

# Designing an International Policy and Legal Framework for the Control of Emerging Infectious Diseases: First Steps

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As the pace of emergence and reemergence of infectious diseases quickens, the International Health Regulations, which have served as the legal and policy framework of epidemic control for 45 years, are being revised by the World Health Organization (WHO). In this article, we review the recent history, legal construction, and application of these regulations and related international treaty-based sanitary measures, especially the General Agreement on Tariffs and Trade and the Agreement on the Application of Sanitary and Phytosanitary Measures, and the history of applying the regulations in the maritime and aviation industries. This review indicates that revision efforts should address 1) the limited scope of disease syndromes (and reporters of these syndromes) now in the regulations and 2) the mismatch between multisectoral factors causing disease emergence and the single agency (WHO) administering the regulations. The revised regulations should expand the scope of reporting and simultaneously broaden international agency coordination.

The Division of Emerging and Other Communicable Disease Surveillance and Control, World Health Organization (WHO), is revising the often criticized International Health Regulations (referred to as regulations hereon), the central legal framework for addressing the international spread and control of infectious disease (1,2). This process is under way as emerging and reemerging infectious diseases are the objects of broadening efforts and analysis by the national (3) and international public health communities (4). At least 30 new diseases have emerged in the last 20 years, and still others, including tuberculosis, malaria, cholera, dysentery, and pneumonia, have developed varying degrees of resistance to antimicrobial drugs (4).

## The Intersectoral Nature of the Factors Involved in Disease Emergence

Infectious diseases are emerging in the increasingly global context of commercial and demographic activities. The journey of microbial agents from one country to another, often shorter

than the incubation period of the disease, is rendering border controls futile. The response to emerging diseases is increasingly global as well: national agencies, international organizations, and other groups coordinate efforts to monitor, prevent, and control the spread of these diseases (5). While no substitute for adequate national health services and infrastructure, international efforts against emerging diseases have increased in importance as national programs have been compromised by complacency, economic recession, international debt, civil turmoil, or natural disasters (3,5,6). At the same time, detecting new agents often requires up-to-date diagnostic facilities unavailable in many parts of the world. International agencies have improved access to such facilities to help define the causes of disease outbreaks.

## The Current Legal Framework: International Health Regulations

The regulations, which play a central, albeit limited, role in addressing global disease outbreaks (Table 1), have served as the primary legally binding framework for preventing the international spread of infectious disease (Table 2). In addition to its other legal and policy options for promoting international public health, WHO's

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## Perspective

Table 1. Selected international health regulatory provisions pertinent to emergent infectious disease

Provision	Source/Lead Agency
International Health Regulations	World Health Organization
Agreement on the Application of Sanitary and Phytosanitary Measures	World Trade Organization
Codex Alimentarius	FAO/WHO Codex Alimentarius Commission
Annex 9: Facilitation to the Convention on International Civil Aviation	International Civil Aviation Organization

World Health Assembly is specifically authorized to adopt regulations concerning “sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease” (7, art. 21[a]). The twin objectives of the regulations balance “maximum security against the international spread of diseases with a minimum interference with world traffic” (1, Foreword).

The regulations evolved from efforts to deal with epidemics. The use of quarantine dates back at least to the Middle Ages (3). Steps to regulate countries’ actions to protect themselves against the introduction of communicable diseases and to report disease outbreaks developed before the International Sanitary Regulations were adopted in 1951 (8). Inadequacies of the current regulations have been associated with outdated quarantine and frontier-based practices.

The current regulations outline procedures for limiting disease transmission in international traffic, including the disinsectization, disinfection, and deratting of ships and aircraft and the provision of sanitary conditions and health facilities at sea and airports. In addition, the regulations focus on two core obligations of member states relating to disease incidence reporting and response; these obligations apply primarily to the three diseases subject to the regulations: cholera, plague, and yellow fever (1, art. 1). First, states must report to WHO, within specific periods, cases of these three diseases within their territories (1, arts. 3-7,9,11-12). Second, to facilitate reporting and deter unnecessary interference with international travel and trade, members must limit their responsive health measures (applied to international traffic for the protection of their territories against these diseases) to maximum measures permitted by these regulations (1, art. 23). States must also

report to WHO any health measures they have applied to international traffic (1, art. 8). Most of such permitted health measures (and related provisions in the regulations limiting or prohibiting health measures) focus on cholera, plague, and yellow fever; some more general provision, however, limit measures directed at other diseases (1, arts. 28, 29, 31, 81; 9).

