CHICKEN FLU FOR THE INTERNATIONAL SOUL: UNDERSTANDING AND APPLYING INTERNATIONAL INFECTIOUS DISEASE REGULATIONS

INTRODUCTION

In 1918, over 1 billion people (half the world's population) contracted a virulent form of avian flu.[1] Spain was the first country to report an outbreak of the disease, and that flu strain was subsequently known as the Spanish Flu. The virus killed more than 8 million Spaniards in one month.[2] Influenza killed approximately 50 million people worldwide that year, including 500,000 in the United States.[3]

In 2003, a strain of avian flu known as H5N1 spurred new fears of an epidemic in South Korea.[4] Authorities culled the region's entire poultry population (over 150 million birds) in response.[5] To date, fifteen countries have reported cases of the "highly pathogenic H5N1" virus in poultry.[6] Five of those countries have reported 120 cases of interspecies transmission to humans.[7] 67 cases have ended in death.[8]

While an infectious disease pandemic may implicate many parts of international law, most of those parts lack sufficient maturity to provide any concrete guidance during a pandemic. A good example of its limited usefulness is the application of human rights law in *Case of D v.*

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[1] *Time Trip: Killer Flu of 1918*, 2 CURRENT EVENTS 105, Sep. 23, 2005.
[2] *Id.*
[3] *Hot Topic: Avian Flu: Pandemic on the Horizon?*, WALL ST. J., Oct. 22, 2005, at A5.
[4] *In a Flap – Avian Influenza*, THE ECONOMIST, Oct. 22, 2005.
[5] *Id.*
[6] World Health Organization, *H5N1 Avian Influenza: Timeline*, Oct. 28, 2005, *available at* http://www.who.int/csr/disease/avian_influenza/Timeline_28_10a.pdf.
[7] *Id.*
[8] *In a Flap – Avian Influenza*, THE ECONOMIST, Oct. 22, 2005.

United Kingdom.[9] The European Court of Human Rights held that Britain could not deport a convicted drug trafficker back to St. Kitts. The developing nation lacked the health standards necessary to treat D's late stage AIDS.[10] To deport D would violate human rights norms against inhuman treatment or punishment because he would "spend his remaining days in pain and suffering in conditions of isolation, squalor and destitution."[11] The European Court's application of normative international human rights law was arguably correct, and it seems noble for the developed world to aspire to such standards. However, a cursory glace over the history of infectious disease will quickly rid the *Case of D* of any practical application during an emergency. With some officials estimating 150 million human deaths in a H5N1 epidemic,[12] the United Kingdom would likely enforce its own conditions of isolation on suffering infected individuals if it meant preserving the greater population.

Similarly, principles from the law of war or international environmental law tangentially address infectious disease through topics such as the treatment of detainees, the use of biological weapons, air and water quality, and deforestation.[13] Like in *Case of D*, these issues have value during isolated incidents or in cultivating national policyHowever, they provide no practical guidance in the prevention of or reaction to widespread infectious disease. Fortuitously, scholars and practitioners of international law have not been blind to the threat of disease. In fact, nations have been forming multilateral agreements to halt the spread of infection for more than 150 years.[14] Not surprisingly, the impetus for the original agreements was to protect the flow of

[9] Case of D v. United Kingdom, 423 Eur. Ct. H.R. 24 (1997).
[10] *Id*. at para. 54.
[11] Id. at paras. 40, 41.
[12] *World Health Agency Tones Down Alarm on Possible Flu Pandemic*, N.Y. TIMES, Oct. 1, 2005.
[13] DAVID P. FIDLER, INTERNATIONAL LAW AND INFECTIOUS DISEASES chs. 7-8 (Clarendon Press 1999) [hereinafter INFECTIOUS DISEASES].
[14] *Id*. at ch. 2 (examining the history of international control of infectious disease).

commercial goods and tourists across borders.[15] However, as the world's population has tripled to 6.5 billion over the last 50 years and national economies have become increasingly interdependent,[16] priorities in the control of infectious disease have matured.

The overarching purpose of this paper is to outline and analyze the role of international law with respect to infectious disease. Acknowledging that other aspects of international law and domestic regulations play an enormous role, this paper will narrowly focus on the two major United Nations ("UN") agreements that attempt to compel and limit the activities of Member States surrounding infectious disease: the International Health Regulations ("IHR") and the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement").[17] Part I analyzes the transition from the old IHR to the newly adopted IHR and analyzes the rights and duties of States created by this framework. Part II similarly looks at the SPS Agreement, but analyzes in detail specific illustrations of the Agreement at work. Parts I & II both provide real and hypothetical examples of health emergencies. The goal of these examples is to create context for analyzing the regulations and to fill in some of the peripheral gaps created by the narrow focus of this paper. Finally, Part III notes some of the strengths and weaknesses of the regulations by applying themto a simple hypothetical pandemic of the H5N1 avian flu.

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[15] *Id*. at 61.
[16] *Total Midyear Population for the World: 1950-2050*U.S. Census Bureau, International Database, *available at* http://www.census.gov/ipc/www/worldpop.html.
[17] Revisions of the International Health Regulations, W.H.A. 58/3, art. 59.2, U.N Doc. A58/4 (May 23, 2005) [hereinafter IHR]; Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, art. 2(2), *available at* http://www.worldtradelaw.net/uragreements/spsagreement.pdf [hereinafter SPS Agreement].

