## UNDERSTANDING AND APPLYING INTERNATIONAL INFECTIOUS DISEASE LAW: U.N. REGULATIONS DURING AN H5N1 AVIAN FLU EPIDEMIC

TIMOTHY J. MIANO<sup>\*</sup>

#### **INTRODUCTION**

In 1918, over one billion people – half the world's population – contracted a virulent form of bird flu.<sup>1</sup> Spain was the first country to report an outbreak of the disease, and thus the flu strain became known as the Spanish Flu. The virus killed more than eight million Spaniards in one month.<sup>2</sup> Influenza killed approximately fifty million people worldwide that year, including 500,000 people in the United States.<sup>3</sup>

In 2003, a strain of avian flu known as H5N1 spurred new fears of a flu pandemic, this time in South Korea.<sup>4</sup> In response, Korean authorities culled the region's entire poultry population, killing over 150 million birds.<sup>5</sup> As of December 2005, fifteen countries have reported cases of the "highly pathogenic" H5N1 virus in poultry.<sup>6</sup> Five of those countries have reported 120 cases of interspecies transmission to humans,<sup>7</sup> 67 of which were fatal.<sup>8</sup>

Although an infectious disease pandemic implicates many areas of international law, most of those areas of law lack sufficient maturity to provide any concrete guidance during a large-scale emergency. For example, in *Case of D v. United Kingdom*,<sup>9</sup> the European Court of Human Rights held that Britain could not deport a convicted drug trafficker back to his home

<sup>&</sup>lt;sup>\*</sup> George Mason University School of Law, Juris Doctor Candidate, May 2007; Articles Editor, George Mason Law Review, 2006-2007; University of Virginia, B.A., Physics, May 2004. The author thanks Professor David P. Fidler for providing access to his forthcoming work on the revised International Health Regulations; and Kristin Lehner for always caring.

<sup>&</sup>lt;sup>1</sup> *Time Trip: Killer Flu of 1918*, 105 CURRENT EVENTS 3, (Sept. 23, 2005).

 $<sup>^{2}</sup>$  Id.

<sup>&</sup>lt;sup>3</sup> Lauren Etter, Avian Flu: Pandemic on the Horizon, WALL ST. J., Oct. 22, 2005, at A5.

<sup>&</sup>lt;sup>4</sup> In a Flap – Avian Influenza, ECONOMIST, Oct. 22, 2005.

<sup>&</sup>lt;sup>5</sup> Id.

<sup>&</sup>lt;sup>6</sup> World Health Organization, *H5N1 Avian Influenza: Timeline*, Oct. 28, 2005, *available at* http://www.who.int/csr/disease/avian\_influenza/Timeline\_28\_10a.pdf.

 $<sup>^{7}</sup>$  Id.

<sup>&</sup>lt;sup>8</sup> ECONOMIST, *supra* note 4.

<sup>&</sup>lt;sup>9</sup> 24 Eur. Ct. H.R. 423, 2 B.H.R.C. 273 (1997).

country of St. Kitts because the developing nation lacked the health standards necessary to treat D's late stage AIDS.<sup>10</sup> The European Court found that deporting D would have violated human rights norms requiring humane treatment because D would have spent "his remaining days in pain and suffering in conditions of isolation, squalor and destitution."<sup>11</sup> Although the theory behind the European Court's application of normative international human rights law had merit,<sup>12</sup> other courts have declined to follow *Case of D* in the absence of "compelling circumstances."<sup>13</sup> Broadly speaking, despite its noble aspirations, the rule of law espoused in *Case of D* carries little practical weight when applied to an emergency of notable magnitude because this rule presumes that the nation adjudicating the claim is not actively under the threat of an epidemic.<sup>14</sup>

Like the human rights law applied in *Case of D*, principles from the law of war and international environmental law tangentially address infectious disease through such topics as the treatment of detainees, the use of biological weapons, the standards of air and water quality, and the problems accompanying deforestation.<sup>15</sup> As in *Case of D*, these areas of international law have value during isolated incidents or in cultivating national policy. However, these international doctrines provide no practical guidance in the prevention of or in the reaction to widespread infectious disease.

<sup>&</sup>lt;sup>10</sup> *Id.* at 436.

<sup>&</sup>lt;sup>11</sup> *Id.* at 445.

<sup>&</sup>lt;sup>12</sup> See Stephanie Palmer, AIDS, Expulsion, and Article 3 of the European Convention on Human Rights, 5 EUR. HUM. RTS. L.REV. 533, 536 (2005).

<sup>&</sup>lt;sup>13</sup> *Id.* at 533 (citing N v. Sec'y of State, 4 Eng. Rep. 1017 (H.L. 2005)).

<sup>&</sup>lt;sup>14</sup> Some officials estimate 150 million human deaths in a H5N1 epidemic. *World Health Agency Tones Down Alarm on Possible Flu Pandemic*, N.Y. TIMES, Oct. 1, 2005. The United Kingdom likely would enforce its own conditions of isolation and suffering on infected individuals in the case of a pandemic, and every country lacking the capacity to handle the pandemic would become a country of isolation, squalor, and destitution.

<sup>&</sup>lt;sup>15</sup> DAVID P. FIDLER, INTERNATIONAL LAW AND INFECTIOUS DISEASES chs. 7-8 (Clarendon Press 1999) [hereinafter FIDLER, INFECTIOUS DISEASES].

Industrialized nations, international law practitioners, and scholars have not been blind to the threat of disease. For more than 150 years, nations have been forming multilateral agreements designed to halt the spread of infection.<sup>16</sup> The impetus for the original agreements was to protect the flow of commercial goods and tourists across borders.<sup>17</sup> However, as the world's population has tripled to 6.5 billion over the last fifty years<sup>18</sup> and national economies have become increasingly interdependent, priorities in the control of infectious disease have matured.

This article will focus on the two major United Nations ("UN") agreements that have attempted to regulate the activities of Member States as they relate to infectious disease. The International Health Regulations ("IHR")<sup>19</sup> protects public health directly by providing a structure for global disease reporting and by enumerating the rights and duties of individual states in controlling the spread of disease.<sup>20</sup> The Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement")<sup>21</sup> protects public health indirectly by dictating the circumstances under which international trade may be restricted to prevent the spread of disease.<sup>22</sup>

Part I of this article analyzes the transition from the old International Health Regulations ("IHR") to the newly revised IHR and the rights and duties of States created by this new framework. Part II considers the Agreement on the Application of Sanitary and Phytosanitary

<sup>&</sup>lt;sup>16</sup> *Id.* at ch. 2 (examining the history of international control of infectious disease).

<sup>&</sup>lt;sup>17</sup> *Id.* at 61.

<sup>&</sup>lt;sup>18</sup> U.S. Census Bureau, International Data Base, Total Midyear Population for the World: 1950-2050 (April 26, 2005), available at http://www.census.gov/ipc/www/worldpop.html.

<sup>&</sup>lt;sup>19</sup> Revision of the International Health Regulations, WHA Res. 58.3, World Health Assembly, 58th Ass. (May 23, 2005), available at http://www.who.int/csr/ihr/WHA58 3-en.pdf. [hereinafter IHR]

<sup>&</sup>lt;sup>20</sup> *Id.* at pmbl. 6(2).

<sup>&</sup>lt;sup>21</sup> Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Annex 1A, Legal Instruments-Results of the Uruguay Round vol. 27, available at http://www.wto.org/english/docs e/legal e/15-sps.pdf [hereinafter SPS Agreement]. <sup>22</sup> See id.

Measures ("SPS Agreement") and analyzes specific illustrations of the SPS Agreement at work. Both Parts I and II provide real and hypothetical examples of health emergencies in order to create context for analyzing the regulations and to fill in some of the peripheral gaps. Finally, Part III notes some of the strengths and weaknesses of the regulations by applying them to a simplified hypothetical H5N1 avian flu pandemic.