Like most international agreements, the regulations are to be implemented through national laws and policies that incorporate or otherwise accommodate the regulations’ various provisions, minimum requirements, and limitations. The regulations have served as international reference standards for some states creating their own national quarantine provisions; this relationship magnifies the effect of outdated and problematic aspects of the regulations (and increases the urgency of their timely revision).

Even though the regulations pose a legal obligation for WHO members who have not officially “opted out” from participating, lack of compliance has been an ongoing problem (8,9). The regulations have weaknesses: 1) the limited scope of reported information vis-a-vis the burgeoning scope of new infections, and 2) the mismatch between the narrow institutional, political, and legal bases of the regulations issued under the circumscribed authority of a single specialized United Nations (U.N.) agency, WHO, and the varied factors affecting the international emergence and control of infectious disease. The factors include international trade and travel, economic development and land use, changes in human demographics and behavior, and the breakdown of public health infrastructure (3). WHO’s broad mandate within the U.N. system (10, art. 57) and under the WHO Constitution (7, preamble, arts. 1-2), to address these factors is ultimately rooted in the one agency. While WHO’s natural institutional allies tend to be

Table 2. Development of the International Health Regulations

Year(s)	Action
1951	WHO Int’l Sanitary Regulations and additional regulations in 1955, 1956, 1960, 1963, 1965)
1969	Revised and renamed Int’l Health Regulations (regulations)
1973	Regulations revised
1981	Regulations revised (current version)
1995	WHO resolves to revise regulations

national health ministries, the factors affecting disease emergence are multisectoral and can be more directly addressed by a constituency of international organizations and agencies. WHO members' violations of regulations during epidemics (e.g., the implementation of unjustified and illegal health-based trade barriers) are critical symptoms of the institutional mismatch. Such barriers are rarely the product of sole actions by the Ministry of Health, and WHO has little influence over other national agencies such as Ministries of Trade, Commerce, or Planning.

These core weaknesses are exacerbated by the administration of regulations. In spite of the regulations' strong legal basis, WHO has frequently preferred nonmandatory urging or mediation to a legally binding approach to members' obligations (8,11). In the area of trade, for example, a Pan American Health Organization epidemiologic bulletin on the 1991 cholera outbreak in Latin America referred to unjustified trade restrictions imposed on Peruvian marine exports as "not in accordance with the recommendations of WHO" (12). More substantive is the ambiguous, indeterminate, or otherwise vague nature of many of the regulations' articles, which create further difficulties in application (1, arts. 46[1] and 36 [3]). WHO is unlikely to use formal mandatory enforcement such as sanctions against member states who do not comply with the regulations (13). Under the WHO Constitution, typical of such treaties (13), there are no formal punitive sanctions. While under article 7 of the Constitution, the World Health Assembly is authorized in "exceptional circumstances" to withdraw membership privileges, under treaties, such provisions are rarely invoked and then usually on political grounds against otherwise marginalized states (13). These sanctions would also hinder the WHO objectives of tracking, controlling, and preventing incidence and transmission of disease.

The regulations contain a dispute resolution provision that authorizes member states to refer "any question or dispute" concerning the regulations to the Director General or a WHO committee to "settle," rather than to enforce (1, art. 93[1]). If this referral process fails, a member state is authorized to bring the dispute to the International Court of Justice in the Hague for decision (1, art. 93[3]). The International Court of Justice has, however, never determined a case under the regulations and is a relatively rare choice for disposition of international disputes

(13). WHO's right to request advisory opinions from the International Court of Justice has yielded court rulings in only two cases. Thus, disputes appear to be usually handled informally through the WHO bureaucracy (8).

