure – additional measures on basis of evidence obtained), 27(1) (Affected conveyances – additional measures to prevent spread of disease), 28(2) (Ships and aircraft at points of entry – free pratique) and 31(2)(c) (Health measures relating to entry of travellers – compelling travellers to undergo additional health measures in case of imminent public health risk).
a risk to human health, or where such evidence is insufficient, the available
information including from WHO and other relevant intergovernmental organiza-
tions and international bodies”, and “any available specific guidance or advice from
WHO.” This guidance or advice presumably would include WHO recommenda-
tions issued under the Regulations, but, having considered them, states are author-
ized to take measures going beyond those recommendations provided the
conditions in this Article are met. All of these categories of information must also
be considered when the measure is reviewed and review must take place within
three months.

Where additional measures are implemented that “significantly interfere with
international traffic”,81 the WHO must be promptly informed of the measures and
their basis, and will share this information with other states.82 After assessing the
information, the WHO “may request that the State Party concerned reconsider the
application of the measures”. States which are affected may request consultations
to clarify the basis for the measures and try to “find a mutually acceptable solution”.
This is in addition to a provision on formal dispute resolution in Article 56, which
provides for referral of disputes to the Director-General or to binding arbitration.

All measures taken pursuant to the Regulations must be implemented in
accordance with certain conditions and requirements. Article 42 requires measures
to be taken without delay and “applied in a transparent and non-discriminatory
manner”. Other requirements relate specifically to the treatment of individuals. The
IHR (1969) do address some of the same issues, for example providing that
measures should not cause “undue discomfort” or injury to health (Article 25), and
requiring the use of less restrictive measures,83 but the revised Regulations reflect
a much more explicit focus on the rights and freedoms of affected individuals. The
guiding principles of the IHR (2005) include “full respect for the dignity, human
rights and fundamental freedoms of persons” (Article 3(1)) and a later provision
requires that in “implementing health measures under these Regulations, States
Parties shall treat travellers with respect for their dignity, human rights and
fundamental freedoms and minimize any discomfort or distress associated with
such measures” (Article 32). Health measures to which travellers are subjected
require their “prior express informed consent” (Article 23(3)) except where “there
is evidence of an imminent public health risk”, in which case travellers may be
advised or compelled to submit to examination,84 vaccination or other prophylaxis,
or “additional established health measures” such as isolation, quarantine or obser-

81 Significant interference is defined for these purposes as “refusal of entry or departure of international
travellers, baggage, cargo, containers, conveyances, goods, and the like, or their delay, for more than 24
hours”, ibid. at Art. 43(3).
82 Ibid. at Art. 43(3), (5). Article 43(5) requires notification of measures within 48 hours unless the
measure is one covered by a temporary or standing recommendation.
83 Ibid. at Articles 27 and 39(2) (require surveillance to be used rather than isolation unless the risk of
transmission is “exceptionally serious”).
84 This examination must be the least invasive and intrusive that would achieve the public health
objective, ibid. at Art. 31(2)(a).
vation, to the extent necessary to control the risk (Article 31(2)). These compulsory measures must also be in accordance with the national law and international obligations of the state (Article 23(3)).

Finally, the relationship between the IHR and other international legal instruments also has a significant impact on the scope for additional measures. During consultations concerns were raised that the IHR might interfere with rights and obligations under other agreements, and several specific changes were made to the initial draft to eliminate possible conflicts. The IHR (2005) reflects a clear decision to give priority to other agreements; that is, in the event of a conflict, the other agreement will prevail over any inconsistent provisions in the IHR. This is explicitly set out in Article 57(1), which states that the “provisions of the IHR shall not affect the rights or obligations of any State Party deriving from other international agreements”. Earlier drafts had suggested that the IHR would not affect these other rights and obligations “provided they are compatible with the purpose of these Regulations” or “provided they do not represent a direct conflict with these Regulations”, but these limitations were dropped in the final version, leaving an unqualified rule that other agreements will prevail. This interpretive principle in Article 57(1) is in addition to specific restrictions on measures being subject to “applicable international agreements”. This means that measures authorized by other applicable agreements will be permitted, regardless of whether they pass the Article 43 test for additional measures. Article 57(1) also states that “the IHR and other relevant international agreements should be interpreted so as to be compatible”. Compatibility is further promoted by requiring the WHO to cooperate and coordinate its activities with other competent international bodies (Article 14(1)) and listing “relevant international standards and instruments” among the criteria to be considered by the Director-General in relation to WHO recommendations (Article 17(e)).

In summary, the revision of the IHR yielded a fundamental change to the Regulations’ approach to restraining national health measures. It abandoned an approach which prohibited all measures save those specifically authorized by the Regulations, and moved toward a set of restrictions based on certain principles (e.g. the need for scientific evidence, and the use of the least restrictive measures

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85 Ibid. These “additional measures” provided for in Article 31(2)(c) are subject to the requirements in Article 43(2).
86 See e.g. WHO, Summary report of regional consultations, WHO Doc. A/IHR/IGWG/2 (14 September 2004) at para. 6 and the discussion below in part C.1.
87 WHO, Review and approval of proposed amendments to the International Health Regulations: relations with other international instruments, WHO Doc. A/IHR/IGWG/INF.DOC./1 (30 September 2004) at para. 8-9.
88 September 2004 Draft, supra note 19 at Art. 58(1).
89 January 2005 Draft, supra note 20 at Art. 58(1). This wording was bracketed in the draft text.
90 See e.g. IHR (2005), supra note 21 at Articles 25 (Ships and aircraft in transit), 35 (General rule – health documents).
91 Most of the relevant articles state that the restriction applies subject to Article 43 or as provided in (or unless authorized by) applicable international agreements. See ibid. at Articles 25, 26, 28, 30, 33.
reasonably available) and procedures (e.g. notifying the WHO of additional measures, and reviewing measures within three months). These principle- and process-based restrictions are aligned with other international legal obligations, as will be discussed in the next section. This concern with compatibility of the IHR with other instruments was also an important aspect of the revision process, resulting in the subordination of the IHR to other relevant sources of obligations. The result is that states are free to take additional measures beyond those provided for or recommended, despite the apparent restrictions in the IHR provisions, if those measures are authorized by "applicable international agreements" or if they meet the conditions in Article 43.

C. Analysis of the new regime

The restraint of national health measures has become a more serious issue for states for several reasons. The narrow scope of coverage of the IHR (1969) has meant that the range of measures affected by the prohibition on excessive measures is likewise narrow. The IHR (2005) will apply to a much broader range of diseases, situations, and health measures. The Regulations also have a higher profile following the revision process and the SARS epidemic, so the political cost of non-compliance may be higher. As will be seen below, some measures are also subject to stronger enforcement mechanisms through the WTO system. Previously, relatively few health measures were affected by the IHR, and widespread non-compliance occurred with impunity, but the stakes are now considerably higher. As a result, the nature and extent of restrictions on national health measures were targeted during the revision process.