I. THE REVISED INTERNATIONAL HEALTH REGULATIONS

In March 2003, Severe Acute Respiratory Syndrome ("SARS") plagued several parts of the world.[18] After nine months of outbreaks, the World Health Organization ("WHO") reported "8422 cumulative cases world-wide with 916 deaths."[19] SARS was a first in many respects. SARS was the first severe infectious disease of the 21st century fueled by global air travel.[20] As such, SARS was the first infectious disease not subject to traditional limitations of transmission. SARS would not have been able to "burn itself out" by killing off its primary population because it was not "an infectious disease confined to a particular geographical location."[21] Moreover, SARS was the first novel pandemic to allow WHO to appraise the potential influence of its new set of health regulations, which were in revision at the time of the outbreak. In 2005, after ten years of work, the Member States of World Health Assembly (WHA) adopted the revised International Health Regulations (IHR).[22] The goal of this new convention is 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."[23] Not surprising, the revision of the IHR was "a closely watched and often controversial international legal reform effort" because of its implications on state sovereignty and independence.[24] Nonetheless, these revised regulations have a large impact on the responsibly of state actors, the rights between

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[18] Jason W. Sapsin et al., *Symposium: SARS, Public Health, and Global Governance*, 77 TEMP. L. REV 155, 159-61 (2004).
[19] DAVID P. FIDLER, SARS, GOVERNANCE AND THE GLOBALIZATION OF DISEASE 3 (Palgrave Macmillan 2004) [hereinafter SARS, GOVERNANCE, AND GLOBALIZATION].
[20] *Id*. at 6.
[21] *Id*.
[22] IHR, *supra* note 17, at art. 59.2; 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 *Security: The New IHR*].
[23] IHR, *supra* note 17, at pmbl 6(2).
[24] *Security: The New IHR, supra* note 22, at 2.

states, and the authority of WHO in dealing with the control and containment of infectious disease.

The new IHR will become binding on Member States in 2007 (24 months after WHO Director-General adopted them).[25] The old IHR, adopted 1951 as the International Sanitary Regulations ("ISR"), were much narrower in scope and intent.[26] Under this regime, WHO had no enforcement capabilities, countries largely ignored many disease notification requirements.[27] This disregard, in part, prevented disease control custom from maturing into binding international law.[28] To understand the new rules and their effect on states, one must first examine the original IHR and compare it to the new IHR.

A. *The History and Development of the Old IHR*

In 1851, industrialized nations held the first international sanitary conference. In 1951, WHO formally adopted the ISR.[29] Between those two benchmark dates, there was little change in the objective of international infectious disease regulation. The goal was to "protect States against the international spread of infectious disease in a way that minimized interference with international trade and travel."[30] This principle concisely reflected the three primary obligations under the old IHR: notification, transport hygiene, and vaccination certification.[31] Though appearing broad, these objectives were limited in three ways. First, these were the only

[25] IHR, *supra* note 17, at art 59.2.
[26] Lawrence O. Gostin, *World Health Law: Toward a New Conception of Global Health Governance for the 21st Century*, 5 YALE J. HEALTH POL'Y L & ETHICS 413, 413-414 (2005).
[27] INFECTIOUS DISEASES, *supra* note 13, at 65-67.
[28] *Id*. at 102.
[29] IHR, *supra* note 17, at art. 59.2; *Security: The New IHR*, *supra* note 22, at 3.
[30] *Security: The New IHR*, *supra* note 22, at 5.
[31] Lawrence O. Gostin, *International Infectious Disease Law: Revision of the World Health Organization's International Health Regulations*, 291 J. AM. MED. 2623, 2524 (June 2, 2004).

international regulations to cover infectious diseases. Second, the only diseases covered were cholera, plague, and yellow fever.[32] Third, the measures laid out in the IHR were "the maximum measures applicable to international traffic, which a state may require for the protection of its territory."[33] With this in mind, it is clear that the old IHR were a commerce-centered safety measure designed to react to spreading infectious disease and to prevent states from harming international trade by overreacting.

In the limited context of sea trade, these measures were comparatively reasonable. However, it is easy to see the immense modern shorting comings of a reactive system. Under the old regulations, countries were bound by honor to report to WHO any case of the three listed diseases.[34] Such an idealistic requirement was doomed to failure. The poor countries with the highest rates of disease lacked the resources to report, where as wealthy countries lacked the incentive to report events that would harm trade and tourism.[35] With the health and vaccination certificate requirements, poor countries lacked resources. Rich countries often "required health certificates for nonlisted diseases" because those disease (such as HIV) posed a greater health. [36] Similarly, the hygienic transport hubs requirements, such as clean water and food, health inspections, and appropriate quarantine facilities, were neglected.[37] Again, poor countries lacked the resources. The problem with the wealthy countries here was not execution, but effectiveness. Cholera, plague, Ebola, AIDS, and SARS often were not symptomatic infectious diseases during ingress and egress, but became so after transit.

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[32] *Security: The New IHR*, *supra* note 22, at 7.
[33] *Id*. at 2524 (quoting the old IHR).
[34] *Id*.
[35] INFECTIOUS DISEASES, *supra* note 13, at 66.
[36] Lawrence O. Gostin, *International Infectious Disease Law: Revision of the World Health Organization's International Health Regulations*, 291 J. AM. MED. 2623, 2524 (June 2, 2004).
[37] *Id*.