In this article, we propose two steps for improving the effectiveness of the regulations. Some of the following issues are addressed in the December 1995 Report of WHO Informal Consultation of Experts on Revision of the Regulations (14,15).

### Step One: Expand the Information Base

#### The Limited Scope of Reporting Under the Regulations

The current narrow scope of disease reporting undercuts the relevance of the regulations and has been criticized (16). In contrast to the long list of known emerging and other infectious diseases that threaten world communities and the threats posed by as yet unknown or unrecognized diseases or syndromes, only three diseases (cholera, plague, and yellow fever) are expressly covered by the regulations' reporting requirements.

Additional obstacles to effectiveness and compliance regarding both outbreak reporting and minimizing of health restrictions arise from limiting the range of information sources that can report on these issues to WHO. WHO has been criticized for relying solely on information reported officially by member states regarding outbreaks within their borders or health measures applied to traffic from the country involved in an outbreak (9). To avoid self-incrimination, members do not report on a timely basis, if at all, as required (8,9,16). A related problem arises from the right of the affected country's health administration to determine the "infected area" of an outbreak (1, art. 1), although that decision can influence health measures other countries may apply to persons, vehicles, and cargo from the outbreak area (1, arts. 46[1], 59, 64[2], and 66). WHO appears to limit its sources for listing infected areas in the Weekly Epidemiological Review "only [to] official governmental information" (17).

#### Consequences of an Inadequate Information Base

Driven by political and economic pressures and other concerns (8,18), neighbors or trading partners of countries affected by epidemics often overreact by setting up border or other restrictions in excess of those permitted under the

regulations. From the beginning of the seventh cholera pandemic into Latin America in 1991, for example, trading partners of affected countries—particularly Peru—at times rejected food imports (19) or even nonfood manufactured goods (20), restricted travel (19), or closed their borders. Peru lost an estimated \$770 million because of the epidemic (4). In response to the 1994 plague outbreak in India, some countries severed air and shipping links with India; the country sustained a reported \$1.3 billion in export losses in 2 months (21). Concerns about potential trade and travel restrictions have caused countries not to report outbreaks within their borders (8,12,22).

### **Proposed Solutions to Information Weaknesses in Regulations**

The regulations' disease coverage, reporting of outbreaks, and disease incidence (and permitted responsive health measures) should be based upon an up-to-date schedule of the most relevant clinical syndromes in conjunction with a broadened list of relevant serious diseases. Syndromes should be reportable until the underlying disease is identified. Descriptions of syndromes and appropriate and inappropriate health responses should be stated as clearly and specifically as possible in the regulations. This approach would align the coverage of the binding regulations with the most appropriate and dangerous diseases; it would also facilitate more direct and coherent risk evaluation and present a framework for addressing unknown or unrecognized diseases and syndromes. It is also likely to expedite reporting as there would be no need for disease identification. It may also stimulate participation by member states that have ceased complying with what they regard as an outdated system (16). An operations research effort by WHO and its member states could facilitate the adoption of these suggested improvements by testing the sensitivity and specificity of syndromic outbreak reporting.

Similarly, to enhance the effectiveness of the regulations, the acceptable sources of information on disease outbreaks and health measures put in place by member states under the regulations should be broadened to include other reliable sources. WHO's use and acceptance of reliable outside information for such determinations will provide more accurate information and may also prompt more timely reporting by the affected countries faced with preemption by WHO and others.

The complex issues arising in international relations are discussed elsewhere (14,23-26), but the history of noncooperation with the regulations does not preclude potential for improved compliance in the future. If the regulations are substantially and meaningfully revised (14,15) and key countries are sufficiently concerned about the dangers of emerging diseases to press for compliance with the revised scheme, compliance should improve (14).

### **Step Two: Expand Policy and Programmatic Collaboration**

International organizations other than WHO deal more directly with the underlying issues affecting the transmission of disease. The expansion of international regulatory provisions in all areas has increased the potential for overlapping policies and even regulation.