1. Sovereignty and international legal obligations

Two broad concerns raised during consultations are directly relevant to the issue of restraint of national health measures and shaped the outcome of the revision process. The first relates to state sovereignty. Sovereignty issues were raised in respect of several different aspects of the IHR, such as the provision for WHO assistance and cooperation within member states' territories – many states wanting reassurance that "WHO teams should enter countries only with the consent of the affected Member State." They were also specifically raised in connection with "excessive" or "additional" measures. This concern was perhaps most clearly and forcefully expressed in the following comments from the United States, although it was echoed by others, especially from Europe:

The first [sovereignty concern] relates to the extent to which several provisions ... would prevent a State from implementing measures to protect against international public health risks if such measures go beyond those recommended by the WHO or those otherwise authorized by ‘applicable international agreements.’ ... We believe these are

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92 WHO, Summary report of regional consultations, supra note 86 at para. 8.
inappropriate restrictions on a Member State’s prerogative to apply additional measures to protect its nationals and others residing within its borders where such measures are consistent with international law and sound public health practice such as vaccination requirements. We are conscious of the WHO’s desire to strike a balance between the need to provide security against international spread of disease, while avoiding unnecessary interference with international traffic. However, some of the measures proposed ... do not strike the right balance and constitute an impermissible infringement on a Member State’s sovereign prerogatives. Member States should have the right to regulate ‘goods’ based on reasons unrelated to IHR issues and to institute border actions according to what they determine to be an appropriate level of protection.\(^93\)

It was suggested by others that member states be permitted to adopt additional or stricter measures, but should be required to provide a scientific justification for doing so.\(^94\)

The second general concern relevant to this issue is the relationship between the IHR and other international agreements. It was noted by many during the consultations that the subject matter of the IHR overlaps with issues covered by other agreements and dealt with by other international organizations.\(^95\) These include, for example, the WTO agreements, conventions on air and marine pollution, nuclear safety conventions, human rights agreements and the law on diplomatic relations. The question of relationships with other international agreements was explored in a review commissioned by the WHO Secretariat\(^96\) and discussed

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\(^95\) See e.g. WHO, Summary report of regional consultations, supra note 86 at para. 6.

\(^96\) WHO, Review and approval of proposed amendments to the International Health Regulations: relations with other international instruments, supra note 87.
in consultations with member states and relevant organizations. Some states argued that the IHR should avoid conflict with and be subordinate to other instruments, especially trade agreements,\(^97\) while others suggested that the IHR allow public health concerns to prevail over other obligations.\(^98\) As was seen above, the former view ultimately prevailed.

These two concerns, sovereignty and the relationship between the IHR and other instruments, are related because the desire to protect sovereignty in the area of health measures entailed a determination by certain countries not to allow the scope for national regulatory autonomy in other international agreements – especially the WTO agreements – to be affected by additional overlapping constraints in the IHR. This position influenced the final outcome of the revision process and is important to understanding the way in which the new regime will operate.

States’ resistance to limits on their health measures relates to both the degree of restrictiveness and the way in which it operates. That is, it reflects concerns with how strict the constraints are and also by whom and on what basis the constraints are imposed. Whenever states become parties to international agreements, their sovereignty is affected in the sense that their international legal commitments will set limits on what might formerly have been sovereign prerogatives. It is a trite proposition of public international law that the scope of a state’s domestic jurisdiction, in which it exercises sovereignty without interference by other states or international organizations, is defined by reference to that state’s international legal obligations.\(^99\) Legal obligations agreed to by a state become valid limits on its exercise of sovereignty; it is somewhat misleading, therefore, to describe an IHR provision restricting states’ discretion in respect of national health measures as an "impermissible infringement" on sovereignty.\(^100\) Rather, the issue is whether the restriction is one that states would be prepared to accept as a binding legal obligation. It became clear through the revision process that at least some states would not accept binding obligations that would preclude outright their choice of certain health measures or that would give the WHO authority to define the set of permissible health measures in a given situation. The new power of the WHO to issue recommendations could be seen as a response to the need for greater flexibility as compared to the IHR (1969). However, its member states were not prepared to be bound by these recommendations.

\(^{97}\) Preliminary comments of the European Community and its Member States on the draft-revised International Health Regulations (IHRs), supra note 93 at 2; Second U.S. Government Comments on the First Draft of the Proposed Revision of the International Health Regulations (IHRs), supra note 93 at 4.

\(^{98}\) WHO (Regional Office for South-East Asia), Second Regional Consultation on the Proposed Revised International Health Regulations (27 September 2004) at 21, online: WHO <http://www.who.int/entity/csr/ihr/revisionprocess/searo2004_09_27.pdf>.


\(^{100}\) To use the language of the United States consultation comments, see supra note 91 and accompanying text.
The IHR (2005) does impose constraints on national health measures, principally through the conditions in Article 43. Though some flexibility is allowed, the restrictions imposed are real and by no means insignificant. Why, then, would states accept these conditions but at the same time refuse to allow the WHO’s recommendations, tailored to particular situations and arrived at through a new more transparent process,101 to bind them? In part this can be explained in terms of the nature and structure of international law. The classic view of international law is that it is based (for the most part102) on obligations that are voluntarily assumed. When a state negotiates and then becomes party to an international agreement, this is an exercise of its sovereignty much in the same way that an individual may exercise autonomy by entering into a contract. International law is also a decentralized system which relies on auto-interpretation – each state interpreting and applying norms for itself rather than following the prescriptions of a higher authority.103 Giving the WHO authority to issue recommendations which would be binding on its member states would challenge both of these fundamental characteristics of the international legal system. Thus one needn’t presume that governments are especially suspicious of the WHO’s authority to explain their reluctance to be bound by its recommendations. Agreeing to certain principles and requirements governing their national measures, to be interpreted and applied by each state, fits more comfortably within the traditional framework of international law.104

The particular form of restrictions embodied in the final version of Article 43 on additional measures was also more likely to be acceptable to states because it mirrors obligations that most of them already have under other international agreements. It was clear that some states would strongly resist any restrictions in the IHR that would derogate from the rights that they had under other agreements, here in particular the WTO agreements. By aligning the conditions set out in Article 43 with those agreements and defining the relationship between the IHR and other instruments in such a way that the IHR would be subordinate, they ensured that this would not happen. Questions relating to the nature and scope of restrictions on states’ freedom to take regulatory measures for health purposes have been extensively discussed in relation to other international agreements. The language used in Article 43 of the IHR (2005) borrows from the provisions and jurisprudence of these agreements, and so can best be understood in reference to them.