## I. THE REVISED INTERNATIONAL HEALTH REGULATIONS

The revised International Health Regulations will become binding on Member States in 2007, twenty-four months after the WHO Director-General adopted them.<sup>23</sup> The original IHR, adopted in 1951 and initially titled the International Sanitary Regulations ("ISR"), was comparatively narrow in scope and intent.<sup>24</sup> The WHO had no enforcement capabilities under the old regulatory scheme and, as a result, countries largely ignored many disease notification requirements.<sup>25</sup> This disregard, in part, prevented any disease control custom from maturing into binding international law.<sup>26</sup>

The World Health Assembly adopted the revised IHR in the era of modern infectious disease.<sup>27</sup> In March 2003, Severe Acute Respiratory Syndrome ("SARS") plagued several parts of the world.<sup>28</sup> After nine months of outbreaks, the World Health Organization ("WHO") reported 8422 SARS cases and 916 SARS deaths worldwide.<sup>29</sup> SARS was a first in many respects; for example, SARS was the first severe infectious disease of the 21<sup>st</sup> century fueled by

<sup>&</sup>lt;sup>23</sup> IHR, *supra* note 19, at art 59.2.

<sup>&</sup>lt;sup>24</sup> Lawrence O. Gostin, World Health Law: Toward a New Conception of Global Health Governance for the 21<sup>st</sup> Century, 5 YALE J. HEALTH POL'Y L & ETHICS 413, 415 (2005) [hereinafter Gostin, World Health Law].
<sup>25</sup> FIDUED INFECTIOUS DISEASES, summa pote 15, et 65, 67

<sup>&</sup>lt;sup>25</sup> FIDLER, INFECTIOUS DISEASES, *supra* note 15, at 65-67.

<sup>&</sup>lt;sup>26</sup> *Id.* at 102.

<sup>&</sup>lt;sup>27</sup> IHR, *supra* note 19; David P. Fidler, *From International Sanitary Convention to Global Health Security: The New International Health Regulations*, CHINESE J. INT'L L. (forthcoming 2005) (manuscript at 1, on file with author) [hereinafter Fidler, *Security: The New IHR*].

 <sup>&</sup>lt;sup>28</sup> See Jason W. Sapsin et al., SARS, Public Health, and Global Governance, 77 TEMP. L. REV. 155, 159-161 (2004).
 <sup>29</sup> DAVID P. FIDLER, SARS, GOVERNANCE AND THE GLOBALIZATION OF DISEASE 3 (Palgrave Macmillan 2004) [hereinafter FIDLER, SARS, GOVERNANCE, AND GLOBALIZATION].

global air travel.<sup>30</sup> As such, SARS was the first infectious disease not subject to traditional limitations of transmission. Specifically, the disease could not have "burned itself out" by killing off its primary population because it was not "an infectious disease confined to a particular geographical location."<sup>31</sup> SARS also was the first pandemic during which the WHO was able to appraise the potential influence of the revised health regulations.

In 2005, after ten years of work, the Member States of the World Health Assembly ("WHA") adopted the revised IHR.<sup>32</sup> The goal of this new convention was to ensure "the application of adequate measures for the protection of public health and strengthening of the global public-health response to the international spread of disease."<sup>33</sup> The revision of the IHR was "a closely watched and often controversial international legal reform effort" as the revisers sought the proper balance between protection of state sovereignty and independence on one hand and adequate global protection from the spread infectious disease on the other.<sup>34</sup> The revised IHR is broader in scope than the original regulations and affects the responsibilities of state actors, the rights among states, and the authority of the WHO in dealing with the control and containment of infectious disease.

#### A. The Original International Health Regulations: The IHR

From the first international sanitary conference, held in 1851, until the WHO formally adopted the ISR in 1951, there was little change in the objective of international infectious disease regulation.<sup>35</sup> The goal of the ISR – subsequently renamed the IHR – was to "protect States against the international spread of infectious disease in a way that minimized interference

<sup>31</sup> *Id*.

<sup>&</sup>lt;sup>30</sup> *Id*. at 6.

<sup>&</sup>lt;sup>32</sup> IHR, *supra* note 19; Fidler, *Security: The New IHR*, *supra* note 27.

<sup>&</sup>lt;sup>33</sup> IHR, *supra* note 19, at pmbl 6(2).

<sup>&</sup>lt;sup>34</sup> Fidler, *Security: The New IHR, supra* note 27, at 2.

 $<sup>^{35}</sup>$  *Id.* at 3.

with international trade and travel.<sup>36</sup> This principle was concisely reflected in the three primary obligations under the old IHR: notification, transport hygiene, and vaccination certification.<sup>37</sup> These objectives were limited in three ways. First, these were the only international regulations to cover infectious diseases. Second, the only diseases covered were cholera, plague, and yellow fever.<sup>38</sup> Third, these measures were "the maximum measures applicable to international traffic,"<sup>39</sup> and therefore Member States could not impose more stringent requirements. Ultimately, the IHR were commerce-centered safety measures designed both to react to spreading infectious disease and to prevent states from harming international trade by overreacting to the threat of disease.

The reactive system created by the IHR, though ambitious for its time, ultimately was ineffective. Economic realities and the lack of an enforcement mechanism rendered the states' obligations of notification, certification, and hygienic transport both economically unfeasible and practically unenforceable. Under the old regulations, nations were bound only by honor to report any case of the three listed diseases to the WHO and, under the IHR, nations suffered no penalties for noncompliance.<sup>40</sup> Such an idealistic requirement was doomed to fail. Poorer nations with the highest rates of disease lacked the resources to report, while wealthy nations lacked incentive to report events that would harm trade and tourism.<sup>41</sup> Certification requirements were equally problematic. When wealthy nations required health certificates, the subject diseases frequently were unlisted diseases, such as HIV, that nonetheless posed a great health risk.

<sup>39</sup> Gostin, International Infectious Disease Law, supra note 37, at 2624 (quoting the first IHR).

<sup>&</sup>lt;sup>36</sup> *Id.* at 5.

<sup>&</sup>lt;sup>37</sup> Lawrence O. Gostin, International Infectious Disease Law: Revision of the World Health Organization's International Health Regulations, 291 J.A.M.A. 2623, 2624 (June 2, 2004) [hereinafter Gostin, International Infectious Disease Law].

<sup>&</sup>lt;sup>38</sup> Fidler, Security: The New IHR, supra note 27, at 7.

<sup>&</sup>lt;sup>40</sup> Id.

<sup>&</sup>lt;sup>41</sup> FIDLER, INFECTIOUS DISEASES, *supra* note 15, at 66.

Again, whether for listed or for unlisted disease, poorer nations simply lacked the resources to comply with certification requirements.<sup>42</sup>

Similarly, the hygienic transport hubs requirements, including clean water and food requirements, health inspections, and appropriate quarantine facilities, were neglected because poor nations lacked the resources to meet the requirements.<sup>43</sup> Wealthy nations also struggled with the transport hub requirements, but the difficulty was effectiveness rather than execution. Cholera, plague, Ebola, AIDS, and SARS often are not symptomatic infectious diseases during ingress and egress, but only become so after transit.<sup>44</sup> Therefore, although some nations were facially compliant with the transport hubs requirements, those countries still were unable to stop diseases at the door.

Moreover, the IHR's reactive nature ultimately doomed the system because it provided no guidance for dealing with new and unknown infectious diseases. Rather, "[a]ny new pathogen, or resurging old ones, not listed as 'disease subject to the Regulations' fell outside IHR's surveillance system."<sup>45</sup> Emerging health threats such as Ebola and HIV/AIDS were neither reportable under the IHR nor subject to its tracking requirements. In 1995, with HIV/AIDS and the proliferation of biological weapons drawing attention to world health issues, the WHO began revising the IHR.<sup>46</sup> Further, the emergence of the SARS disease and the WHO's ineffective handling of the outbreak accelerated the revision process.<sup>47</sup> These events also demonstrated that the new IHR needed to be "a flexible framework that [could] respond to

<sup>&</sup>lt;sup>42</sup> Gostin, International Infectious Disease Law, supra note 37.

<sup>&</sup>lt;sup>43</sup> Id.

<sup>&</sup>lt;sup>44</sup> See generally National Center for Infectious Diseases, *Infectious Disease Information, available at* http://www.cdc.gov/ncidod/diseases/index.htm (last visited April 9, 2006).

<sup>&</sup>lt;sup>45</sup> Fidler, *Security: The New IHR*, *supra* note 27, at 16.

<sup>&</sup>lt;sup>46</sup> *Id*.