These regulations failed because they were commercecentered and reactively designed. "Any new pathogen, or resurging old ones, not listed as 'disease subject to the Regulations' fell outside IHR's surveillance system."[38] In 1995, with HIV/AIDS and the "proliferation of biological weapons" drawing attention to world health issues, WHO "started the process of revising the IHR."[39] In November 2002, the first cases of SARS emerged in China's Guangdog Province.[40] By August 2003, over 30 countries reported cases of the disease to WHO.[41] "This outbreak and its effective handling by WHO" accelerated the IHR revision process.[42] It was clear that the new IHR needed to be "a flexible framework that [could] respond to unknown disease events rapidly."[43] In May 2005, WHO adopted the new IHR proclaiming the "effective death" of the traditional outbreak/response approach.[44]

B. *The Changes and Scope of the New IHR*

Like the old system, the new IHR's goals include avoiding "unnecessary interference with world trade and travel."[45] Unlike the old system, the new IHR's proactive measures center on public health and take qualified priority over commercial interests. To understand the new IHR, one must first look at the scope and overarching goals. First, the IHR applies to broadly defined events. Second, the IHR centralizes information at WHO and incorporates non-state actors.

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[38] *Security: The New IHR*, *supra* note 22, at 16.
[39] *Id*.
[40] Jason W. Sapsin et al., *Symposium: SARS, Public Health, and Global Governance*, 77 TEMP. L. REV 155, 155 (2004).
[41] SARS, GOVERNANCE, AND GLOBALIZATION, *supra* note 19, at 4.
[42] *Security: The New IHR*, *supra* note 22, at 30.
[43] *Id*.
[44] *Id* at 2.
[45] IHR, *supra* note 17, at art. 2.

Whereas the old IHR was limited to a small number of specific diseases, the new IHR applies to communicable and non-communicable public health emergencies of international concern and encompasses both natural and artificial threats.[46] The IHR defines a public health emergency as "an extraordinary event which 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."[47] This seemingly vast definition requires some unpacking.

An international public health emergency exists when there is a manifestation (or clear danger of a manifestation) of a significant human medical illness that poses a threat to the international population *or* would require a coordinated multinational response. The language is broad enough to address ongoing long-term diseases (HIV/AIDS) and future wildfire diseases. Moreover, the language applies to current but merely perceived threats. For example, in October 2005, both Romania and Turkey reported the first cases of the H5N1 avian influenza in Europe.[48] With only 117 cases of human transmission worldwide, H5N1 is not a medical condition harming a large human population.[49] However, the 1918 Spanish-flu epidemic claimed more than 50 million lives, and it "originated in birds before mutating and spreading to humans."[50] Thus, given the mobility of the disease, evidence of cross-border transmission, and the historical significance, the current virus "could present significant harm to humans."[51] It too, therefore, would fall under the new IHR.

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[46] *Id*. at Annex I.
[47] *Id*. at art 1.
[48] Mark Champion & James Hookway, *Europeans Gird to Check for Spread of Bird-Flu Virus*, WALL ST. J. INT'L, Oct. 11, 2005, at A14.
[49] *Id*.
[50] *Id*.
[51] IHR, *supra* note 17, at art. 1.

The second important structural component of the IHR is the centralization of information and the use of non-state actors. Under the new IHR, WHO has the "authority and responsibility . . . to collect and act upon sources of information."[52] That is, WHO must collect disease event reports from States, must maintain qualified confidentiality on information, must declare international public health emergencies, and may use non-state sources of information concerning public health.[53] When utilizing NGO data, the IHR "imposes duties on WHO to engage in such collection efficiently and effectively" and requires "WHO to verify such information."[54] According to one commentator:

> The 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.[55]

The value of this dynamic system is two-fold. First, the IHR creates incentive for States to report health event and mitigates the international impact because WHO can collect from NGO sources and declare public health emergencies in a State without that State's consent. Second, it requires transparency in WHO's process because WHO must verify NGO data and show effective data collection techniques. Thus, the IHR diffuses the disincentives of reporting health events that plagued the old system.

Within this broad scope, one can analyze the IHR's content by dividing it into two components: (1) the obligations of states and (2) the rights of states. In this way, one can see that the new regulations take a formalistic international law form, which includes positive duties and

[52] *Security: The New IHR*, *supra* note 22, at 52.
[53] IHR, *supra* note 17, at art. 51.
[54] *Security: The New IHR*, *supra* note 22, at 52.
[55] *Id*. at 51.

enforcement. This allows the IHR to be the central international framework for combating international infectious disease.