101 See IHR (2005), supra note 21 at Articles 49, 53.
102 There are some norms of international law (“peremptory norms” or jure cogens) that will bind a state notwithstanding its objections and cannot be contracted out of by treaty; however these are the exception rather than the rule.
103 So, for example, even decisions of the International Court of Justice do not establish precedents but are binding only on the parties to the particular dispute. See Statute of the International Court of Justice at Article 59.
104 Although the IHR function differently than most treaties in that they are adopted by the World Health Assembly and binding on WHO member states, they are still voluntary because it is possible to reject or make reservations to the IHR thus avoiding or modifying their binding effect. IHR (2005), supra note 21 at Articles 61, 62.
2. Understanding the IHR (2005) provisions on national health measures: context and interpretation

In order to understand how they will operate, the IHR (2005) provisions governing national health measures must be read alongside relevant provisions in other international agreements, for several reasons. The relationship between the IHR (2005) and those other agreements has been defined in such a way that the latter continue to apply: the rights and obligations under them are unaffected by the IHR provisions\textsuperscript{105} and it is specifically provided that additional measures permitted by the terms of Article 43 must still comply with a state’s other relevant obligations.\textsuperscript{106} The enforcement of these other obligations provide an important constraint on national measures, given that the IHR themselves contain relatively weak provisions to ensure compliance.\textsuperscript{107} Furthermore, the IHR provisions, especially Article 43, were drafted in such a way that they parallel obligations under other agreements, and will be interpreted “so as to be compatible” with them.\textsuperscript{108} Although the IHR overlap with many international agreements, the key sources in this context are trade agreements, with respect to measures affecting goods, and human rights treaties, with respect to measures imposed on individual persons.\textsuperscript{109}

(a) International trade law

The General Agreement on Tariffs and Trade (GATT),\textsuperscript{110} which imposes a range of trade disciplines with respect to trade in goods,\textsuperscript{111} contains an exception in Article XX(b) allowing members to take measures that would otherwise violate their GATT obligations where the measures are “necessary to protect human ... life

\textsuperscript{105} IHR(2005), supra note 21 at Art. 57(1).
\textsuperscript{106} Ibid. at Art. 43(1).
\textsuperscript{107} Ibid. at Art. 43(4) (WHO may request that a state reconsider its application of additional measures), Art. 43(7) (a state affected by additional measures may request consultations), and Art. 56 (settlement of disputes between states concerning the interpretation or application of the Regulations, including through mediation, reference to the Director-General or arbitration).
\textsuperscript{108} Ibid. at Art. 57(1).
\textsuperscript{109} The IHR (2005) deal with measures imposed on “travellers”, which are defined as natural persons “undertaking an international voyage”, ibid. at Article 1. Trade agreements, in particular the General Agreement on Trade in Services, Annex 1B to the Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, 1867 U.N.T.S. 3, may also have some relevance to such measures, where they interfere with tourism or other services, particularly in respect of international trade in services through movement of natural persons. This would entail, for example, non-discrimination among foreign service providers (most-favoured-nation treatment, Article II) and transparency of measures (Article III), but other commitments of members under this agreement vary among states (according to each member’s Schedule of Commitments on national treatment and market access). Analysis of the potential impact of these commitments is beyond the scope of the present discussion.
\textsuperscript{111} The key obligations are non-discrimination between other countries (“most-favoured nation” principle), non-discrimination between domestic and imported products (“national treatment” principle), restrictions on tariffs and prohibition of “quantitative restrictions” such as quotas or import bans, ibid.
or health”. This and other Article XX exceptions are subject to the general provision, referred to as the chapeau of Article XX, that such measures must not be “applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade”. Many of the measures likely to be taken under the IHR would also be subject to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement),112 which applies, inter alia, to measures “to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs” and measures “to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests”.113 These measures can include, for example, inspection, certification procedures, and quarantine of animals or plants.114 With respect to these measures, the SPS Agreement imposes both substantive and procedural requirements. Measures that conform to the SPS Agreement provisions are also presumed to be consistent with GATT (Article 2.4).

The requirement in Article 43(1) that additional measures “shall not be more restrictive of international traffic ... than reasonably available alternatives that would achieve the appropriate level of health protection” has several important parallels in the GATT and the SPS Agreement. Article 5.6 of the SPS Agreement states that measures must not be “more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection”; a note to this provision states that this means there must be no other “reasonably available” measure that would be “significantly less restrictive”. The existence of “reasonably available alternatives” has also been an important part of the analysis of whether measures are “necessary” to protect health for the purposes of GATT Article XX(b). A measure will not be considered “necessary” where reasonably available alternatives exist that would not breach GATT obligations.115 Similarly, the need to have a scientific basis for measures has been part of the interpretation of the GATT and is explicitly provided for in the SPS Agreement. In determining whether measures are necessary to protect health under GATT Article XX(b), a WTO dispute Panel

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113 Ibid. at Annex A, para. 1(b), (c).
114 Ibid. at para. 1.
will assess evidence of a risk and of a rational connection between the risk and the measure.\textsuperscript{116} The SPS Agreement requires measures to be based on “scientific principles”, supported by “sufficient scientific evidence”, and based on a risk assessment that takes into account “available scientific evidence” (Articles 2.2, 5.1-5.2). These are echoed in Article 43(2) of the IHR (2005) which provides that determinations whether to implement additional health measures must be based on “scientific principles” and “available scientific evidence of a risk to human health”.

Though Article 43 is the central provision on additional measures, Article 42 on implementation of health measures imposes important disciplines on all national measures, and parallels to these also exist in the WTO agreements. Article 42 requires that health measures be “applied in a transparent and non-discriminatory manner”. Transparency in the application of measures has been read into the GATT Article XX\textsuperscript{117} and is explicitly required in the SPS Agreement (Article 7). Annex B of the SPS Agreement gives some indication as to what is required for transparency, including publication of regulations, facilitating access to information, and notification of measures.\textsuperscript{118} The non-discrimination obligation is included in the SPS Agreement (Article 2.3, 5.5), and central to the GATT (Articles I, III, and the Article XX\textsuperscript{chapeau}). As a result it has been extensively discussed in GATT jurisprudence, which may provide some guidance as to what is required in terms of equality of treatment as between states or between foreign and domestic goods. Specific points on which the WTO jurisprudence might be helpful include identifying products and situations which are sufficiently similar so as to require equal treatment, and issues relating to indirect or \textit{de facto} discrimination.

Given the similarities between these instruments, interpretation of the WTO agreements provides some important indications as to the nature and extent of restrictions on national health measures under the new regime. Views differ on just how strict the WTO disciplines are and whether they strike the right balance between national regulatory autonomy and restraining illegitimate trade-restrictive measures.\textsuperscript{119} Though some uncertainty remains, dispute resolution decisions have

\textsuperscript{116} EC – Asbestos, \textit{ibid} at para. 157-67.

\textsuperscript{117} United States – Import Prohibition of Certain Shrimp and Shrimp Products (1998), WTO Doc. WT/DS58/AB/R at para. 180-84 (Appellate Body Report), online: WTO \textlangle http://docsonline.wto.org\textrangle (lack of transparency and predictability in certification process resulting in “arbitrary” discrimination);


\textsuperscript{118} Notification is already specifically required in the case of additional measures under Article 43(3) and 43(5) of the IHR. In addition, when states notify the WHO of a potential PHEIC, they must also notify any health measures implemented in response to the event: Article 6(1).

provided guidance on key points. For instance, it has been observed in several cases that the measures chosen are more likely to be accepted as “necessary” where their objective is very important – for example a life-threatening risk to human health.120 “Reasonably available alternatives” have been interpreted in such a way that states may be required to use alternatives even where they may be difficult, for example because of the administrative burden or a lack of information,121 but not where they are not feasible or are unlikely to be effective.i22 The WTO Appellate Body’s decision on France’s asbestos ban made the significant statement that a state cannot be reasonably expected to take an alternative measure that would entail accepting a higher level of risk than the state has decided is appropriate.123 Similarly, the SPS Agreement requires states to adopt less trade-restrictive measures only where these are “reasonably available taking into account technical and economic feasibility”, are “significantly less restrictive to trade” and would achieve the “appropriate level of sanitary or phytosanitary protection”.124 There must be sufficient evidence that available alternatives meet these criteria,125 and it is up to the complaining party to establish a prima facie case on this point.126