<sup>&</sup>lt;sup>47</sup> *Id.* at 30.

unknown disease events rapidly."<sup>48</sup> In May 2005, the WHO adopted the new IHR, proclaiming the "effective death" of the traditional outbreak/response approach embodied in the old IHR.<sup>49</sup>

# **B.** The Revised International Health Regulations: Expanded Goals and Broadened Scope

Like the old system, the revised IHR's goals include the avoidance of "unnecessary interference with world trade and travel."<sup>50</sup> Unlike the old system, the new IHR's proactive disease-prevention measures center on public health and take qualified priority over commercial interests. The broadened scope of the revised IHR reflects this shift in priorities.

## 1. Broadened Definition of Disease

The new IHR applies to broadly defined events. Whereas the old regulations were limited to a small number of specific diseases, the revised IHR applies to all communicable and non-communicable public health emergencies of international concern and encompasses both natural and artificial threats.<sup>51</sup> The IHR defines a public health emergency as "an extraordinary event [that] is determined, as provided in these Regulations: (i) to constitute a public health threat risk to other States through the international spread of disease[;] and (ii) to potentially require a coordinated international response."<sup>52</sup> This definition requires some unpacking.

An international public health emergency exists when there is a manifestation – or a clear danger of a manifestation – of a significant human medical illness that either poses a threat to the international population *or* requires a coordinated multinational response. The language is broad enough to encompass both ongoing long-term diseases such as HIV/AIDS and future fast-

<sup>48</sup> Id.

<sup>&</sup>lt;sup>49</sup> *Id.* at 2.

<sup>&</sup>lt;sup>50</sup> IHR, *supra* note 19, at art. 2.

<sup>&</sup>lt;sup>51</sup> *Id.* at Annex I.

<sup>&</sup>lt;sup>52</sup> *Id.* at art 1.

spreading communicable diseases that have not yet been identified. Moreover, the definition also includes current but yet unrealized threats of such illnesses.

Twenty-first century diseases such as SARS will be classified as public health emergencies under the revised IHR. SARS first emerged in China in late 2002 and had been identified in Singapore, Hong Kong and Canada by March of 2003.<sup>53</sup> The mobility of the disease and the evidence of cross-border transmission both suggest that SARS would have qualified as a threat to the international population.<sup>54</sup> Furthermore, characteristics of the newlydiscovered disease, including the lack of diagnostic tests and a vaccine, the lack of effective treatment, and SARS' 15% fatality rate <sup>55</sup> suggested both a threat to the international population and the need for a coordinated multinational response. Thus, newly-discovered diseases like SARS now will fall under the IHR and will be subject to these international regulations as well as to country-specific treatment and prevention measures.<sup>56</sup>

# 2. Broadened Reporting Structure: Information Centralization and Incorporation of Non-State Actors

The second important structural component of the IHR is the WHO's centralization of information and its incorporation of non-state actors. Under the new IHR, the WHO has the "authority and responsibility . . . to collect and act upon sources of information."<sup>57</sup> That is, the WHO must collect disease event reports from Member States, must maintain qualified confidentiality on information, and must declare international public health emergencies.<sup>58</sup> The

<sup>&</sup>lt;sup>53</sup> See Sapsin et al., *supra* note 28 (discussing SARS outbreaks and governmental responses in various affected nations).

<sup>&</sup>lt;sup>54</sup> IHR, *supra* note 19, at art. 1.

<sup>&</sup>lt;sup>55</sup> Sapsin et al., *supra* note 28, at 157.

<sup>&</sup>lt;sup>56</sup> See id.

<sup>&</sup>lt;sup>57</sup> Fidler, *Security: The New IHR*, *supra* note 27, at 52.

<sup>&</sup>lt;sup>58</sup> IHR, *supra* note 19, at art. 5.

WTO also may use non-state sources of information concerning public health.<sup>59</sup> When utilizing data from non-governmental organizations ("NGOs"), the IHR "imposes duties on [the] WHO to engage in such collection efficiently and effectively . . . [and] verify such information."<sup>60</sup> According to one commentator:

[t]he New IHR . . . [makes] non-State actors formally part of the governance mechanism of the revised Regulations. Increasing the scope of participation in this way highlights how the process of achieving global health security differs from the State-centric approach of international health security found in the classical regime. WHO's ability to gather and use non-governmental sources of information and the obligation on States Parties to respond to request for verification of such information received from WHO mean that States no longer dominate or control the process of epidemiological surveillance.<sup>61</sup>

The value of this dynamic system is two-fold. First, the IHR creates incentives for states to report health events while simultaneously allowing the WHO to collect data from NGO sources and declare public health emergencies in a state without that state's consent.<sup>62</sup> Second, the IHR requires transparency in the WHO's process because the WHO must verify any NGO data that it relies on and also must demonstrate effective data collection techniques used by the particular NGO providing the data.<sup>63</sup> Thus, the IHR diffuses the disincentives of reporting health events that plagued the old system.

# C. The Content of the Revised IHR

The content of the revised IHR may best be understood by dividing the revision into two components: (1) the obligations of states and (2) the rights of states. The new regulations take a formalistic international law approach, including the establishment of positive duties and the

<sup>&</sup>lt;sup>59</sup> *Id* at art. 7. NGOs played a substantial role in the tracking the spread of SARS, but although NGOs may be reliable sources of information about infectious diseases, at least one commentator has argued that the WHO ought not to rely on the actions of parties that are not legally bound to the WHO. *See* David Bishop, Note, *Lessons from Sars: Why the WHO must Provide Greater Economic Incentives for Countries to Comply with International Health Regulations*, 36 GEO. J. INT'L L. 1173 (2005).

<sup>&</sup>lt;sup>60</sup> Fidler, *Security: The New IHR*, *supra* note 27, at 52.

<sup>&</sup>lt;sup>61</sup> *Id.* at 51.

<sup>&</sup>lt;sup>62</sup> IHR, *supra* note 19, at art. 7.

<sup>&</sup>lt;sup>63</sup> Fidler, *Security: The New IHR, supra* note 27, at 52.

handling of enforcement. The revised IHR will become the central international framework for combating international infectious disease.

#### 1. The Duties of States Under the Revised IHR

The IHR unquestionably raises issues of sovereignty because it imposes affirmative obligations on the independent nations that are members of the WHA.<sup>64</sup> As Article 3.4 makes clear, "States . . . have the sovereign rights to legislate and to implement legislation in pursuance of their health policies. In doing so they should uphold the purpose of these Regulations."<sup>65</sup> Clearly, the IHR runs into the same enforcement problems as other multilateral treaties.<sup>66</sup> As noted however, these regulations provide incentives for nations, especially developed nations, to follow their obligations because Member States have no veto power over the WHO's health emergency reports.<sup>67</sup>

Annex I of the revised IHR spells out the "core capacity requirements for surveillance and response,"<sup>68</sup> detailing states' obligations under the IHR. In particular, nations must "detect events involving disease," must "assess reported events," must "notify [the] WHO immediately," and must "report all essential information."<sup>69</sup> Additionally, each state must create and maintain a "public health emergency contingency plan."<sup>70</sup> The responsibilities of states follow the overarching themes of the IHR: respond to the emergency and mitigate any resulting damage. Specifically, the IHR places duties on states by building a streamlined event reporting system and by importing binding aspects of international law into the health regulations.

<sup>&</sup>lt;sup>64</sup> See, generally, Jose E. Alvarez, The New Treaty Makers, 25 B.C. INT'L & COMP. L. REV. 213 (2002) (for a discussion of the interplay between treaty making, intergovernmental organizations, and state sovereignty).

<sup>&</sup>lt;sup>65</sup> IHR, *supra* note 19, at art. 3.4.

<sup>&</sup>lt;sup>66</sup> See infra Part III.B.

<sup>&</sup>lt;sup>67</sup> Fidler, *Security: The New IHR, supra* note 27, at 52.

<sup>&</sup>lt;sup>68</sup> IHR, *supra* note 19, at Annex I.

<sup>&</sup>lt;sup>69</sup> Id.

<sup>&</sup>lt;sup>70</sup> Id.