1. The Duties of States Under the New IHR

The IHR unquestionably raises issues of sovereignty. Principle 4 of the instrument holds, "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."[56] Clearly, these regulations run into the same enforcement problems as other multilateral treaties. As noted however, these regulations incentivise states, especially developed nations, to follow their obligations because there are no veto powers over WHO'shea lth emergency reports. Annex I spells out the "core capacity requirements for surveillance and response."[57] In particular, Parties must "detect events involving disease", "assess reported events", "notify WHO immediately," and "report all essential information."[58] Additionally, actors must create and maintain a "public health emergency contingency plan."[59] One can see that the responsibilities of states follow the overarching theme of the IHR: respond to the emergency and mitigate the 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.[60]

States must follow the IHR's decision instrument in deciding which events to report to WHO.[61] This instrument describes three paths for reporting public health events.[62] Each path

[56] IHR, *supra* note 17, at art. 3.4.
[57] *Id*. at Annex I.
[58] *Id*.
[59] *Id.*
[60] *Id.*
[61] *Id.* at art. 6.1.
[62] *See infra* Appendix I. IHR, *supra* note 17, at Annex II.

begins with a different class of diseases: (1) known diseases whose outbreaks are unexpected and serious (a new influenza strain or SARS), (2) known diseases with a demonstrated ability to become emergencies (plague or Ebola), and (3) unknown or potential threats. A state must report any case of (1), and must analyze the need to report to WHO in cases of (2) or (3) using the instrument.[63] The analysis weighs factors of seriousness, expectation, risk of spreading, and impact on trade.[64] For example, a case where a Romanian farmer contracts the H5N1 avian flu would satisify the notification requirement in (1). But if a rural healthcare worker in Zambia contracts Cholera, the threat of international spread is lower and the event is less unusual. Under (2), Zambia would not be obliged to report the case. By contrast, the same situation might trigger a report in South Korea where cases are uncommon, a high population density exists, and international travel is more common.

The other markedly different way that the IHR obliges states is by appropriating other aspects of international law and integrating them into the public health requirements.[65] 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."[66] However, "such measures shall not be . . . more intrusive to persons than reasonably available alternatives."[67] This requirement invokes the Siracusa Principles, which "offer detailed guidance on the use of public health powers in ways that are consistent with human rights."[68] Unlike the decision instrument, which places a positive duty on states, the Siracusa Principles place a

[63] IHR, *supra* note 17, at Annex I.
[64] *Id*.
[65] 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 17, at art. 43.1.
[66] IHR, *supra* note 17, at art. 43.1; The Siracusa Principles, *supra* note 65.
[67] IHR, *supra* note 17, at art. 43.1.
[68] The Siracusa Principles, *supra* note 65; Lawrence O. Gostin, *International Infectious Disease Law: Revision of the World Health Organization's International Health Regulations*, 291 J. AM. MED. 2623, 2526 (June 2, 2004).

negative duty. They "require heath measures to be necessary, proportionate, and fair."[69] In effect, the IHR couches public health in the broader context of international human rights law.

Take, for example, Canada's first reported SARS patent in March 2003.[70] The Canadian government amended the Quarantine Act and Regulations to "authorize detention of travelers with suspected SARS for up to twenty days."[71] The U.S. Centers for Disease Control now report that the incubation period for SARS is one to twelve days.[72] Suppose China reported ten new cases of SARS among dockworkers. If the Canadian government further amended its statute and quarantined 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 inclusive, i.e. "more restrictive of international traffic . . . than reasonably available alternatives."[73] Second, the Canadian measure would not be "based on scientific principles,"[74] given that the average SARS incubation is four days.[75] To quarantine ships and travelers for 60 days violates the clear language of the IHR.[76] 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."[77] Thus, the IHR "balance sovereignty, science and public health" by requiring appropriate information and enjoining irrational or ill-suited reactions to public health emergencies.[78]

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[69] Lawrence O. Gostin, *World Health Law: Toward a New Conception of Global Health Governance for the 21st Century*, 5 YALE J. HEALTH POL'Y L & ETHICS 413, 423 (2005).
[70] Jason W. Sapsin et al., *Symposium: SARS, Public Health, and Global Governance*, 77 TEMP. L. REV 155, 161 (2004).
[71] *Id*.
[72] 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.
[73] IHR, *supra* note 17, at art. 43.1.
[74] *Id*.
[75] 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.
[76] The Siracusa Principles, *supra* note 65; IHR, *supra* note 17, at art. 43.1.
[77] *Security: The New IHR*, *supra* note 22, at n. 311.
[78] *Security: The New IHR*, *supra* note 22, at 59.

2. The Rights of the States Under the New IHR

The IHR lays out the rights that states have against WHO and makes clear the domestic rights with respect to public health emergencies.[79] Only a few of these need mentioning because the notion of rights of states implicates larger topics in international law. The value of enumerating the rights of states with the treaty is that it makes WHO accountable, and that it clarifies proper state action in difficult scenarios. Thus, the negative duties of WHO create positive rights for states. One example is confidentiality of information. WHO is obliged to keep all health data collected confidential unless there is a "public health emergency of international concern" or state control measures "are unlikely to succeed."[80] The value of this system is clear. The right to confidentiality encourages the flow of information and mitigates the unnecessary loss of international commerce, but does not extend far enough to threaten the public at large. However, this is merely a relationship right. The IHR also clarifies some activities that states may rightfully undertake irrespective of WHO. One broad example of this is 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."[81] Singapore used fines, in-home cameras, and arrests to enforce the

[79] IHR, *supra* note 17.
[80] IHR, *supra* note 17, at art. 11.
[81] Jason W. Sapsin et al., *Symposium: SARS, Public Health, and Global Governance*, 77 TEMP. L. REV 155, 159 (2004).

quarantine of over 740 people.[82] These measures are all acceptable under the new IHR. While the IHR requires medical examinations to be the "least obtrusive [measures] . . . that would achieve the public health objective,"[83] the same standard does not apply to vaccination, prophylaxis, isolation, or quarantine. Thus, a State may quarantine a person" not giving his or her consent" when the State deems that "such a compulsory measure is necessary to control an imminent public health threat."[84] More importantly, "the revised Regulations do not contain requirements that States Parties accord those subject to compulsory measures due process protection, such as the right to challenge such measures in court."[85] This means that the IHR affirms a State's right to restrict and protect its population as it sees fit.