Decisions involving the SPS Agreement also provide some guidance as to what it means for determinations on the implementation of measures to be based upon scientific principles and an appropriate risk assessment using available scientific evidence. In order for a measure to be “based on” scientific principles and evidence, there must be an objective, rational relationship between the measure and its scientific basis.127 The evidence relied on need not necessarily represent a majority or consensus view among scientists, but it must be more than a mere opinion and derived from scientific studies.128 It must specifically address the risk to which the measure is directed.129 Where evidence is insufficient, both the SPS Agreement and the IHR (2005) allow states to take measures based on available information, provided these are reviewed in light of further information.130


120 Korea – Beef, supra note 115 at para. 162; EC – Asbestos, supra note 115 at para. 172.
122 EC – Asbestos, supra note 115 at para. 174.
123 Ibid.
124 SPS Agreement, supra note 112 at Art. 5.6 and n. 3.
130 SPS Agreement, supra note 112 at Art. 5.7; IHR (2005), supra note 21 at Art. 43(2)(b), 43(6). The IHR
(b) Human rights law

Measures applied to individuals have economic impacts – for example the impact of restrictions on business travel or tourism on national and local economies – but they also entail potential restrictions on individuals’ rights and freedoms. National measures to deal with a PHEIC or other identified threat to health may come into conflict with rights such as freedom of movement, liberty and security of person, privacy, or freedom of assembly and association which are recognized in international instruments, notably the International Covenant on Civil and Political Rights (ICCPR). Article 4 of the ICCPR provides that many rights protected by the Covenant may be derogated from in the event of a “public emergency which threatens the life of the nation”. This may include an outbreak of infectious disease, but not every event that constitutes a PHEIC under the IHR will qualify. However, the possibility of limiting certain rights for the purposes of health protection would apply in all cases. The right to freedom of movement within a state’s territory and to leave a country, freedom to manifest one’s religion or beliefs, freedom of expression (including freedom to seek, receive and impart information), freedom of assembly, and freedom of association are subject to restrictions which are necessary to protect health.

Just as there are parallels between the IHR (2005) provisions on health measures and trade agreements, links can also be found with human rights instruments. The general provisions on application of measures (Article 42) and additional measures (Article 43) apply equally to measures affecting individual travellers. The non-discrimination obligation in Article 42 parallels the rule that provision requires all additional measures to be reviewed within 3 months, while the SPS Agreement requires provisional measures under Article 5.7 to be reviewed “within a reasonable period of time”.


132 Certain rights may not be derogated from, even in an emergency: right to life; freedom from torture or cruel, inhuman or degrading treatment; freedom from slavery and servitude; right not to be imprisoned solely on the ground of inability to fulfil a contractual obligation; non-retrospective application of criminal laws; right to recognition as a person before the law; and freedom of thought, conscience and religion: ibid. at Article 4(2).

133 The emergency must be a “situation of exceptional and actual or imminent danger” and one that “threatens the life of the nation”, which has been interpreted to mean that it affects the whole population and threatens the integrity of the state’s population or territory, or its political independence or institutions. Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights, ESCOR, 41st Sess., Annex, Agenda Item 18, U.N. Doc. E/ CN.4/1985/4(1985) at para. 39, online: UN <http://unbisset.un.org>; reprinted (1985) 7 Hum. Rts. Q. 3 [Siracusa Principles]. Many events which are emergencies according to the IHR criteria will not meet this high threshold.

134 ICCPR, supra note 131 at Articles 12(2), 18(3), 19(3)(a), 21, 22.

emergency measures under ICCPR Article 4 must not “involve discrimination solely on the ground of race, colour, sex, language, religion or social origin”. The limitation clauses in the ICCPR have also been interpreted as providing that states must not discriminate when limiting rights for public health protection. Therefore both the provisions of the IHR (2005) themselves and other relevant international legal obligations would preclude health measures that discriminate against individuals on grounds of race, gender or national origin, for example.

As we have seen, Article 43 requires that additional measures, if they are taken, are “not more restrictive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection”. Although this language owes more to trade law, analogous human rights provisions require measures to be necessary to achieve a legitimate public health objective and to be no more restrictive than necessary for their purpose. ICCPR Article 4 states that measures may derogate from rights only “to the extent strictly required by the exigencies of the situation”. An influential interpretation of this provision states that a measure “is not strictly required by the exigencies of the situation where ordinary measures permissible under the specific limitation clauses of the Covenant would be adequate” to deal with the threat. The limitation clauses in the ICCPR that allow restriction of rights as “necessary” for health protection have been interpreted to mean that the measure must be proportionate to a legitimate, pressing need and no more restrictive than required to achieve its purpose.

Finally, scientific evidence and principles are not specifically referred to in the context of human rights obligations, but the derogation provision in the ICCPR does entail duties to assess risks and to take measures only as required to respond to actual threats and not “merely because of an apprehension of potential danger”. It has also been said that limitations on public health grounds must be justified by and aimed at serious threats to health. The IHR (2005) Article 43(2) requirements for determinations on additional measures to be based on scientific principles and available scientific evidence of a risk to health articulate more specifically the basis on which limitations or derogations of rights can be justified.

136 ICCPR, supra note 131 at Article 4(1).
137 Siracusa Principles, supra note 133 at para. 9. This interpretation is supported by the fact that the relevant provisions state that restrictions on these rights must be consistent with other rights in the Covenant, and Article 2(1) of the Covenant requires states to ensure rights to all individuals within their territory and jurisdiction “without distinction of any kind”.
138 Note that “international traffic” refers to movement of natural persons as well as goods, IHR (2005), supra note 21 at Article 1.
139 Siracusa Principles, supra note 133 at para. 53.
140 Ibid. at para. 10-11.
141 Ibid. at para. 52.
142 Ibid. at para. 54.
143 Ibid. at para. 25.
This is one example of the IHR usefully contributing to existing law on restricting human rights for health purposes. In this context, the essential principles are consistent, but the IHR provides greater detail on some of these principles. That is, existing obligations require measures to have a health justification, but the IHR (2005) specify that this must be a justification based on scientific principles and scientific evidence of a risk to health. Furthermore, the IHR are binding on WHO member states, whereas some of the interpretive documents that have previously attempted to flesh out the implications of the ICCPR provisions are non-binding instruments. The IHR (2005) also appear to contribute to the progressive development of law in this area by imposing specific constraints on health measures that arguably go beyond existing obligations. One example of this is Article 36, which provides that a “traveller in possession of a certificate of vaccination or other prophylaxis [properly issued], shall not be denied entry as a consequence of the disease to which the certificate refers, even if coming from an affected area, unless the competent authority has verifiable indications and/or evidence that the vaccination or other prophylaxis was not effective.” This purports to prohibit states from taking additional measures in this context, for example refusing entry to travellers from an affected area under these circumstances.

Freedom of movement in Article 12 of the ICCPR does not include freedom to enter a country, except one’s own country, and even then it only protects against “arbitrary” deprivations of this right. To the extent that the IHR (2005) protect individuals from being refused entry in particular circumstances, they establish a protection which does not otherwise exist at international law – albeit a limited one. Broader obligations relating to informing individuals of risks and minimizing risks (Article 23), minimizing discomfort and distress (Article 32), and protection of personal information (Article 45) also arguably go beyond existing international obligations, though they reflect established best practice and evolving norms.