The IHR lays out a mandatory disease reporting system; states must follow the IHR's decision instrument in deciding which events it must report to the WHO.<sup>71</sup> This instrument describes three paths for reporting public health events.<sup>72</sup> Each path lays out a course of treatment for a different class of diseases: (1) known diseases whose outbreaks are unexpected and serious, such as a new influenza strain or SARS; (2) known diseases with a demonstrated ability to become emergencies, including the plague or Ebola; and (3) unknown or potential threats.<sup>73</sup> The instrument dictates that states *must report* any disease outbreak falling under class (1), and states *must analyze the need to report* to the WHO any disease outbreak falling under classes (2) and (3).<sup>74</sup> The analysis weighs factors of seriousness, expectation, risk of spreading, and impact on trade.<sup>75</sup>

For example, if a Romanian farmer contracts SARS, Romania must report the incident to WHO under class (1) because the outbreak would be of a disease known to be a serious threat. But if a rural healthcare worker in Zambia contracts cholera then the threat of international spread is lower and the event is less unusual. The Zambia outbreak would not be "unexpected," and the automatic reporting requirement under class (1) would not be triggered. Under a class (2) analysis, Zambia may not be obliged to report the case. In contrast, a cholera outbreak in South Korea might trigger a mandatory report by that country because cases are uncommon, a high population density exists, and international travel is more prevalent.

Another markedly different way that the revised IHR obliges states is by appropriating other aspects of international law and integrating them into the domestic public health

 <sup>&</sup>lt;sup>71</sup> *Id.* at art. 6.1.
 <sup>72</sup> *Id.* at Annex II.
 <sup>73</sup> *Id.*

<sup>&</sup>lt;sup>74</sup> IHR, *supra* note 19, at Annex I.

<sup>&</sup>lt;sup>75</sup> Id.

requirements.<sup>76</sup> Though states must satisfy the IHR health measures, the regulations do not preclude states from implementing domestic laws that "achieve the same or greater level of protection."<sup>77</sup> However, "such measures shall not be . . . more intrusive to persons than reasonably available alternatives."<sup>78</sup> This requirement invokes the Siracusa Principles, which outline the ways individual human rights may be curtailed for the protection of public health.<sup>79</sup> Unlike the decision instrument, which places a positive duty on states, the Siracusa Principles place a negative duty on states. The Siracusa Principles require that states must enact only those health measures that are "necessary, proportionate, and fair".<sup>80</sup> and prohibit states from enacting health measures that fall outside the bounds of these criteria.<sup>81</sup> In effect, the IHR couches public health in the broader context of international human rights law.

Consider, for example, Canada's first reported SARS patient in March 2003.<sup>82</sup> The Canadian government amended its Quarantine Act and Regulations to "authorize detention of travelers with suspected SARS for up to twenty days."<sup>83</sup> The U.S. Centers for Disease Control now report that the incubation period for SARS is one to twelve days.<sup>84</sup> Suppose China reports ten new cases of SARS among dockworkers. If the Canadian government further amends its statute and quarantines all Chinese freight ships and crew suspected of carrying SARS for sixty days, Canada would violate the IHR. First, Canada's quarantine of all ships would be over-

<sup>&</sup>lt;sup>76</sup> The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights, reprinted in 7 Hum. Rts. Q. 3, 7 (1985) [hereinafter The Siracusa Principles]; IHR, *supra* note 19, at art. 43.1.

<sup>&</sup>lt;sup>77</sup> IHR, *supra* note 19, at art. 43.1; The Siracusa Principles, *supra* note 76.

<sup>&</sup>lt;sup>78</sup> IHR, *supra* note 19, at art. 43.1.

<sup>&</sup>lt;sup>79</sup> The Siracusa Principles, *supra* note 76; Gostin, *International Infectious Disease Law, supra* note 37, at 2626.

<sup>&</sup>lt;sup>80</sup> Gostin, World Health Law, supra note 24, at 423.

<sup>&</sup>lt;sup>81</sup> See, generally, Allyn L. Taylor, *Globalization and Biotechnology: UNESCO and an International Strategy to Advance Human Rights and Public Health*, 25 AM. J.L. & MED. 479, 505 (1999) (discussing the Siracusa Principles and their application to public health regulations).

<sup>&</sup>lt;sup>82</sup> Sapsin et al., *supra* note 28, at 161.

<sup>&</sup>lt;sup>83</sup> *Id*.

<sup>&</sup>lt;sup>84</sup> Martin I. Meltzer, *Multiple Contact Dates and SARS Incubation Periods*, 10 EMERGING INFECTIOUS DISEASES 207, 208 (Feb. 2004), *available at* http://www.cdc.gov/ncidod/EID/vol10no2/pdfs/03-0426.pdf.

inclusive because the quarantine would be "more restrictive of international traffic . . . than reasonably available alternatives."<sup>85</sup> Second, the Canadian measure would not be "based on scientific principles,"<sup>86</sup> given that the average SARS incubation is four days. To quarantine ships and travelers for sixty days violates the clear language of the IHR.<sup>87</sup> Moreover, the broader human rights protections in the Siracusa Principles require that "government infringing on the enjoyment of human rights provide justification for such infringements."<sup>88</sup> Thus, the IHR "balance[s] sovereignty, science and public health" by requiring appropriate information and enjoining irrational or ill-suited reactions to public health emergencies.<sup>89</sup>

## 2. The Rights of the States Under the New IHR

The IHR lays out the rights that states have with respect to the WHO and clarifies domestic rights relating to public health emergencies.<sup>90</sup> Although the notion of states' rights implicates larger topics in international law, the IHR creates positive rights for states by outlining the WHO's negative duties under the new regulations. By enumerating states' rights through the IHR, the WHO may be held expressly accountable for its actions. Further, proper state action in difficult scenarios becomes clear when states understand not only their obligations but also the boundaries of their rights.

One such right is the states' right to confidentiality. The WHO is obliged to keep all health data confidential except in the case of a "public health emergency of international concern" or where state control measures "are unlikely to succeed."<sup>91</sup> The value of this system is clear; the right to confidentiality encourages the flow of information and mitigates the

<sup>&</sup>lt;sup>85</sup> IHR, *supra* note 19, at art. 43.1.

<sup>&</sup>lt;sup>86</sup> Id.

<sup>&</sup>lt;sup>87</sup> The Siracusa Principles, *supra* note 76; IHR, *supra* note 19, at art. 43.1.

<sup>&</sup>lt;sup>88</sup> Fidler, Security: The New IHR, supra note 27, at n. 311.

<sup>&</sup>lt;sup>89</sup> *Id.* at 59.

<sup>&</sup>lt;sup>90</sup> IHR, *supra* note 19.

<sup>&</sup>lt;sup>91</sup> IHR, *supra* note 19, at art. 11.

unnecessary loss of international commerce without extending so broadly as to threaten the public at large. However, this right extends only to the relationship between the WHO and the Member States.

The IHR also clarifies some activities that states may rightfully undertake irrespective of WHO, most notably the right to quarantine. In April 2003, Singapore amended its Infectious Disease Act to "require persons with [possible SARS] to report to designated treatment centers, . . . enforce home quarantine with electronic tagging and forced detention; and allow the quarantine and destruction of SARS-contaminated property."<sup>92</sup> Singapore used fines, in-home cameras, and arrests to enforce the quarantine of over 740 people.<sup>93</sup> All of these measures are acceptable under the new IHR. Although the IHR requires medical examinations to be the "least obtrusive [measures] . . . that would achieve the public health objective,"<sup>94</sup> the same standard does not expressly apply to vaccinations, prophylaxes, isolations, or quarantines. Furthermore, "the revised Regulations do not contain requirements that State Parties accord those subject to compulsory measures due process protection, such as the right to challenge such measures in court."<sup>95</sup> In this manner, the IHR affirms a State's right to restrict and protect its population as it sees fit.

Rather than establishing rules for uniform quarantine policies among states, the IHR does not expressly attempt to limit or guide the use of quarantine.<sup>96</sup> Instead, a state may quarantine a person without that person's consent when the state deems that "such a compulsory measure is

<sup>&</sup>lt;sup>92</sup> Sapsin et al., *supra* note 28, at 159.

<sup>&</sup>lt;sup>93</sup> *Id.* at 159, 164.

<sup>&</sup>lt;sup>94</sup> IHR, *supra* note 19, at art. 23.

<sup>&</sup>lt;sup>95</sup> Id.