This is notable because the IHR does not attempt to limit or guide the use of quarantine. There are three reasons for making this an unquestionable state's right. First, WHO would have no enforcement mechanisms. Adding superfluous or symbolic requirements to what are meant to be binding regulations weakens the overall system. Second, it is unlikely thatMember States would agree to give up sovereign rights of self-governance and domestic population control (even if it was merely an unenforceable gesture) because such an act might gestate binding international custom. Third, it is not in the interest of WHO or Member States to impose hard and fast limits on the ability of states to isolate sections of its population, 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

[82] *Id*. at 159, 164.
[83] IHR, *supra* note 17, at art. 23.
[84] *Security: The New IHR*, *supra* note 22, at 45.
[85] *Id*.

unpredictable. As such, the threat the population's welfare outweighs the lack of "compulsory due process protections, such as the right to challenge [quarantine] in court."[86]

The SARS outbreak was instructive on this point. 740 people were under full quarantine measures within 24 days of the first SARS cases in Singapore.[87] Through these measures, "the average time from onset of SARS symptoms to isolation of probable cases declined . . . from 6.8 days to 1.3 days."[88] In total, there were 238 cases reported with a population density of 6,400 persons per square kilometer.[89] In Hong Kong, more than 1,000 people were place in quarantine 23 days after the first case.[90] Hong Kong had a similar population density of 6,300 persons per square kilometer, but reported 1,755 cases in total.[91] This data says nothing about how many or how quickly a state must quarantine to control the spread of infectious disease, but it does indicate that WHO is not is a position to uniformly constrain quarantine policy. Thus, by affirming national control of quarantine, the IHR preemptively defuses a politically controversial subject and promotes responses that are more adaptable.

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

Not surprisingly, the IHR is not the system of international regulations that seek to protect against infectious disease. In 1998, WHO presented information to the World Trade

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[86] *Id*.
[87] Jason W. Sapsin et al., *Symposium: SARS, Public Health, and Global Governance*, 77 TEMP. L. REV 155, 159, 164 (2004).
[88] *Id*.
[89] SARS, GOVERNANCE, AND GLOBALIZATION, *supra* note 19, at 4; CIA World Factbook, Hong Kong, http://www.cia.gov/cia/publications/factbook/geos/hk.html (last updated Nov. 1 2005).
[90] Jason W. Sapsin et al., *Symposium: SARS, Public Health, and Global Governance*, 77 TEMP. L. REV 155, 160 (2004).
[91] SARS, GOVERNANCE, AND GLOBALIZATION, *supra* note 19, at 4.; CIA World Factbook, Hong Kong, http://www.cia.gov/cia/publications/factbook/geos/hk.html (last updated Nov. 1 2005).

Organization ("WTO") on the IHR.[92] 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 WTO.[93] One of the founding pillars of WTO is the Agreement on the Application of Sanitary and Phytosanitary Measures.[94] 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."[95] Given that members of WHO are members of WTO and that WTO has binding enforcement mechanisms, WHO felt that "harmonizing the IHR and SPS Agreement would reflect [a] common purpose and avoid any potential conflict in the obligations of Member States."[96] Consequently, the revised IHR was tailored to comport with the SPS Agreement. As such, one cannot understand the IHR or the complete infectious disease international law régime without a careful examination of 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."[97] The infrastructure of this agreement addressed the behavior of States that could affect public health.[98] The framers of GATT attempted to "balance the sovereign right to keep out products that may threaten a

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[92] *The World Trade Organization and the IHR*, 73WEEKLY EPIDEMIOLOGICAL RECORD 233, 235-236 (WHO) (1998), *available at* http://www.who.int/docstore/wer/pdf/1998/wer7331.pdf.
[93] *Id.*
[94] SPS Agreement, *supra* note 17, at art. 11.
[95] *The World Trade Organization and the IHR*, 73WEEKLY EPIDEMIOLOGICAL RECORD 233, 235-236 (WHO) (1998), *available at* http://www.who.int/docstore/wer/pdf/1998/wer7331.pdf.
[96] *Id.*
[97] General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT]; INFECTIOUS DISEASES, *supra* note 13, at 121.
[98] GATT, *supra* note 97; INFECTIOUS DISEASES, *supra* note 13, at 121.

nation's health with disciplines to prevent this right from being misused for discriminatory or protectionist purposes."[99]

In 1996, Britain reported several cases of mad-cow disease (Bovine Spongiform Encephalopathy ("BSE")), which scientists linked to a fatal human brain disease, Creutzfeldt-Jakob disease.[100] In reaction, the European Union ("EU") banned all exports of British beef.[101] By 1997, the disease claimed 10 human lives, and by 1999, the British beef industry had lost over $2.37 billion dollars.[102] 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 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.[103]

In the case of BSE, the disease posed a significant threat of spreading to domestic cattle and infecting humans. 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.[104]