144 Gruskin, supra note 135 at 323 (describes the framework for justifying rights limitations as “still rudimentary”).

145 The key instrument here is the Siracusa Principles, supra note 133 which were adopted by a group of experts at a conference in Siracusa in 1984 and later submitted to the U.N. Commission on Human Rights. Although the Principles have been widely cited since and were intended to reflect existing law, they are not in themselves binding. The UN Human Rights Committee, which is responsible for the ICCPR, has also adopted relevant General Comments, for example: UN Human Rights Committee, General Comment 29: States of Emergency (article 4), U.N. Doc. CCPR/C/21/Rev.1/Add.11 (Geneva: UN 31 August 2001), online: UN <http://unbisnet.un.org>. The ICCPR itself is, of course, a treaty which imposes binding obligations on its states parties.

146 Article 36 is not one of the provisions referred to in Article 43. However, Article 43(1)(a) also allows for additional measures that “achieve the same or greater level of health protection than WHO recommendations”, apparently as an alternative to those provisions that are specifically mentioned in 43(1)(b). It is not clear whether this would allow states to depart from Article 36.

147 Article 12(3) allowing limitations on public health grounds only applies to movement within a territory and freedom to leave a country. It does not apply to the right to enter one’s own country in Article 12(4).

148 The IHR (1969) contain a specific provision of similar effect with respect to yellow fever vaccination, supra note 2 at Art. 66(3).

149 The European Convention on Human Rights and Biomedicine, 4 April 1997, E.T.S. No. 164, includes...
may advance somewhat existing protections and contribute to the further elaboration of human rights principles.

(c) Oversight and enforcement

Given that other international agreements impose similar obligations to the IHR (2005) which continue to operate, there is the potential for other oversight and enforcement mechanisms to contribute to states’ compliance with limits on national measures, which has historically been poor under the IHR. In particular, the overlap between the IHR (2005) provisions and those of the SPS Agreement and GATT suggests that under the new IHR regime, mechanisms within the WTO will have an important role in encouraging compliance with limits on additional measures. Additional measures which do not comply with the Article 43 conditions are also likely to breach relevant obligations of those states which are also WTO members.150 Although there is provision for dispute settlement in the IHR, the WTO dispute settlement regime is more likely to be effective because it is well-established and is widely regarded as having more “teeth” than most international dispute settlement mechanisms. As a result, the WHO anticipated that links between the IHR and the WTO agreements would provide an added incentive for compliance as one aspect of the expected “synergy” between the WTO regime and the revised IHR.151 The oversight of the SPS Committee, the WTO body responsible for implementation of the SPS Agreement, provides an additional mechanism to deal with excessive measures. WTO members are required to notify the WTO of regulations which are not “substantially the same” as international standards and which “may have a significant effect on trade of other Members”.152 The SPS Committee provides a forum for members to raise concerns about others’ measures as a precursor or alternative to commencing formal consultations under the dispute settlement system.153 This mechanism will now work alongside the potential for consultations and dispute settlement under the IHR.

the requirement of informed consent including the right to be given appropriate information on risks (Article 5), but most WHO members are not parties to this Convention (at 2 September 2005 it had 19 parties, all from Europe).

150 As of December 2005 there are 149 members of the WTO and 192 member states of the WHO, meaning that most though not all WHO member states bound by the IHR will also be bound by the WTO agreements.


152 SPS Agreement, supra note 112 at Annex B, para. 5.

Incentives to conform to WHO recommendations and IHR (2005) provisions will be further increased if these are treated as “international standards” under the SPS Agreement. Article 3 of the SPS Agreement requires members to “base their sanitary and phytosanitary measures on international standards, guidelines or recommendations, where they exist”, although they may use measures resulting in a higher level of protection if there is a scientific justification or as a consequence of the level of protection it has deemed to be appropriate, provided they comply with all the other obligations in the agreement. It also provides that measures conforming to such international standards will be presumed to be consistent with the SPS Agreement and the GATT. Annex A lists the Codex Alimentarius Commission (CAC), in relation to food safety, and the International Office of Epizootics (also known as the OIE or World Organisation for Animal Health), in relation to animal health and zoonoses, among the international standards, guidelines and recommendations recognized for this purpose. Others may be identified by the SPS Committee, but the IHR and WHO recommendations under them do not presently have this status. If they are recognized as international standards for the purposes of the SPS Agreement, then measures that conform to them will be presumed consistent with the SPS Agreement and the GATT, which would encourage states to give greater weight to them in decisions on national measures.

Although linkages with the WTO will encourage compliance, it must be recognized that neither the IHR (2005) nor other international regimes can ensure that states do not take excessive measures that would breach their provisions. This is to a large degree inherent in the characteristics of the international legal system discussed above. Moreover it must be noted that the WTO dispute settlement mechanisms – though among the strongest in international law – cannot induce compliance by a recalcitrant state, and they will be of limited usefulness particularly in the case of short-term emergency measures, given the length of time that dispute settlement will take and the absence of any provision for retrospective compensation. The institutional framework of the United Nations human rights regime, including the Human Rights Committee responsible for the ICCPR, has an important role to play in monitoring and encouraging compliance with relevant human rights norms, but has notoriously weak powers of enforcement. There is no doubt

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154 The Codex Alimentarius Commission is the international body responsible for the Codex Alimentarius, a collection of standards, guidelines and recommendations on food, including food safety.
155 SPS Agreement, supra note 112 at Annex A, para. 3(a), (b). Zoonoses are diseases transmitted among animal species (including between non-human animals and humans).
156 Ibid. at para. 3(d). Note that this only applies to “matters not covered by” the other paragraphs, so it appears that the Codex Alimentarius Commission and International Office of Epizootics are the exclusive sources of international standards on their particular topics for these purposes.
157 The WTO Dispute Settlement Understanding (DSU) provides for suspension of concessions or compensation in the event that the losing party fails to implement recommendations to bring its measures into compliance. However, compensation is voluntary (therefore rare) and is intended to induce compliance, not to compensate for past harms. See Understanding on the Rules and Procedures Governing the Settlement of Disputes, Annex 2 to the Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, 1867 U.N.T.S. 3, Article 22.
158 Under the Optional Protocol to the International Covenant on Civil and Political Rights, 16 December
that there are more mechanisms to encourage compliance than previously existed, but we must be realistic about the limits of their effectiveness.

(d) Summary and assessment of new regime

Under the new regime, we can distinguish four categories of health measures: measures specifically provided for in the IHR (2005); measures recommended by the WHO under the provisions on temporary or standing recommendations; “additional” measures which comply with Article 43 or are authorized by other international agreements; and “excessive” measures which are not provided for or recommended and do not meet the Article 43 requirements. The last category of excessive measures may include measures that do not respond to an identified health risk supported by scientific evidence, measures that are not rationally connected to their scientific basis, or measures that are more restrictive than reasonably necessary to avert a risk. Such measures would not be permitted as additional measures and they would breach states’ obligations under the IHR as well as trade and human rights obligations, because of the alignment of the Article 43 requirements with principles in other international agreements. These same principles are to be taken into account in the formulation of WHO recommendations (Article 17), so neither recommended nor additional measures should be inconsistent with these basic principles. The effect of Article 43 is to allow for differences in interpretation and application of the principles, meaning that recommended and additional measures will not be identical, but should be consistent to a large extent.