#### **Interorganizational and Interagency Consultations**

Revising the regulations presents an opportunity to establish interorganizational and interagency consultations and address potential contributions of agencies and organizations that can most directly affect the factors involved in the emergence and control of infectious disease. A first step would be an interorganizational summit led by WHO to examine potential joint or coordinated programs. The breadth and focus of the summit will depend on the specific programs most compatible with such an approach. WHO has a long record of cooperation with other agencies and organizations, and joint activities are part of its programs addressing infectious disease control (4). Contacts need not be limited to the WHO-affiliated international organizations but can include other groups: WHO will need to evaluate whether participation by such agencies, nongovernmental organizations, and other entities would be beneficial in a particular context, and if so, at what points in the process.

Establishing new connections and building on existing relationships between WHO and other institutions and organizations (e.g., the World Trade Organization, the International Civil Aviation Organization, and the International Maritime Organization) present many benefits: WHO can bring its influence closer to the underlying processes and organizational entities directly involved in disease emergence and control; it can more

effectively use its limited resources; and it can address initiatives in other organizations that may be insufficiently sensitive to key public health concerns. From an international relations perspective, such contacts may ultimately develop into direct links between the administration of WHO regulations and that of other international or multilateral organizations.

### World Trade Organization

Health-related trade restrictions are regulated by multilateral organizations and agreements (Table 1), such as the recently established World Trade Organization (WTO) and its related multilateral agreements, including the General Agreement on Tariffs and Trade (GATT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS agreement). Like the WHO regulations, parts of this complex trade regulatory scheme address the health-based trade constraints that countries may implement to protect their citizens and territories from infectious disease threats. Peru's appeal to the GATT Council for assistance in protecting its exports from unjustified rejection during the 1991 cholera outbreak at the same time that PAHO was directly involved in dealing with the epidemic exemplifies this potential overlap of regulation (20).

The WTO agreements specify which health-based trade barriers that would otherwise violate a trade rule of WTO may be justified under the exceptions in GATT article XX(b) for measures "necessary to protect human, animal, or plant life or health" and *inter alia* under the related SPS agreement that governs health measures pertinent to most infectious disease threats. Therefore, a WTO member's "sanitary and phytosanitary measures" (certain health-based trade restrictions) that meet the SPS agreement's detailed requirements are deemed in compliance with GATT's XX(b) exception. The SPS agreement addresses all sanitary and phytosanitary measures that a member may apply that potentially affect international trade (27, arts. 1, 2.4) The WTO agreements, in contrast to the WHO regulations, are not disease-specific. The sanitary and phytosanitary measures described in the SPS agreement focus on risks to humans from diseases carried by animals, plants, and their products; the entry or spread of pests; and additives, contaminants, toxins, and disease-causing organisms

in food and beverages (27, Annex A, par. 1). The SPS agreement contains measures focusing on, for example, cholera as transmitted in international trade in food and beverages and insectborne disease risks in international trade. Measures directed against many health risks to animals and plants are also covered (27, Annex A, par. 1). Although the SPS agreement does not refer specifically to epidemics, its stated scope is broad enough to cover them, assuming the agreement's various requirements are met (27, arts. 5.7 and Annex B, pars. 2,6). However, aspects of the relevant applications of the SPS agreement are as yet not entirely clear. The WTO agreement and related Dispute Settlement Understanding have been in force only since 1995. Measures directed at trade-related infectious disease risks not covered under the SPS agreement may be addressed by the Separate Agreement on Technical Barriers to Trade, which concerns product standards, or by the GATT article XX[b] exception itself (28).