However, Article XX(b)'s coverage was not always clear. Parties made radical changes to GATT in the Uruguay Round.[105] In 1993, WTO substantially replaced GATT and adopted the SPS Agreement.[106] The Agreement moved 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

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[99] INFECTIOUS DISEASES, *supra* note 13, at 121.
[100] *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.
[101] *Id.*
[102] *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.
[103] GATT, *supra* note 97, at art. XX(b).
[104] *Id*.
[105] INFECTIOUS DISEASES, *supra* note 13, at 133.
[106] *Id*. at 134.

scientific principles and is not maintained without sufficient scientific evidence."[107] In 1991, Peru reported a cholera outbreak with more than 300,000 infected persons.[108] Due to worldwide bans of Peruvian imports, the country lost over $12.9 billion in trade.[109] "Peru complained to the GATT Council repeatedly that the GATT rules were being ignored and other states were imposing trade-damaging health protection measures against Peru that lacked scientific support or clear public health rationales."[110] The SPS Agreement's scientific justification clause solves this problem. "No longer can health policy that affects trade be created out of fear, superstition, or any other illegitimate basis" because trade restriction due to infectious disease outbreaks must be "made fairly and for legitimate reasons."[111]

The second substantial difference in the SPS Agreement is that Member States must participate.[112] As one of the founding WTO multilateral agreements, "any State wanting to become a Member State of WTO has to accept the SPS Agreement."[113] This means that WTO has the authority to settle any dispute between Member States over protectionist trade bans "involving scientific or technical issues."[114] Unlike the GATT procedure where a party could block the decision of a dispute settlement panel, WTO's dispute settlement panel allows states to impose trade sanctions for violations.[115] Whereas under GATT, Peru had no practical means to attack "trade-damaging health measures that lack scientific rationale," [116] the binding dispute settlement provisions attached to the SPS Agreement would assure Peru a chance to argue its

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[107] SPS Agreement, *supra* note 17, at art. 2(2).
[108] David P. Fidler et al., *Emerging and Reemerging Diseases: Challenges for International, National, and State Law*, 31 INT. LAW. 773, 778 (1997).
[109] Julia A. Jones, Comment, *International Control of Cholera: An Environmental Perspective to Infectious Disease Control*, 74 IND. L. J. 1035, 1044 (1999).
[110] *Id*. at 1064.
[111] *Id*. at 1065.
[112] SPS Agreement, *supra* note 17.
[113] INFECTIOUS DISEASES, *supra* note 13, at 134.
[114] SPS Agreement, *supra* note 17.
[115] SPS Agreement, *supra* note 17.
[116] INFECTIOUS DISEASES, *supra* note 13, at 131.

position to WTO. Thus, the SPS Agreement is "the first international agreement attempting to balance trade and public health that contains a compulsory dispute settlement mechanism."[117]

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 threatens to disrupt highly profitable trade, the strength and scope of the SPS Agreement come under fire. In 1999, the EU responded to the BSE scare by uniformly banning the use of animal remains with a high risk of containing BSE.[118] The ban covered such things as the feed given to animals and secondary products containing animal parts.[119] For example, the ban extended to foreign imports, including pharmaceuticals, cosmetics, and lubricants that contain tallow (boiled animal fat).[120] Tallow derivatives are the key ingredients in more than $4.5 billion of U.S. pharmaceuticals exports.[121] After negotiates with the U.S., the EU dropped its ban on products containing tallow, though EU officials maintained that soaps and cosmetics containing beef products could transmit BSE.[122] In 2001, WTO's SPS Committee met to discuss the application of the SPS Agreement to the BSE epidemic.[123] One major point of contention was whether the EU's trade barriers and risk classification system were "a legitimate exercise of the

[117] INFECTIOUS DISEASES, *supra* note 13, at 143.
[118] 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).
[119] *Id*.
[120] *Id*.
[121] *Id*.
[122] *Trade Disputes – Big Beef*, ECONOMIST, Jan 24, 1998.
[123] Michael B. Abramson, *Mad Cow Disease: An Approach to its Containment*, 7 J. HEALTH CARE L. & POL'Y 316, 352 (2004).

precautionary principle."[124] Specifically, Peru, Chile, and the United States have complained that the EU's restrictions on certain type of feed for cattle are not scientifically justified.[125]

The EU has taken the position that the SPS Agreement permits them "to ban a product as long as there is a legitimate belief that the product poses a threat to health and the environment even if no concrete scientific evidence supports such a belief."[126] 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."[127] The implication of the EU's new position is that under the precautionary principle "a state could prevent an import indefinitely until evidence convinces it otherwise."[128] Article 5.7 of the SPS Agreement clearly limits such an argument.[129]

> 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*.[130]

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[124] *Id*.
[125] WTO News, Sanitary, Phytosanitary Measures Committee, *Mad Cow Disease*, July 10-11, 2001, http://www.wto.org/english/news_e/news01_e/010711_spsctte_e.htm.
[126] Linda Coleman, Comment, *The European Union: An Appropriate Model for a Precautionary Approach?*, 25 SEATTLE U. L. REV. 609, 627 (2002).
[127] 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.
[128] 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).
[129] SPS Agreement, *supra* note 17, at art. 5(7).
[130] *Id*.

Certainly, a ban on products shown to transmit BSE to humans or a ban on a feeding practices shown to transmit BSE between cattle would satisfy SPS requirements (even if the risk is particularly low). However, no such evidence exists in this case.