The relevant WTO obligations as interpreted to date suggest that states have a significant, though not unlimited, degree of discretion when it comes to adopting health protection measures. There must be objective, scientific evidence of a risk. This must point to the existence of an ascertainable risk, even if it is very small, rather than merely unsubstantiated fears or a purely theoretical risk. That this is also required under the IHR is reinforced by the condition in Article 43(1) that additional measures be “in response to specific public health risks or public health emergencies of international concern”. This wording suggests that a specific risk must be identified and there must be some evidence that it exists. This will be satisfied where a PHEIC has been identified through the assessment process provided for in Annex 2 of the IHR, and in other circumstances would require at least the initial stages of a risk assessment to have been carried out.

1966, 999 U.N.T.S. 171, individuals alleging violations of the ICCPR may submit communications to be considered by the Human Rights Committee and the Committee will provide its “views” on the matter to the complainant and the state. States must also submit periodic reports on their implementation of the ICCPR which are considered and commented on by the Committee, ICCPR, supra note 131 at Art. 40. Some regional mechanisms may be more effective in ensuring compliance with analogous provisions in relevant treaties.

159 Australia – Salmon, supra note 125 at para. 123 (a mere possibility of disease is insufficient); EC – Hormones, supra note 127 at para. 186 (requirement of an “ascertainable” or “identifiable” risk does not entail a minimum threshold of risk).

160 Annex A of the SPS Agreement, supra note 112, defines risk assessment as “evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing
However, once the existence of a health risk is established, a state is entitled to decide on the level of risk that it is willing to accept. It has even been said that states may legitimately pursue a “zero-risk” policy. It does seem clear, then, that under the WTO regime, states are free to take a very strict or risk averse position, even if this means that measures will have an impact that many would consider disproportionate to the seriousness of the risk. Article 43(1) of the IHR refers to the “appropriate level of health protection”; the equivalent phrase in the SPS Agreement is defined as meaning the “level of protection deemed appropriate by the Member establishing [the measure]”. This suggests that it is within each individual state’s discretion to define its “appropriate” level, and that this will not be subjected to an external, objective review. Under both the IHR and the SPS Agreement, states are encouraged to take into account the objective of minimizing trade restrictions in determining the appropriate level of protection, but this does not amount to an enforceable constraint.

The choice of measures to avert the risk must be rationally connected to their scientific basis but there appears to be some latitude for other factors such as social concerns or cultural preferences to be taken into account. This is subject to the obligation not to discriminate in applying measures, however. This obligation imposes important constraints, for example precluding individuals or goods from one country from being treated more harshly than those from another unless there is a clear health justification for this, supported by the relevant evidence. Measures must be transparent, so that they can be scrutinized and their application will be predictable.

If, as is very likely, the IHR (2005) provisions are given interpretations consistent with the parallel provisions in other agreements, they will allow deference to national decisions on levels of risk and some degree of flexibility as to choice of measures. Does this position adequately balance freedom to take health measures for the protection of national populations with the need to prevent excessive or disproportionate measures that will harm other states and act as a

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161 Australia – Salmon, supra note 125 at para. 121.
162 SPS Agreement, supra note 112 at Annex A, para. 5 [emphasis added].
163 See ibid. at Article 5.4; IHR (2005), supra note 21 at Article 3(4) (in legislating and implementing measures states should uphold the purpose of the Regulations, which includes avoiding unnecessary interference with trade).
164 For discussion on this point, see Button, supra note 119 at 103-113 (and the sources cited therein). While noting significant controversy on this point, she concludes that these factors can be taken into account provided their impact is not so significant as to sever the rational connection between the scientific evidence and the measure, and provided they relate to actual risks rather than unsubstantiated public fears.
disincentive to notification? The WTO provisions relating to health measures, on which the IHR (2005) provisions appear to be based, were not designed to deal with the specific concerns of public health surveillance and response. In particular, the impact of excessive measures on compliance with notification obligations was not taken into account in drafting or interpreting the GATT or SPS Agreement provisions. The IHR (2005) adopt the WTO approach of restraining illegitimate measures – that is, those without an adequate scientific basis or that are more restrictive than they need to be to achieve their objective – as opposed to the IHR (1969) objective of minimizing interference with traffic and trade. This shift in approach is reflected in the revised purpose statement which refers to avoiding unnecessary interference rather than minimizing interference per se. The difference is that the new regime allows even significant interference provided it is “necessary” to achieving the level of protection a state has chosen in response to a substantiated risk.

The debates in the WTO show the difficulty of precisely defining the right balance between regulatory autonomy and principled restraint. It remains to be seen whether further controversies will arise in the IHR context, but the current balance does seem reasonable. The requirement to have a scientific basis and to choose measures that are no more restrictive than necessary to avert the risk will be adequate to address the worst instances of excessive measures, such as the examples noted above.\(^{165}\) In any case, an alternative approach which would allow the WHO or another international organization to overrule national decisions about appropriate levels of risk exposure would have been unacceptable to most, if not all, states. However, the fact remains that the new regime allows measures to be taken “whose cost to the international trading system may be quite disproportionate to their benefits”\(^{166}\) and the trade effects of which may still discourage compliance with notification obligations. Thus, even if states fully comply with their obligations under the IHR and the WTO agreements, there is still the potential for some measures that could have a significant negative impact on global disease control as well as on directly affected individuals and states. Finally, then, we must consider whether there may be adequate alternative ways to prevent or respond to this potential.

3. Addressing the impact of health measures – the bigger picture

The discussion above identified several reasons for concern about excessive health measures. The immediate concern in the IHR regime is their impact on states’ willingness to share information about threats to health, and the resulting weakening of global surveillance and control. However, there is a broader issue about the economic impact of excessive measures, in particular given the important links between disease and poverty. The prospect of excessive measures following a

\(^{165}\) See above at notes 36-39 and accompanying text.

\(^{166}\) Button, supra note 119 at 91-92. This statement is made in reference to the SPS Agreement, but would be a fair assessment of the IHR (2005) as well given the similarities noted above.
state’s good faith compliance with its surveillance and notification obligations also seems fundamentally unfair, shifting a disproportionate share of the costs of disease control onto affected states. While there are common threads running through these concerns, they may require distinct responses. They are addressed to different degrees in the new IHR regime.

Here it is necessary to broaden the discussion somewhat beyond excessive measures. Excessive measures can be presumed to have the worst effects, because they will be harsh and likely discriminatory. However, other measures, including both recommended measures and additional measures permitted by Article 43, will also have an impact, and even a very substantial impact. Consider, for example, the impact of measures such as travel advisories issued by the WHO and others during the 2003 SARS outbreak. Even for those measures accepted as necessary, the economic fallout was significant.167 As noted above, the existing regime allows scope for measures that are very strict and even disproportionate to the harms they aim to avoid. Furthermore, the media and decisions taken by private sector actors may also have important effects, yet fall outside the scope of this regime. Therefore, it is not just the impact of excessive measures by states that need to be considered, though these may be the main concern.