<sup>&</sup>lt;sup>96</sup> States are not entirely unrestricted in their right to quarantine, however, because the IHR, the Siracusa Principles and other international human rights law still function as a check on state action. *See* The Siracusa Principles, *supra* note 76; IHR, *supra* note 19, at art. 43.1

necessary to control an imminent public health threat.<sup>97</sup> There are three reasons for making this an unquestionable states' right. First, the WHO lacks the ability to enforce uniform domestic quarantines. Adding superfluous or symbolic requirements to binding regulations weakens the overall system. Second, nations would be unlikely to agree to give up sovereign rights of self-governance and domestic population control in making quarantine decisions. Even if quarantine rules were merely an unenforceable gesture, such an act might gestate into binding international custom despite states' objections. Third, the imposition of hard and fast limits on the ability of states to isolate sections of its population is not in the interest of the WHO or its Member States, even when extreme circumstances would implicate human rights. These regulations are not meant to symbolically handcuff states in the face of international public health threats, especially when those threats are unpredictable. The threat to the population's welfare outweighs the lack of "compulsory due process protections, such as the right to challenge [quarantine] in court."

The SARS outbreak illustrates why the WHO is not in a position to uniformly constrain quarantine policy. In Singapore, 740 people were under full quarantine measures within twenty-four days of the first SARS cases.<sup>99</sup> Through the emergency measures, "the average time from onset of SARS symptoms to isolation of probable cases declined . . . from 6.8 days to 1.3 days."<sup>100</sup> In total, Singapore reported 238 cases with a population density of 6,400 persons per square kilometer.<sup>101</sup> Similarly, in Hong Kong more than 1,000 people were quarantined within twenty-three days after the first case of SARS in that country.<sup>102</sup> Hong Kong has a similar

<sup>&</sup>lt;sup>97</sup> Fidler, Security: The New IHR, supra note 27, at 45.

<sup>&</sup>lt;sup>98</sup> Id.

<sup>&</sup>lt;sup>99</sup> Sapsin et al., *supra* note 28, at 159.

 $<sup>^{100}</sup>$  *Id*.

<sup>&</sup>lt;sup>101</sup> FIDLER, SARS, GOVERNANCE, AND GLOBALIZATION, *supra* note 29, at 4; CIA, *The World Factbook, Hong Kong*, *available at* http://www.cia.gov/cia/publications/factbook/geos/hk.html (last updated Nov. 1, 2005).

<sup>&</sup>lt;sup>102</sup> Sapsin et al., *supra* note 28, at 160.

population density of 6,300 persons per square kilometer, but reported 1,755 cases in total.<sup>103</sup> This data says nothing about how many people must be quarantined or how quickly a state must quarantine them to control the spread of infectious disease, but it does indicate that WHO is not is a position to uniformly constrain quarantine policy. Ultimately, by affirming national control of quarantine, the IHR avoids emersion in a politically controversial subject and promotes responses that are more adaptable to circumstances in individual states.

# II. THE AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES AND JUSTIFIED TRADE RESTRICTION

The IHR is not the only system of international regulations that functions to protect against infectious disease. In 1998, the WHO presented information to the World Trade Organization ("WTO") on the IHR.<sup>104</sup> The goal of this meeting was to coordinate the new public health measures of the IHR with the existing and binding public health framework of the WTO.<sup>105</sup> One of the founding pillars of the WTO is the Agreement on the Application of Sanitary and Phytosanitary Measures.<sup>106</sup> This agreement seeks to reduce international trade barriers by ensuring that "countries apply measures to protect human, animal and plant health based on assessment of risk."<sup>107</sup> Given that practically all members of the WHO also are members of the WTO and that the WTO has binding enforcement mechanisms, those in the WHO charged with revising the IHR understood that "harmonizing the IHR and SPS Agreement would reflect [a] common purpose and avoid any potential conflict in the obligations of Member

<sup>&</sup>lt;sup>103</sup> FIDLER, SARS, GOVERNANCE, AND GLOBALIZATION, *supra* note 29, at 4.; CIA, *The World Factbook, Hong Kong, available at* http://www.cia.gov/cia/publications/factbook/geos/hk.html (last updated Nov. 1, 2005). <sup>104</sup> World Health Organization, *Revision of the International Health Regulations: Progress Report*, 73 Weekly

Epidemiological Record 233, 236 (July 31, 1998), *available at* http://www.who.int/docstore/wer/pdf/1998/wer7331.pdf.

 $<sup>^{105}</sup>$  *Id.* 

<sup>&</sup>lt;sup>106</sup> SPS Agreement, *supra* note 21, at art. 11.

<sup>&</sup>lt;sup>107</sup> World Health Organization, *supra* note 104, at 235.

States."<sup>108</sup> Consequently, the revised IHR was tailored to comport with the SPS Agreement. As such, an understanding of the IHR and the complete infectious disease international law régime requires careful examination of the WTO's role in protecting public health.

## A. The History and Scope of the SPS Agreement

The 1947 General Agreement on Tariffs and Trade ("GATT") became "the first multilateral trade agreement that attempted to provide rules for global trade."<sup>109</sup> The infrastructure of this agreement addressed state behaviors that could affect public health.<sup>110</sup> The framers of GATT attempted to "balance the sovereign right to keep out products that may threaten a nation's health with disciplines to prevent this right from being misused for discriminatory or protectionist purposes."<sup>111</sup>

The treatment of British exports following the discovery of mad cow disease serves as an example of a public health emergency under GATT. In 1996, Britain reported several cases of mad cow disease (Bovine Spongiform Encephalopathy ("BSE")), which scientists linked to a fatal human brain disease called Creutzfeldt-Jakob disease.<sup>112</sup> In reaction, the European Union ("EU") banned all exports of British beef.<sup>113</sup> The disease claimed ten human lives by 1997, and the British beef industry had lost over \$2.37 billion dollars by 1999.<sup>114</sup> Though not in force at the time, this incident illustrates a clear public health emergency under Article XX(b) of GATT:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevails, or a distinguished restriction on

<sup>&</sup>lt;sup>108</sup> *Id.* at 236.

<sup>&</sup>lt;sup>109</sup> General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194 [hereinafter GATT]; FIDLER, INFECTIOUS DISEASES, *supra* note 15, at 121.

<sup>&</sup>lt;sup>110</sup> GATT, *supra* note 109; FIDLER, INFECTIOUS DISEASES, *supra* note 15, at 121.

<sup>&</sup>lt;sup>111</sup> FIDLER, INFECTIOUS DISEASES, *supra* note 15, at 121.

 <sup>&</sup>lt;sup>112</sup> EU Agrees to Ban Exports of British Beef --- While Major Wins a Delay, Decision Could Force Wide Cattle Slaughter, WALL ST. J., Mar. 26, 1996, at A14.
 <sup>113</sup> Id

<sup>&</sup>lt;sup>114</sup> 1996 Year-end Review of Markets and Finance, WALL ST. J., Jan. 2, 1997, at R2; EU Commission Ends 3-Year Ban on British Beef, WALL ST. J., July 15, 1999, at A13.

international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: . . . necessary to protect human, animal or plant life or health.<sup>115</sup>

In the case of BSE, the disease posed a significant threat of spreading to domestic cattle and infecting humans. Despite huge financial losses that resulted from the ban, Britain would have had no recourse under GATT because the ban (1) was not arbitrary, (2) was not disguised or unjustifiably discriminatory, and (3) was meant to protect life and health.<sup>116</sup>

However, Article XX(b)'s coverage was not always clear. Parties made radical changes to GATT in the Uruguay Round.<sup>117</sup> In 1993, the WTO substantially revised the goals and principles of GATT and adopted the SPS Agreement.<sup>118</sup> The SPS Agreement moves beyond Article XX(b) in two substantial ways. First, a protective sanitary trade measure meets the SPS Agreement if and only if it "is based on scientific principles and is not maintained without sufficient scientific evidence."<sup>119</sup> For example, in 1991, Peru reported a cholera outbreak with more than 300,000 infected persons.<sup>120</sup> Peru lost over \$12.9 billion in trade because of worldwide bans of Peruvian imports that nations imposed at the time of the cholera outbreak.<sup>121</sup> Peru complained "that the GATT rules were being ignored and other states were imposing tradedamaging health protection measures against Peru that lacked scientific support or clear public health rationales."<sup>122</sup> The SPS Agreement's scientific justification clause solves this problem

<sup>&</sup>lt;sup>115</sup> GATT, *supra* note 109, at art. XX(b).

<sup>&</sup>lt;sup>116</sup> *Id.*; FIDLER, INFECTIOUS DISEASES, *supra* note 15, at 133.