Furthermore, WTO rejected similar arguments by the EC with respect to its ban on beef containing certain hormones in the late 1990s.[131] In that case, WTO Appellate Panel noted, "the precautionary principle has been incorporated and given a specific meaning in Article 5.7 of the SPS Agreement."[132] The Panel stated that it was responsible 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."[133] Although the panel indicated that Member States disserve some deference when acting to protect against "irreversible . . . damage to human health" it affirmatively stopped short of creating an SPS loophole devoid of scientific evidence.[134]

Through the SPS participation requirement and the enforcement mechanisms, WTO affords nations the ability to demand objective and verifiable evidence to support trade barriers. This cleverly encourages nations to take a proactive role preventing infectious disease. Whereas under GATT, a state could use the unverifiable prospective threat of disease to defy or continuously relitigated import bans, the new regime compels preventive and reactive research to protect domestic populations from harm and to protect exports from deceptive trade practices.

[131] WTO Report of the Appellate Body on EC Measures Concerning Meat and Meat Products (Hormones) WT/DS26, 48/AB/R, Jan. 16, 1998.
[132] *Id*.
[133] *Id*.
[134] *Id*.

Thus, the SPS Agreement encourages infectious disease measures "based on international standards and recognition of equivalent standards that achieve the same level of protection."[135]

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

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

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 nonpecuniary cost of death and illness) of more than $150 billion."[136] 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]."[137] The question then is, 'What role would the IHR and SPS Agreement play in the event of an avian flu out break?'

An outbreak of this kind could follow a pattern similar to that of the SARS outbreak, except on a larger scale. Suppose that in November 2008 a NGO in China reports thatduring the past week 1% of the population of Hong Kong (130,000) have begun showing flu-like symptoms. The Chinese government denies these reports, but begins substantially limiting travel into and out of the country and begins blackballing the foreign media. Suppose further that Singapore reports outbreaks of a mutated form of the H5N1 flu to WHO, and thatt he Netherlands reports to WHO the localized transmission of an unknown pathogen to several

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[135] Starla L. Borg, Note, *Waiting for the River: the United States and the European Union Heads Up and High Stakes in WTO---Genetically Modified Organisms in WTO*, 43 WASHBURN L.J. 681, 693, (2004).
[136] Richard Posner, *Economics, Politics, and Psychology: The Case of Avian Flu*, The Becker-Posner Blog, (Nov. 7, 2005) http://www.becker-posner-blog.com.
[137] Victor Mallet, *Influenza Outbreak 'Could Halt Asia Growth*,' FINANCIAL TIMES, Nov 4, 2005, at 6.

Rotterdam dockworkers, their families, and the staff at a local hospital (20 people, including 4 Belgium nationals – 2 deaths). Singapore reports over 8,000 confirmed H5N1 cases with 1,050 deaths, has ordered the in-home quarantine of over 20,000 citizens, and has stopped all egress travel. In response, Canada bans all travel or trade to or from China, Singapore, and the Netherlands and places a trade ban on allBelgium chocolate.

Under the IHR, the situations in Singapore and China would clearly constitute an international public health emergency.[138] In both situations, there is a public health threat of spreading a serious disease that requires a coordinated international response.[139] The IHR decision instrument properly compels Singapore to report the human infection and unexpected outbreak of new form influenza and the Siracusa Principles support Singapore's containment policy,[140] so long as it does not violate minimum human rights norms (i.e. those quarantined have access to food and water).[141] Because China refuses to provide information about a possible outbreak, WHO may rely on reports from the NGO.[142] If verified, the magnitude and the expectation of spreading compels WHO to declare the Chinese outbreak a health emergency of international concern.[143] The situation in the Netherlands is less clear. The Netherlands may have been proper to report the outbreak because it is unexpected, carries a high potential for serious impact, and may affect international trade, but given the small size and unknown pathogen, there remains a subjective determination by the Dutch.[144]

[138] IHR, *supra* note 17, at Annex I.
[139] *Id*. at art. 3.4.
[140] *Id*.
[141] The Siracusa Principles, *supra* note 65.
[142] IHR, *supra* note 17, at art. 51.
[143] *Id*. at art. 11.
[144] *Id*. at Annex I.

Under the SPS Agreement, Canada's ban on all goods from China, Singapore, and the Netherlands is proper.[145] Clearly, a sovereign nation may limit the traffic from Singapore who openly reports contamination. Similarly, the reported magnitude of the outbreak in China and the refusal of the Chinese government to cooperate with world health officials gives Canada just cause to close its borders to Chinese imports.[146] Likewise, Canada's reaction to the Dutch is defensible because there is an arguable link between Dutch dockworkers coming into contract with people or goods from Asia.[147] However, the SPS Agreement would only allow this application of the Precaution Principle to run so long as the data supported Canada's position.[148] If the Netherlands reports that the outbreak is contained and unrelated to the outbreak in Asia, Canada would need either to submit scientific evidence to the contrary or drop its ban. Similarly, if several weeks go by with no new cases in Holland or health workers offered medically sound treatment and containment, Canada could not justify its position.[149] Finally, Canada's ban on Belgium chocolate would violate the SPS Agreement.[150] The ban would be discriminatory, impacting only one particular item, and unjustified as no cases are reported in Belgium, merely cases of Belgium nations in Holland.