Like those of the regulations, the general purposes of the SPS agreement include limiting health-based restrictions to those that are necessary and as minimally burdensome to trade as possible. The SPS agreement provides detailed rules and standards for determining what sanitary or phytosanitary measures are permitted on the basis of scientific support, risk assessment, and other factors (27, arts. 2.2, 3.3, 5 and Annex A par. 4), as well as numerous other provisions. The SPS agreement provides, for members' use, where applicable, certain established "international standards, guidelines or recommendations" (rather than their own standards) to promote international consistency on these measures. A member must justify, scientifically and otherwise, implementation of higher standards if they result in a greater restriction on trade than the stipulated international standard (27, art. 3 and Annex A, pars. 2-3). For example, regarding food safety issues, the SPS agreement designates the "standards, guidelines and recommendations" established by the WHO-Food and Agriculture Organization Codex Alimentarius Commission. The Codex Alimentarius is an extensive code that addresses a broad range of food production issues including food additives, limits on pesticide residues, food labeling requirements, product composition, recommendations on food processing

techniques, and suggested inspection procedures regarding food products and production (27, Annex A, par. 3[a]). However, the regulations do not mention the Codex (although it is a key part of WHO guidelines on food issues).

WTO mechanisms for dispute resolution differ substantially from those of the WHO regulations: among other differences, ultimate adjudication authority remains within WTO. Under GATT articles XXII and XXIII and the Understanding on Rules and Procedures Governing the Settlement of Disputes (Dispute Settlement Understanding), if the disputing parties' consultation and other preliminary steps do not resolve a dispute, they ordinarily resort to adjudication before a WTO three-person panel (29). The panel's report (including its recommendation if a violation has been found) is adopted by the WTO members (sitting as the Dispute Settlement Body), unless there is a consensus to reject it. There is also a potential appellate procedure, before the seven-person Appellate Body, regarding legal issues. If the challenged trade restriction is found to be unjustified (and the related rulings, usually to bring the violating measure into compliance, are not implemented nor is negotiated compensation obtained), the injured member can be authorized to obtain compensation by retaliation: a proportional reduction in a trade concession or obligation owed to the violator. The overall value of this mechanism is controversial. However, since its establishment in 1995, some 50 requests to start consultations on disputes of all kinds have been initiated; several cases are before panels; two panels have completed proceedings; there has been one appellate ruling; and ten disputes have been resolved by consultation without resort to a panel (30).

Given the parallels between the WHO and WTO regulatory systems and the interplay between epidemics and trade, WHO consultations with WTO would enhance coordination (or other more or less formal arrangements) on trade issues related to disease threats. Coordination seems particularly appropriate in light of the current revision of the regulations. As the range of diseases and syndromes covered by the regulations is substantially broadened, areas of potential overlap or parallel may grow (15).

The SPS agreement provides for consultation and coordination between the WTO system and those of other international organizations (27, art. 11.3). The Committee on Sanitary and

Phytosanitary Measures established under the SPS agreement has a mandate to consult with other international organizations in the field of sanitary or phytosanitary protection (including the Codex Alimentarius Commission); to obtain scientific and technical advice for administering the agreement; to avoid unnecessary duplication of efforts; and to identify other international standards, guidelines, or recommendations relevant to sanitary and phytosanitary measures that have a major impact on trade. (27, art. 12). Consultation is also recommended for dispute resolution. The SPS agreement encourages dispute resolution panels deciding cases that involve the agreement on scientific or technical issues to seek advice from experts, including the relevant international organizations (27, art. 11.2).

The WTO also has a Committee on Trade and Environment, which addresses the relationship of regulation and policy on trade and Environment issues, including issues concerning the SPS agreement (31-32). In an example of a potential consultation between WHO and WTO, a bulletin of the Committee on Trade and Environment indicates that the Conference of the Parties of the Biodiversity Convention (an environmental treaty) had requested that its Secretariat "liaise with the WTO Secretariat and invite it to provide input in identifying the synergies and relationship between the objectives" of the convention and one of the WTO agreements (33).

Collaboration and consultation on health-related trade issues will depend on accommodating the many differences between the two organizations, as well as WHO's constitutional provisions concerning such relationships (7, arts. 70-71) and the more limited articles in the current regulations on such contacts (1, arts. 46[3], 85). While establishing working relationships with WTO might not be a panacea for the many trade-related concerns under the WHO regulations, it would provide opportunities for reinforcement of the legal and institutional bases for the prevention of inappropriate trade restraints.