<sup>&</sup>lt;sup>117</sup> FIDLER, INFECTIOUS DISEASES, *supra* note 15, at 133.

<sup>&</sup>lt;sup>118</sup> *Id.* at 134.

<sup>&</sup>lt;sup>119</sup> SPS Agreement, *supra* note 21, at art. 2(2). A complete analysis of the SPS Agreement requires consideration of the Agreement's nine key elements. *See* Timothy M. Reif & Julie Eckert, *Courage You Can't Understand: How to Achieve the Right Balance Between Shaping and Policing Commerce in Disputes Before the World Trade Organization*, 42 COLUM. J. TRANSNAT'L. L. 657, 703 (2004) (considering four of these elements in detail and noting the other five).

<sup>&</sup>lt;sup>120</sup> David P. Fidler et al., *Emerging and Reemerging Diseases: Challenges for International, National, and State Law*, 31 INT. LAW. 773, 778 (1997).

<sup>&</sup>lt;sup>121</sup> Julia A. Jones, Comment, International Control of Cholera: An Environmental Perspective to Infectious Disease Control, 74 IND. L. J. 1035, 1044 (1999).

<sup>&</sup>lt;sup>122</sup> *Id.* at 1064.

because "[n]o longer can health policy that affects trade be created out of fear, superstition, or any other illegitimate basis."<sup>123</sup> Instead, trade restrictions imposed in response to infectious disease outbreaks must be "made fairly and for legitimate reasons."<sup>124</sup>

The SPS Agreement also moves beyond GATT's initial scope because all WTO Member States must adopt its terms.<sup>125</sup> As one of the founding WTO multilateral agreements, "any State wanting to become a Member State of WTO has to accept the SPS Agreement."<sup>126</sup> Therefore the WTO has the authority to settle any dispute between Member States over whether trade bans "involving scientific or technical issues" actually are protectionist measures designed to keep foreign products out of a state's economy.<sup>127</sup> Unlike the prior GATT procedure, where little recourse could be taken against a party that disagreed with the decision of a dispute settlement panel, the WTO's dispute settlement procedure allows states to impose trade sanctions for violations.<sup>128</sup> Whereas prior to the SPS Agreement Peru had no practical means to attack "tradedamaging health measures that lack[ed] scientific rationale,"<sup>129</sup> the binding dispute settlement provisions attached to the SPS Agreement would assure Peru a chance to argue its position to the WTO. Thus, the SPS Agreement is "the first international agreement attempting to balance trade and public health that contains a compulsory dispute settlement mechanism."<sup>130</sup>

#### **B.** The SPS Agreement, the Precautionary Principle, and Scientific Justification

Scientific justification under the SPS Agreement is a highly contentious issue when applied to the spread of infectious disease. Not surprisingly, when an infectious disease

<sup>&</sup>lt;sup>123</sup> *Id.* at 1065.

 $<sup>^{124}</sup>$  Id.

<sup>&</sup>lt;sup>125</sup> SPS Agreement, *supra* note 21.

<sup>&</sup>lt;sup>126</sup> FIDLER, INFECTIOUS DISEASES, *supra* note 15, at 134.

<sup>&</sup>lt;sup>127</sup> SPS Agreement, *supra* note 21.

<sup>&</sup>lt;sup>128</sup> Id.

<sup>&</sup>lt;sup>129</sup> FIDLER, INFECTIOUS DISEASES, *supra* note 15, at 131.

<sup>&</sup>lt;sup>130</sup> *Id.* at 143.

threatens to disrupt highly profitable trade, the strength and scope of the SPS Agreement come under fire.

The interplay between the scientific justification requirement and the Precautionary Principle was at issue as nations struggled with the threat of made cow disease (BSE). The Precautionary Principle embodies the rule that "countries may take precautionary measures to protect their populace from disease."<sup>131</sup> In 1999, the EU responded to the BSE scare by uniformly banning the use of animal remains with a high risk of containing BSE.<sup>132</sup> The EU ban included a prohibition on imports of animal feed and secondary products containing animal parts, including pharmaceuticals, cosmetics, and lubricants that contain tallow (boiled animal fat).<sup>133</sup> Tallow derivatives are the key ingredients in more than \$4.5 billion of U.S. pharmaceutical exports.<sup>134</sup> After negotiations with the United States, the EU dropped its ban on products containing tallow while still maintaining that soaps and cosmetics containing beef products could transmit BSE.<sup>135</sup> In 2001, the WTO's SPS Committee met to discuss the application of the SPS Agreement to the BSE epidemic.<sup>136</sup> Peru, Chile, and the United States complained that the EU's restrictions on certain type of feed for cattle were not scientifically justified.<sup>137</sup>

One major point of contention was whether the EU's trade barriers and risk classification system were "a legitimate exercise of the Precautionary Principle."<sup>138</sup> The EU took the position that the SPS Agreement allowed it "to ban a product as long as there is a legitimate belief that

<sup>&</sup>lt;sup>131</sup> Michael B. Abramson, Mad Cow Disease: An Approach to its Containment, 7 J. HEALTH CARE L. & POL'Y 316, 352 (2004).

<sup>&</sup>lt;sup>132</sup> Ryan D. Thomas, Where's the Beef? Mad Cows and the Blight of the SPS Agreement, 32 VAND. J. TRANSNAT'L L. 487, 488 (1999).  $^{133}$  *Id*.

<sup>&</sup>lt;sup>134</sup> *Id*.

<sup>&</sup>lt;sup>135</sup> Trade Disputes – Big Beef, ECONOMIST, Jan 24, 1998, at 71.

<sup>&</sup>lt;sup>136</sup> Abramson, *supra* note 131, at 352.

<sup>&</sup>lt;sup>137</sup> World Trade Organization, Committee Discusses Foot and Mouth Disease, BSE and Equivalence, (2001), available at http://www.wto.org/english/news\_e/news01\_e/010711\_spsctte e.htm.

<sup>&</sup>lt;sup>138</sup> ECONOMIST, *supra* note 135.

the product poses a threat to health and the environment even if no concrete scientific evidence supports such a belief."<sup>139</sup> However, the European Commission's ("EC") own communication states that the Precautionary Principle applies "where preliminary objective scientific evaluation indicates that there are reasonable grounds for concern that [there are] potentially dangerous effects."<sup>140</sup> The implication of the EU's position was that under the Precautionary Principle "a state could prevent an import indefinitely until evidence convinces it otherwise."<sup>141</sup> Article 5.7 of the SPS Agreement clearly limits such an argument, <sup>142</sup> stating that:

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information . . . . In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly *within a reasonable period of time*.<sup>143</sup>

A ban on products that actually had been shown to transmit BSE to humans or a ban on feeding

practices shown to transmit BSE between cattle would satisfy SPS requirements, even if the risk

of transmission is low. However, no objective evidence demonstrating a risk of disease

transmission existed in this case.

The WTO rejected the EU's invocation of the Precautionary Principle and required

removal of the EU's ban.<sup>144</sup> The WTO also rejected similar arguments by the EC with respect to

<sup>&</sup>lt;sup>139</sup> Linda Coleman, Comment, *The European Union: An Appropriate Model for a Precautionary Approach?*, 25 SEATTLE U. L. REV. 609, 627 (2002).

<sup>&</sup>lt;sup>140</sup> European Commission, *Communication of the Commission on the Precautionary Principle*, at 3, COM (2000) 1 (Feb 2, 2000). Where action is deemed necessary, measures based on the Precautionary Principle should be, inter alia: proportional to the chosen level of protection, non-discriminatory in their application, consistent with similar measures already taken, based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis), subject to review, in the light of new scientific data, and capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment. *Id.* at 4.

<sup>&</sup>lt;sup>141</sup> Jesse Male, *The State of Genetically Modified Crops in the European Union Following* Monsanto v. Italy *and the Adoption of a Regulatory Framework for Genetically Modified Food and Feed*, 9 DRAKE J. AGRIC. L. 439, 448 (2004).

<sup>&</sup>lt;sup>142</sup> SPS Agreement, *supra* note 21, at art. 5(7).

<sup>&</sup>lt;sup>143</sup> *Id.* (emphasis added).