The issue of compliance with notification obligations is the one that received most attention in the revision process, and as seen above, specific revisions are designed to address this issue. The provision for confidential provisional reporting should help to encourage sharing of information with WHO, and the ability of WHO to rely on unofficial sources of information provides a back-up in the event of non-compliance while at the same time making official concealment ineffective and therefore less likely. These revisions, combined with dramatic changes in technology, are widely accepted as having important implications for notification. They target notification directly and therefore mitigate one of the concerns about excessive measures. Since there is also thought to be a vicious cycle between excessive measures and concealment in the sense that excessive measures may be provoked by lack of openness as well as the reverse,168 this strategy is particularly important.

Fairness concerns have also been addressed, although perhaps less comprehensively. The conditions for additional measures in Article 43, the rules on application of measures in Article 42 and the criteria for recommendations in Article 17, combined with other international legal obligations, all require non-discrimination, thus targeting an important source of unfairness. In addition, they attempt to prevent measures that do not respond to a proven health risk or that are stricter than reasonably necessary to avert a risk, aiming at measures where health

167 See e.g. Flood and Williams, supra note 49 at 241-42 (controversy regarding WHO travel advisory for Toronto), 243 (economic impact of travel advisory); Aginam, “Between Isolationism and Mutual Vulnerability”, supra note 62 at 308 (economic impact of SARS in various countries).

168 Fidler, “Fourth Horseman”, supra note 4 at 847.
risks are likely being used as a pretence for protectionism or for political ends. Although the regime cannot guarantee compliance with these obligations, it is designed to prevent the worst forms of unfair conduct. Affected states are also entitled to be heard in the process set out for formulating recommendations (Articles 49 and 53), and have some options for consultations and dispute settlement (Articles 43 and 56). However, as noted above, it leaves open the potential for measures that are disproportionate in the sense that the economic harm they cause is not objectively justified by the risk they are designed to avert. These are more difficult to address because opinions will differ as to whether they are legitimate, and as a result the current state of international law is to leave room for such measures. They are arguably unfair, though, in that they shift burdens from those insisting on protection of their health to those bearing the cost of measures, regardless of whether that cost is proportionate to the benefit gained or who is better able to bear the cost, and without any effective influence on the decision or entitlement to redress.

Addressing the economic impact in itself and its effect on health in affected areas is a larger, more difficult issue, which perhaps explains why it is the one aspect that is not directly addressed in the revised IHR at all. It extends beyond the IHR into the sphere of other instruments and institutions, as well as the broader mandate of the WHO which is pursued in many different ways. It is notable, however, that there were suggestions for provisions in the revised IHR on compensation or assistance for affected states. These were dropped, while provisions were included calling for the WHO and its members to help states comply with their obligations and in particular to develop public health capacities (Article 44). Assistance is directed at strengthening surveillance and response capacities, which undeniably has great value but, it must be admitted, also reflects a measure of self-interest on the part of states which will benefit from a stronger national mechanisms in other countries in the event of an outbreak. The WHO is also responsible for providing guidance and assistance to states responding to public health risks or a PHEIC. There is no provision for compensation to affected states, even in the event of excessive measures, and assistance to states to cope with the effects of a PHEIC and related measures or to affected individuals is left to be dealt


\[^{170}\text{See e.g. Gostin, “World Health Law”, supra note 54 at 421-22. For further discussion of self-interest and disease control, see Aginam, Global Health Governance, supra note 63, especially at 58-59, 123-24.}\]

\[^{171}\text{IHR (2005), supra note 21 at Article 13(3), (6). The latter paragraph states that “WHO shall provide appropriate guidance and assistance to other States Parties affected or threatened” by a PHEIC, which could be read broadly to include assistance to deal with the impact of other states’ measures, but the context suggests that it was intended to refer to implementing and assessing control measures.}\]

\[^{172}\text{There may be a possibility of compensation being awarded in event of arbitration under Article 56(3), but this depends on acceptance of arbitration by both parties, which seems unlikely, as well as on the affected state being able to quantify and prove the amount of harm caused by the measure.}\]
with on an ad hoc basis by other means. This outcome repeats the pattern observed in the aftermath of the SARS epidemic, in which compensation for economic loss caused by health measures was not “seriously discussed”, despite the fact that aid was provided to some countries to deal with the outbreak itself.173

Commitments to cooperate and provide assistance are typically weak in international agreements, and the obligations in Article 44 of the IHR (2005) are no exception,174 so it is not clear how much practical difference it would make to broaden their scope. Nevertheless, the fact that they might not have been effective is no reason to exclude such provisions, and the omission of any reference to assistance for those disadvantaged as a result of health measures is unfortunate. In order to fill the gap that has been left, there are other possible ways of dealing with this issue.175 If compensation to affected states, communities and individuals is recognized as part of effective control strategies, the lines between assistance for disease control and for coping with the effects of measures are blurred. This will make international support even more justified, and perhaps somewhat more likely.176 It is important that further attention is given to this issue by the WHO and other relevant bodies.

IV. Conclusion

The revision of the IHR included significant changes in the approach to restraining states’ health measures, reflecting developments in the international legal framework and member states’ reluctance to give up too much regulatory autonomy when it comes to protecting the health of their populations. Although it might at first glance seem preferable to give states unlimited freedom in this context, this article has argued that some constraints are necessary to facilitate the effective functioning of the global surveillance regime, to ensure a measure of fairness to states participating in the regime, and to avoid exacerbating the vicious cycle of poverty and disease. A balance must therefore be struck between freedom and restraint, and in the new framework this will be sought by requiring states to adhere to certain principles and processes when choosing to exceed recommended measures.

173 Flood and Williams, supra note 49 at 245.
174 States “shall undertake to collaborate with each other, to the extent possible” for various purposes in Article 44(1).
175 See Flood and Williams, supra note 49 at 245 (citing some precedents and examples of compensation schemes).
176 Flood and Williams, ibid., note that a compensation fund for farmers adversely affected by measures to contain avian influenza has been proposed. More recent documents show that compensation is recommended as part of the global avian influenza strategy, but fail to indicate whether international support will be provided for such compensation or whether it will be left as the responsibility of national and local governments, as is typically the case. See WHO Regional Office for the Western Pacific, Press release: “International conference draws up strategy to fight avian influenza” (6 July 2005).
The revised provisions will thus allow national health measures to be taken in one of a number of circumstances: where measures are specifically provided for in the IHR; where measures are recommended in temporary or standing recommendations issued by the WHO under the IHR; where measures are authorized by another international agreement to which the state is party; or where the Article 43 requirements on additional measures are complied with. Obligations of non-discrimination and transparency must be adhered to in the application of all measures, as well as, in the case of measures applied to individual travellers, respect for human rights. The provisions of the IHR and other relevant agreements reflect common principles, including the need for scientific evidence of a health risk and a scientific basis for measures, the choice of the least-restrictive measures that would effectively avert the risk, non-discrimination, and the need for publication and review of measures. They balance these constraints with a degree of freedom by deferring to national decisions about acceptable levels of risk and by allowing some room for different interpretations of the requirements rather than compelling states to follow a prescribed set of health measures.