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

As opposed to the old IHR, the new IHR is responsive and productive during this potential pandemic. Influenza was not a listed disease under the old IHR, and there was no

[145] SPS Agreement, *supra* note 17, at art. 5(7).
[146] *Id*.
[147] *Id*.
[148] *See* WTO Report of the Appellate Body on EC Measures Concerning Meat and Meat Products (Hormones) WT/DS26, 48/AB/R, Jan. 16, 1998.
[149] SPS Agreement, *supra* note 17, at art. 5(7).
[150] *Id*.

official influenza vaccination certification requirement . Despite the widespread outbreak of an identified infectious disease, under the old IHR Singapore would have no obligation to report to 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, it too would have no duty to report an unidentified widespread illness. More to the point, with greater than $583 billion in exports in 2004, China has a great deal of incentive to keep its export market secure by not reporting a domestic epidemic.[151] Similarly, the Netherlands would have no reason to report any health concerns. It is possible that the illnesses was spread through unsatisfactory sanitary conditions in the Rotterdam seaport, but it is unlikely that a cost benefit analysis would impel the Netherlands take reactive reporting and sanitary measures in light of the limited disease transmission. Lastly, the old IHR would not sustain Canada's imposition of health measures on incoming vessels because the old IHR would not support health measures greater than its own.

The new regulations eliminate many of these problems and allow WHO to play an important role in the public health emergencies of all three countries. First, the IHR creates a system where WHO can collect data and coordinate a response. By using NGO public health data, the IHR compels China to mitigate the impact on exports when WHO makes an unsanctioned infectious disease report. Rectifying public health emergencies and suppressing cross border disease transmission is a positive sum effort, but issues of sovereignty, lack of resources, and lack of motivation would normally limit the international response of individual nations. Through the IHR, WHO can also use NGO and national health data to identify the similarities of the China/Singapore/Netherlands outbreaks, track the geographic transmission pathways, analyze the threat to other nations, and coordinate an international response to

[151] CIA World Factbook, China, http://www.cia.gov/cia/publications/factbook/geos/ch.html (last updated Nov. 1 2005).

mitigate the harm and prevent further spreading. Second, although the IHR affirms Singapore's internal quarantine policy, the international involvement promotes scrutiny of human rights. Though merely a peer pressure system of human rights, IHR's approach is comparatively progressive to the old regime and creates a framework to build upon. Moreover, combined with WHO's response coordination, the IHR raises the likelihood of international participation in funding and maintaining humane quarantine conditions.

The weaknesses of the IHR are similar to those in other international regulations. First, enforcement could be highly problematic, if possible at all. WHO has no recourse to China's refusal to cooperate with health officials. Moreover, under some circumstances, WHO's usage of NGO data could backfire. One can foresee China or Russia further restraining the freedom of NGOs and lessening transparency when a situation threatens export profits. Second, developing nations with limited public health resources face the same problems under the new IHR. International interest in countries with limited trade value will likely wane. As a result, for some countries the new IHR could devolve into a de facto reactive system.

The positive and negative value of the SPS Agreement during this outbreak is much less clear. Prior the outbreak however, the Agreement's benefit is substantial. The scientific justification requirement creates a dual sword and shield for nations who largely depend on international trade. China and the rest of Asia have a strong stimulus to perform research on H5N1 and develop both preventive and reactive scientific solutions. With the knowledge that Canada could uniformly ban all Chinese exports, China would want to implement prophylactic measures both on its bird and human populations. Furthermore, with an effective domestic response mechanism and scientific evidence of a working inoculation, China would have the tools combat an unreasonable and harmful Canadian trade barrier. Thus, the SPS Agreement

encourages proactive and reactive infectious disease response, and creates a system of scientific information leverage in trade disputes.

Despite this potential, the weakness of the SPS Agreement during this outbreak is significant. First, the scientific leverage maybe largely symbolic. As with genetically modified foods in Europe or fear of mad-cow disease in Japan, if the internal political and social pressure is sufficient, 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 could prevent a uniform trade ban despite compelling scientific evidence. Thus, as a reactionary tool, the SPS Agreement may be minimally influential. The second problem is time. Here, Singapore has 1,050 H5N1 deaths in one week. The threat of a binding dispute resolution one to two years after the first trade barriers would be have no impact on the actual reactions of other nations. Such a dispute resolution could provide retroactive relief once the pandemic is over, but like all permissive WTO trade sanctions, a positive resolution would largely be constrained by the practicalities of any changing prices in domestic 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 no) research capabilities, developing nations would have no argument against trade or travel bans if a developed nation claims such bans are scientifically reasonable. Thus, the SPS Agreement leaves developing nations in a position of weakness similar to that experienced under GATT.

In conclusion, one should applaud the development and maturity of the IHR and SPS Agreement as compared to their respective predecessors. The IHR is a foundational agreement allowing the international community to designate 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. Likewise, the SPS Agreement cultivates a scientific justification standard and provides a neutral forum for disputes. Much like environmental international law, these regulations possess weaknesses in enforcement and time constraints that can nullify their value, but from a broad perceptive are clearly progressive. They acknowledge and promote flexible responses by sovereign nations without over reaching. They create incentive for information sharing and encouraging an international body to lead the positive sum effort to prevent and control public health emergencies. As such, the IHR and SPS Agreement are important in the evolution of beneficial and accepted international law.

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