<sup>&</sup>lt;sup>144</sup> Abramson, *supra* note 131, at 352.

its ban on beef containing certain hormones in the late 1990s.<sup>145</sup> In that case, the WTO Appellate Panel noted that "the Precautionary Principle has been incorporated and given a specific meaning in Article 5.7 of the SPS Agreement."<sup>146</sup> The Panel acknowledged its responsibility to determine "whether 'sufficient scientific evidence' exists to warrant the maintenance . . . of a particular SPS measure" and held that "the Precautionary Principle does not . . . relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the SPS Agreement."<sup>147</sup> Although the panel indicated that Member States deserve some deference when acting to protect against "irreversible . . . damage to human health[,]" it affirmatively stopped short of creating an SPS loophole that would allow a state to enact such a protectionist measure without scientific evidence.<sup>148</sup>

Through the SPS participation requirement and the WTO's enforcement mechanisms, nations may demand objective and verifiable evidence to support trade barriers. This structure cleverly encourages nations to take a proactive role in preventing infectious disease. Where under GATT a state could use the unverifiable prospective threat of disease to impose import bans, the SPS Agreement compels preventive and reactive research both to protect domestic populations from harm and to protect exports from deceptive trade practices.

## III. THE ROLE OF THE IHR AND THE SPS AGREEMENT IN A H5N1 AVIAN FLU PANDEMIC

One law and economics commentator noted that "even a 'medium-level' flu pandemic could cause up to 200,000 U.S. deaths and a purely economic impact (that is, ignoring the non-

 <sup>&</sup>lt;sup>145</sup> World Trade Organization, Report of the Appellate Body, *EC Measures Concerning Meat and Meat Products* (*Hormones*), WTO Doc. Nos WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998).
 <sup>146</sup> Id.

 $<sup>^{147}</sup>$  Id.

 $<sup>^{148}</sup>$  *Id*.

pecuniary cost of death and illness) of more than \$150 billion."<sup>149</sup> According to other accounts, a "relatively minor" H5N1 pandemic in Asia would likely cause a "loss of 6.5 per cent of Asian GDP, probably contributing to a global recession and reducing global trade of goods and services by 14 per cent, or [\$2,500 billion dollars]."<sup>150</sup> The magnitude of this threat begs the question: What role would the IHR and the SPS Agreement play in the event of an avian flu outbreak?

# A. Hypothetical H5N1 Outbreak and the Application of International Regulations

An outbreak of avian flu could follow a pattern similar to that of the SARS outbreak, except on a larger scale. Suppose that in November 2008, an NGO in China reports that during the past week 1% of the population of Hong Kong (130,000 people) have begun showing flu-like symptoms. The Chinese government denies these reports, but begins substantially limiting travel into and out of the country and simultaneously freezes out the foreign media. Suppose further that Singapore reports outbreaks of a mutated form of the H5N1 flu to the WHO, including over 8,000 confirmed H5N1 cases with 1,050 deaths. In response, Singapore has ordered the in-home quarantine of over 20,000 citizens and has halted all egress travel. The Netherlands reports to the WHO the localized transmission of an unknown pathogen to several Rotterdam dockworkers, their families, and the staff at a local hospital (twenty people, including four Belgium nationals, and two deaths). In response to these reports, Canada bans all imports from China, Singapore, and the Netherlands and places a trade ban on all Belgian chocolate.

Under the revised IHR, the situations in Singapore and in China constitute international public health emergencies. Both situations indicate a public health threat of spreading a serious disease that requires a coordinated international response. In October 2005, both Romania and

<sup>&</sup>lt;sup>149</sup> Richard Posner, *Economics, Politics, and Psychology: The Case of Avian Flu*, The Becker-Posner Blog, (Nov. 27, 2005), *available at* http://www.becker-posner-blog.com/archives/2005/11/economics\_polit.html.

<sup>27, 2005),</sup> *available at* http://www.becker-posner-blog.com/archives/2005/11/economics\_polit.html. <sup>150</sup> Victor Mallet, *Influenza Outbreak 'Could Halt Asia Growth'*, FINANCIAL TIMES, Nov 4, 2005, at 6.

Turkey reported the first cases of the H5N1 avian influenza in Europe.<sup>151</sup> With only 117 cases of human transmission worldwide, H5N1 was not yet a medical condition harming a large human population.<sup>152</sup> However, the 1918 Spanish-flu epidemic claimed more than fifty million lives, and just like H5N1 avian influenza, it "originated in birds before mutating and spreading to humans."<sup>153</sup> Given the mobility of this disease, evidence of cross-border transmission, and the historical significance of previous incarnations of similar diseases, the current virus "could present significant harm to humans."<sup>154</sup> The situations in Singapore and in China also would fall under the new IHR.

The IHR decision instrument compels Singapore to report the H5N1 human infection and unexpected outbreak of this new form influenza.<sup>155</sup> The Siracusa Principles support Singapore's containment policy so long as it does not violate minimum human rights norms – such as by declining to provide access to food and water for those guarantined.<sup>156</sup> Because China refuses to provide information about a possible outbreak, the WHO may rely on reports from the NGO.<sup>157</sup> If verified, the magnitude and the expectation of the spread of the disease would compel the WHO to declare the Chinese outbreak a health emergency of international concern.<sup>158</sup>

The situation in the Netherlands is less clear. It may be proper for the Netherlands to report the outbreak because the outbreak is unexpected, carries a high potential for serious impact, and may affect international trade. However, given the small number of reported

<sup>&</sup>lt;sup>151</sup> Mark Champion & James Hookway, Europeans Gird to Check for Spread of Bird-Flu Virus, WALL ST. J. INT'L, Oct. 11, 2005, at A14.

<sup>&</sup>lt;sup>152</sup> *Id.* <sup>153</sup> *Id.* 

<sup>&</sup>lt;sup>154</sup> IHR, *supra* note 20, at art. 1.

<sup>&</sup>lt;sup>155</sup> Id.

<sup>&</sup>lt;sup>156</sup> The Siracusa Principles, *supra* note 77.

<sup>&</sup>lt;sup>157</sup> IHR, *supra* note 20, at art. 51.

<sup>&</sup>lt;sup>158</sup> *Id.* at art. 11.

infections and the unknown nature of the pathogen, there remains a subjective determination to be made by the Dutch as to whether a report to the WHO is obligatory.<sup>159</sup>

Under the SPS Agreement, Canada's ban on all goods from China, Singapore, and the Netherlands is defensible.<sup>160</sup> A sovereign nation may limit traffic and goods from Singapore, who openly reported contamination. Similarly, the reported magnitude of the outbreak in China and the Chinese government's refusal to cooperate with world health officials gives Canada just cause to close its borders to Chinese imports.<sup>161</sup> Likewise, Canada's reaction to the Dutch is defensible because there is an arguable link between Dutch dockworkers coming into contact with people or goods from Asia.<sup>162</sup>

However, the SPS Agreement would only allow this application of the Precautionary Principle to run so long as the data supported Canada's position.<sup>163</sup> If the Netherlands reports that the disease outbreak is contained or is unrelated to the H5N1 outbreak in Asia, Canada either would need to submit scientific evidence to the contrary or would need to drop its ban. Similarly, if several weeks go by with no new cases in Holland, or if health workers offered medically sound treatment and containment, Canada could not justify its position.<sup>164</sup> Finally, Canada's ban on Belgian chocolate would violate the SPS Agreement.<sup>165</sup> The ban is discriminatory in that it impacts only one particular item of trade goods and is scientifically unjustified because no cases of H5N1 have been reported in Belgium.

<sup>&</sup>lt;sup>159</sup> *Id.* at Annex I.

<sup>&</sup>lt;sup>160</sup> SPS Agreement, *supra* note 22, at art. 5(7).

<sup>&</sup>lt;sup>161</sup> *Id*.

<sup>&</sup>lt;sup>162</sup> Id.

<sup>&</sup>lt;sup>163</sup> See World Trade Organization, supra note 145.

<sup>&</sup>lt;sup>164</sup> SPS Agreement, *supra* note 21, at art. 5(7).

<sup>&</sup>lt;sup>165</sup> Id.