### **International Civil Aviation Organization (ICAO)**

Because of the importance of international travel (as well as air transportation of cargo) to disease emergence, ICAO is another important collaborative partner. Unlike WTO, however, ICAO has had a long-standing relationship with WHO, dating from the 1940s and including participation

in creating the regulations (8). The conflicting pressures of globalization of world transport (and commerce) and sovereignty have affected the ability of ICAO and WHO to regulate effectively (34).

In preventing infectious diseases, WHO and ICAO have overlapping areas of interest, such as the disinsectization of aircraft and airport health and sanitary facilities. Under the Convention on International Civil Aviation and related instruments, ICAO addresses a variety of civil aviation issues, including many relating to public health and international transmission of disease. The convention provides that each member state "agrees to take effective measures to prevent the spread by means of air navigation of cholera, epidemic typhus, smallpox, yellow fever, plague, and such other communicable diseases as the contracting States shall ... designate" and to "keep in close consultation with the agencies (such as WHO) concerned with international regulations relating to sanitary measures applicable to aircraft" (35). The specific compulsory "Standards" and related "Recommended Practices" in Annex 9 to the convention include those applicable to public health, infectious disease transmission, and related requirements (36). These provisions are fundamentally tied to WHO recommendations and the regulations in Standard 8.12, which requires ICAO member states to "comply with pertinent provisions of the current edition of the [regulations]." Specific ICAO standards and recommendations also refer to WHO recommendations and regulations in key areas, including aircraft disinsectization, provision of safe food and water at airports and on aircraft at international airports, proper facilities for disposal of refuse, waste, wastewater, and other dangerous matter, and yellow fever certificates.

WHO cooperation with ICAO is exemplified by the participation of ICAO in the 1995 informal WHO consultation regarding revision of the regulations; ICAO was the only such international organization to participate in the consultation (15). The consulting group's recommendations suggested that certain sections of the revised regulations concerning sanitation standards at airports and seaports should refer to the applicable requirements (exceptions being health care services for sick persons on arrival, equipment necessary for disinfection, and disinsectization, and control of animal-borne disease), under other international agreements, such as Annex 9. Although this specific recommendation

may have flaws (for example, it effectively renders the regulations incomplete in themselves as a reference or guide to essential rules), it demonstrates ongoing attempts to link the two organizations.

Coordination of WHO and ICAO in dealing with the inappropriate imposition of health measures is particularly relevant now. At a 1995 session of the ICAO division with jurisdiction over such public health issues, "[d]elegates recommended that ICAO work with the World Health Organization ... to draft joint guidelines that, if followed, would prevent adoption by Contracting States of excessive health measures that might disrupt international air transport services in cases of outbreaks or epidemics of diseases" (37).

### **International Maritime Organization (IMO)**

Provisions under the regulations concerning deratting procedures (as noted in the WHO informal consultation on revision of the regulations) (15) and sanitary conditions at seaports also play an important role in maritime health and in containing international disease transmission threats. The regulations also address cholera-contaminated bilge water in certain circumstances on arrival of the ship (1, art. 62[1]). Health authorities are broadly authorized to take measures "to control the discharge from any ship of sewage and refuse which might contaminate the waters of a port, river or canal" (1, art. 29). IMO has recognized the global public health problems of bacterial and viral diseases transmitted in discharges of ballast water and sediment (38). A poll of IMO member states indicated that such transmission is a major international problem expected to worsen (38). The IMO assembly has accordingly adopted (generally nonmandatory) guidelines to prevent the introduction of bacterial and viral pathogens in ballast water and sediment. The IMO resolution traced this concern in part to the 1973 International Conference on Marine Pollution, in which the parties called for WHO, in collaboration with IMO, "to carry out research into the role of ballast water as a medium for the spreading of epidemic disease bacteria" (38).

A sound legal and policy framework is needed to support efforts against emergent infections. Truly intersectoral, interagency, and inter-organizational collaboration in addressing the broad factors of emergence and expanded reporting of disease are major steps in this process. The challenge is broad, but in view of the

increased pace of emergence and the globalization of disease, the importance of a comprehensive legal and policy framework cannot be overstated.

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