Among the many important issues arising in the IHR revision, the restraint of national health measures highlights some significant features of the IHR regime in its larger context. As we saw above, two important themes shaping the outcome of the revisions were the IHR’s relationships with the rest of international law and state sovereignty. The WTO has a potentially important role to play in ensuring that states do not take measures that would be contrary to the IHR (2005) provisions, given the alignment between those provisions and WTO agreements. This represents an unusual twist on the relationship between the trade regime and public health, since in other contexts the main concern has been the tensions between them and the potential for trade law to have a negative effect on public health. In response, some commentators – and publications of the WTO itself – have attempted to minimize the extent to which WTO obligations interfere with national health policy decisions. It is somewhat ironic, then, that in the context of the IHR, with an overriding concern with health protection, we might actually welcome the WTO disciplines and hope that their enforcement will be effective in restraining excessive measures.

The analysis of IHR (2005) provisions and relevant international agreements also revealed some unexpected synergies between human rights and trade principles and ways in which the tripartite relationship between these and the IHR might contribute to the development and understanding of human rights in this context.

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177 The most prominent of these is the impact of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C to the Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, 1867 U.N.T.S. 3, on availability of essential medicines, especially HIV/AIDS medication; others include concerns about liberalization of trade in services and health care, and the impact of trade liberalization on dietary patterns and tobacco consumption.

178 See e.g. Bloche, supra note 119; Motaal, supra note 119; WTO, “10 common misunderstandings about the WTO” (Geneva: WTO, 2003) at 6, online: WTO <http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm>.
Another facet of the relationship between trade and health was also revealed in examining the rationales for restraining health measures. Given the link between trade restrictions, poverty and health, this relationship is not a simple dichotomy and insisting that health should be the primary concern raises almost as many questions as it answers.

The key role that sovereignty concerns played in the negotiations on this issue also provides something of a counterpoint to broader trends in global health governance, analyzed most notably by David Fidler. He has described a recent movement away from “Westphalian” public health, based on “sovereignty, non-intervention, and consent-based international law”,179 toward “post-Westphalian” global health governance, which recognizes the participation of non-state actors and produces “global public goods for health”.180 Some aspects of the IHR revision process, in particular the new provisions affirming the WHO’s ability to rely on information from unofficial sources, reflect this trend and have been described as part of the “de-Westphalianization of the classical regime”.181 However, as we saw above, the way in which states – especially powerful states – resisted attempts to restrain national health measures reflected a traditional Westphalian view of international law, emphasizing sovereignty, the consensual basis of international legal obligations, and decentralization of authority.

The revised IHR show “an inevitable compromise between national sovereignty and the collective international good.”182 Fidler has emphasized the WHO’s “boldness and lack of deference to sovereignty” in taking the radical step, during the SARS epidemic, of issuing specific travel advisories, and notes that states generally did not question the WHO’s authority to take this action (despite contesting the appropriateness of its use in some cases), which is somewhat surprising given states’ reluctance to allow international organizations to take decisions that could cause them economic harm.183 In the revision of the IHR provisions on additional measures, in contrast, we saw sovereignty being reasserted in states’ refusals to accept WHO determinations on appropriate national health measures. The global regime for disease surveillance and control is thus a complex one embodying both “Westphalian” international law and “post-Westphalian” global

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179 Fidler, SARS, supra note 1 at 47.
180 Ibid, at 50-60. Public goods are goods which are non-rivalrous in consumption and non-excludable, that is, their consumption by some does not limit their value to others and they are available to all. Global public goods are public goods which are universally available on a global scale. See e.g. Inge Kaul, Isabelle Grunberg & Marc A. Stern, Global Public Goods: International Cooperation in the 21st Century (Oxford: Oxford University Press, 1999). The term “global public goods for health” has been used to describe the applications of this concept to health: see e.g. Richard D. Smith et al., eds., Global public goods for health: Health economic and public health perspectives (Oxford: Oxford University Press, 2003).
181 Fidler, SARS, supra note 1 at 60-68.
183 Ibid. at 142-43.
health governance, with some of the inherent tensions being played out in the IHR revision process. 184

The history of the IHR also reflect conflicting and shifting interests of various groups of states as they grapple with the “paradox of a global village in a divided world”. 185 In the early years of the IHR and their precursors, the world’s economically powerful countries pressed for restrictions on health measures to address the harm they caused to their trading interests. 186 For this reason restrictions on health measures have been characterized as a manifestation of Westphalian global health governance and the will of the “great powers”.187 In the contemporary context, however, it seems that less powerful and especially developing countries, as common targets of excessive health measures, have more of an interest in restraining measures, while many of the powerful developed countries are fighting to preserve their sovereign prerogative to impose the measures they deem appropriate. The interests of the leading economic powers appear to have shifted, but they have again succeeded in constructing a regime that accommodates their concerns.

Since the new regime has yet to come into force, it would be premature to draw any firm conclusions on its adequacy. It is difficult to predict how the revised Regulations will function, and in particular, whether the record of states’ compliance will be better than under the IHR (1969). The balance sought in the revised provisions seems to be reasonable and if complied with they will avoid the worst examples of excessive measures, which have historically included measures that were discriminatory, lacking sufficient scientific justification, or both. There is still some scope for measures that have an impact disproportionate to their benefits, especially where the acceptable level of risk set very low, but it is not realistic to expect states to give up their discretion on this point. As a result, most, but not all, sources of unfairness in this context have been addressed in the new provisions. The potential effect of excessive measures as a disincentive to reporting has been dealt with through a combination of limits on measures and important changes to the notification regime. These should be reasonably effective, especially considering the impact of developments in information technology which have revolutionized global surveillance. Broader concerns about the economic effects of measures and their potential health implications have not been addressed in the IHR (2005) and will require attention from the WHO and its member states as well as other relevant organizations.

184 Fidler recognizes this (though without making reference to this particular issue) in his discussion of the Westphalian “baggage” including the continuing role of sovereignty and the great powers in global public health, Fidler, SARS, supra note 1 at 170-79. See also Aginam, “Between Isolationism and Mutual Vulnerability”, supra note 62 and Aginam, Global Health Governance, supra note 63 on tensions between contending approaches in global health governance.

185 This phrase is taken from the chapter title of chapter 2 of Aginam, Global Health Governance, ibid.

186 See e.g. ibid. at 62-63.

187 Fidler, SARS, supra note 1 at 57, 150. See also Gostin, “World Health Law”, supra note 54 at 419 (interest of developed countries in free trade as the reason for the focus on trade in IHR).
Ultimately, the best prospects for reducing the use of excessive health measures and the impact of all health measures rest with effective global disease surveillance and control. The more effective the regime for detecting, communicating and containing health risks, the less likely it will be that states feel the need to respond with drastic measures or that large-scale measures with serious economic effects will be necessary. It is not realistic to expect that the possibility of excessive measures will disappear altogether, because states will sometimes have strong political and economic incentives to take measures that are excessive in the sense either that they are protectionist policies in the guise of health protection, or that they respond to public fears out of proportion to substantiated risks. The new legal framework governing national health measures will therefore continue to be important. At the same time, it is significant as an illustration of the complex issues of international law surrounding the IHR (2005). The positive effects it may have must, however, be considered in the broader context of the revised IHR regime and global efforts to respond to poverty and disease.