#### **B.** Strengths and Weakness of International Regulations in an H5N1 Outbreak

As opposed to the original IHR, the revised IHR is responsive and productive during this potential H5N1 pandemic. Influenza was not a listed disease under the old IHR, and there was no official influenza vaccination certification requirement. Despite the widespread outbreak of an identified infectious disease, under the original IHR Singapore would have had no obligation to report to the WHO or any other county the potential danger of a spreading pandemic. Though the flu-like symptoms in China raise the specter of a cholera outbreak, China too would have had no duty to report an unidentified widespread illness. Furthermore, with greater than \$583 billion in exports in 2004, <sup>166</sup> China would have had a great deal of incentive to keep its export market secure by *not* reporting a domestic epidemic.

Similarly, the Netherlands would have had no reason to report any health concerns under the original IHR. The illness may have spread through unsatisfactory sanitary conditions in the Rotterdam seaport, but it is unlikely that a cost-benefit analysis would have compelled the Netherlands to take reactive reporting and sanitary measures in light of the limited disease transmission. Lastly, the old IHR would not have sustained Canada's imposition of health measures on incoming vessels because the old regulations did not permit nations to take any measures to protect public health that were more restrictive than the IHR itself proscribed.

The new regulations eliminate many of these problems and allow the WHO to play a larger role in the public health emergencies of all three countries. First, the revised IHR creates a system where the WHO can collect data and coordinate a response to the emergencies. By using NGO public health data, the IHR compels China to adjust its policies in response to the WHO's unsanctioned infectious disease report. Resolving public health emergencies and suppressing

6 Chi-Kent J. Int'l & Comp. L. 52 (2006).

<sup>&</sup>lt;sup>166</sup> CIA, *World Factbook, China, available at* http://www.cia.gov/cia/publications/factbook/geos/ch.html (last updated Nov. 1, 2005).

cross border disease transmission is a positive sum effort, but issues of sovereignty, lack of resources, and lack of motivation normally would limit the international response of individual nations. Through the revised IHR, the WHO also can use NGO and national health data to identify the similarities between the China, Singapore, and Netherlands H5N1 outbreaks as well as to track the geographic transmission pathways, to analyze the H5N1 threat to other nations, and to coordinate an international response to mitigate the harm and prevent further spreading. These containment measures, which extend beyond the borders of any particular nation, would be essential to minimizing the scope and effect of an international H5N1 epidemic.

Second, although the IHR affirms the sovereign right of Singapore to determine its own internal quarantine policy, international involvement promotes scrutiny of human rights. Though merely an international peer pressure system of human rights, the IHR's approach is comparatively progressive to the old regulations and creates a framework upon which individual states can build. Moreover, combined with the WHO's response coordination, the IHR raises the likelihood of international participation in funding and maintaining humane quarantine conditions.

The weaknesses of the IHR in an H5N1 outbreak are similar to the limitations present in other types of international regulation. First, enforcement is highly problematic in best-case scenarios and impossible under less favorable circumstances. The WHO has no recourse against China for China's refusal to cooperate with health officials. Moreover, in some cases, the WHO's use of NGO data concerning H5N1 outbreaks could backfire. In the face of such a severe health threat, nations such as China or Russia might further restrain the freedom of NGOs

and lessen transparency when disclosure of NGO information threatens national exports and profits.<sup>167</sup>

Second, developing nations with limited public health resources face the same problems under the new IHR as they faced under the old regulations. Although the revised IHR may be more effective in the face of an H5N1 epidemic, the IHR does not, of course, provide nations with the funding to implement the proscribed regulations or even to create the infrastructure necessary for implementation. Given that political interest in countries with limited trade value may be limited, poorer countries are unlikely to have the resources to implement many of the IHR's new requirements. As such, the new IHR could devolve into a de facto reactive system for some countries.

The positive and negative value of the SPS Agreement in an H5N1 outbreak is much less clear. As a preventative measure, however, the SPS Agreement's benefit is substantial. The scientific justification requirement functions as both a sword and a shield for nations whose economies depend largely upon international trade. China – along with the rest of Asia – has a strong motivation to conduct scientific research on the H5N1 avian flu. Nations that understand the nature of the disease and the mechanics of its transmission can use that information to argue against unjustifiable trade bans. Thus the SPS Agreement provides nations with a weapon to combat restrictions on that nation's exports. This same research works as a shield to justify and protect the researching nation's legitimate trade restrictions, providing support for that nation's import bans. Of course, the same H5N1 research inspired for the protection of trade also would be critical to the development of both preventive and reactive scientific solutions to the bird flu epidemic.

<sup>&</sup>lt;sup>167</sup> See, e.g., Guy Chazan, Russia's Putin Tries to Ease Fear Over Nonprofit Law, WALL ST. J. INT'L, Nov. 25, 2005, at A9; Hindrance or Help? Awkward Russia, ECONOMIST, Dec. 3, 2005.

With the knowledge that Canada could uniformly ban all Chinese exports based on a legitimate fear of the H5N1 virus, China would be strongly motivated to implement prophylactic measures in protection of both its bird and its human populations. By implementing an effective domestic response mechanism and by providing scientific evidence of a working inoculation, China would have the tools to combat what could become an unreasonable and harmful Canadian trade barrier. Thus the SPS Agreement encourages both proactive and reactive infectious disease response and it creates a system of scientific information leverage in trade disputes.

The SPS Agreement's weaknesses during an H5N1 outbreak also are significant. First, the scientific leverage may be largely symbolic. As with concerns about genetically-modified foods in Europe or fear of mad cow disease in Japan, if the internal political and social pressure is sufficient then Canada will ban all Chinese goods despite credible evidence that such a reaction would be scientifically unjustifiable. Conversely, as import markets grow dependent on Chinese goods, domestic forces within Canada could prevent a uniform trade ban despite compelling scientific evidence that indicated greater restrictions are warranted. As a reactionary tool to prevent the spread of the H5N1 flu, the SPS Agreement therefore may have limited influence.

The second weakness of the SPS Agreement is the long-term nature of dispute resolution and enforcement though the WTO. In the hypothetical, Singapore has 1,050 H5N1 deaths in one week. The threat of a binding dispute resolution one to two years after the first resulting trade barriers would have no impact on the actual reactions of other nations to the quickly-spreading and relatively short-term threat of H5N1 avian flu. Rather, countries would ban imports from Singapore immediately and worry about international law repercussions later. Such a dispute resolution process could provide retroactive relief for wrongly-affected nations once the pandemic is over. However, like all permissive WTO trade sanctions, a positive resolution would largely be constrained by the practicalities of any changing prices in the domestic market. That is, the seemingly victorious nation would be forced to balance the value accrued through permissive tariffs that diminish the demand for a particular import against the benefits harvested by the domestic population who are able to buy at a higher price and the loss felt by the domestic population shutout of the new market.

Finally, as with other aspects of the WTO, some might claim that the SPS Agreement disregards the needs of developing nations. With limited or nonexistent research capabilities, developing nations would have difficulty advancing any scientifically-supported arguments against trade or travel bans once an industrialized nation claims that a ban is scientifically reasonable. Furthermore, industrialized nations might invoke the Precautionary Principle to justify a trade ban. Developing nations without research capabilities would be unable to provide any scientific evidence to the contrary. Thus, the SPS Agreement leaves developing nations in a position of weakness similar to that experienced under the old GATT.

#### CONCLUSION

In conclusion, both the IHR and SPS Agreement reflect a maturing understanding of the needs of the international community in combating the spread of disease and both agreements would function more effectively than their respective predecessors in the context of a H5N1 bird flu pandemic. The revised IHR is a foundational agreement allowing the international community to designate the WHO as the central data collection body to help prevent outbreak and to coordinate a response that mitigates the impact on infected populations and international neighbors. Unlike the previous international health regulations, the revised IHR would classify

the H5N1 flu as a public health emergency and would dictate the rights and duties of countries facing the emergency within their borders. The SPS Agreement cultivates a scientific justification standard for health-based trade barriers and provides a neutral forum for disputes and, in the face of a developing H5N1 threat, these features of the Agreement should inspire government funding of research to understand, prevent, and combat the disease. Much like environmental international law, these regulations suffer from weaknesses in enforcement mechanisms that could limit their effectiveness, but from a broad perceptive they clearly are progressive. The two sets of regulations acknowledge and promote flexible responses by sovereign nations without overreaching. They create incentive for information sharing and facilitate the role of an international body in leading the positive sum effort to prevent and control public health emergencies. Taken together, the IHR and the SPS Agreement create a more coherent and useful framework for coordinated international response to the serious and contemporary threat of an H5N1 epidemic.