April 27, 2004

SECOND U.S. GOVERNMENT COMMENTS ON THE FIRST DRAFT OF THE PROPOSED REVISION OF THE INTERNATIONAL HEALTH REGULATIONS (IHRs)

NOTE TO WHO AND MEMBER STATES:

We are very pleased that the World Health Organization (WHO) is moving forward with the process to revise the International Health Regulations (IHR). We find the first WHO draft proposal to be a very good initial effort, but we do have a number of concerns regarding this draft. Since the WHO will not be revising this draft until after the regional consultations, and since these consultations have begun, on March 5, 2004 we provided a set of general and specific comments, as well as suggested issues for clarification, which we hope were helpful to both the WHO Secretariat and Member States during these early Consultations. We are now submitting more detailed comments, and specific recommendations, regarding these draft revisions. We have identified general comments, specific comments and questions, and made changes to the WHO draft language where appropriate, by highlighting the modifications made to the original text.

General Comments

A Disease-Specific List is Needed in Addition to an Algorithm:
We support the use of an algorithm to determine "public health emergencies of international concern" (PHEIC). We, however, strongly believe the IHRs also should require reporting of a defined list of certain known, serious, communicable diseases that have the potential for creating a PHEIC. Although the concept is a good one, relying solely on the nonspecific construct—PHEIC-- is insufficient (also, the PHEIC term itself needs to be defined in the IHRs—see comment below). The IHRs should specify certain notification triggering diseases—information that we cannot afford to miss, but might miss, if Member States rely solely on an algorithm that, by its nature, is subject to interpretation. The list should be expandable to include future emerging diseases and should accompany and supplement the algorithm designed to capture PHEIC. See our “suggested new language” under Annex 2 for a list of diseases that we propose to be used for this purpose.
The term “Public Health Emergency of International Concern” Needs a Clear Definition:
This term, which needs to be defined and consistently used, is central to the IHRs. We have proposed an example of such a definition in Article 1. Please note that our suggested definition draws on both the algorithm in Annex 2 and the Disease-Specific List to determine and define “public health emergencies of international concern.”

There are Inconsistencies in the Draft between the terms “National IHR Focal Point”/“Health Administration”/“Health Authority”:
For sake of clarity, the term “National IHR Focal Point” should be used at all times for IHR notification and response purposes. Even when the “health authority” immediately responsible for implementation of IHR measures does not fall under the jurisdiction of the “health administration,” communications with WHO should still be through the National IHR Focal Point. The IHR should designate these situations clearly.

Information-Sharing During a Suspected Intentional Release/Act of Bioterrorism is Crucial:
Given both the obvious law enforcement and national security concerns that could arise in a suspected intentional release situation, the Draft needs to address the distinction between mandatory reporting requirements and permissive reporting requirements needs to be addressed. The IHR should establish a consultative/facilitative role for the WHO Secretariat through which it could, if asked, assist Member States in their recognition or detection of "suspected intentional releases," and their investigation, confirmation, and public health response to such releases. We recognize that this is a complex issue and we have suggested new language for a revised Article 41, and have also identified two areas in Annex 2 that might result in a Member State not reporting/avoiding reporting an intentional release.

The Draft Should Include Fixed Time Periods for Reporting:
The WHO should consider using fixed time periods instead of vague terms (e.g., “immediately” (Art. 7.2) or “as soon as possible” (Art 7.3)) in provisions that stipulate the periods that apply to actions to be taken by Member States or the WHO. We have provided examples of possible time periods for reporting in various sections. These time periods are exemplary and, as such, are offered for consideration by WHO and Member States.

The Draft Should Specify when the WHO Secretariat Will Invoke Confidentiality:
We are concerned that this Draft of the revised IHRs might not clearly specify all instances in which the WHO Secretariat would be required to apply the confidential treatment provided for under Article 5(2) to notifications and other information provided to it under the IHRs. We understand that such treatment would be applied to notifications made and information otherwise obtained pursuant to Articles 4 through 8 (inclusive). We seek clarification that those are the only circumstances under which such treatment would be required.

Several Aspects of the Draft Impinge on the Sovereignty of Member States:
The current iteration of the draft IHRs raises two state sovereignty concerns. The first relates to the extent to which several provisions in the draft IHRs (see e.g., Art. 10.3, 14, 21.1, 21.2, 22, 23.1, 24, 26, 34) would prevent a State from implementing measures to protect against international public health risks if such measures go beyond those recommended by the WHO or those otherwise authorized by "applicable international agreements." See, e.g., Articles 21(2) and 27(2). We believe these are inappropriate restrictions on a Member State's prerogative to apply additional measures to protect its nationals or others residing within its borders where such measures are consistent with international law and sound public health practice such as vaccination requirements. We are conscious of WHO's desire to strike a balance between the need to provide security against the international spread of disease, while avoiding unnecessary interference with international traffic. However, some of the measures proposed, including the examples cited above, do not strike the right balance and constitute an impermissible infringement on a Member State's sovereign prerogatives. Member States should have the right to regulate "goods" based on reasons unrelated to IHR issues and to institute border actions according to what they determine to be an appropriate level of protection.

The second concern relates to provisions in the draft IHR that, for example, purport to give the WHO Secretariat the authority to require that Member States collaborate with WHO teams sent into a country - in the absence of a Member State's request - to conduct on-the-spot studies of the severity of a threat or the adequacy of a Member State's control measures to address a potential threat. We are concerned that any provision that purports to authorize the WHO to conduct on-the-spot studies in a Member State in the absence of a Member State's request and/or requires that a Member State "collaborate with WHO in assessing the severity of the threat" in-country, in the absence of an invitation to the WHO, is an infringement on that Member State's sovereign prerogatives.

The Draft Should Define the Term “Applicable International Agreements”: The draft IHRs contain several references to “applicable international agreements.” The WHO Secretariat should provide Member States with information concerning all those international agreements that it considers applicable to facilitate Member State consideration of the nature of the obligations set forth in the draft IHRs. Every effort should be made to ensure that the revised IHRs do not conflict with other international agreements. Article 48 does include specific international agreements, but it also references other “similar agreements.” The WHO Secretariat needs to consider how best to ensure that the final IHR does not conflict with all relevant international agreements. (See e.g., Art. 17, 19.1, 21.1, 21.2, 22, 24, 26, 29.1, 36, 38, 42, 48, Annex 2)

The Draft Must Recognize the Right of Member States to Communicate and Collaborate with Other Member States: Article 42 explains that Member States can enter into special treaties or arrangements that may be concluded between two or more States. Notwithstanding this and the fact that the regulations focus on Member States’ interactions with WHO, we believe it is important to have a statement in the IHRs to recognize that Member States can
communicate and collaborate formally or informally among themselves, concurrently with their activities under the IHR.
FOREWORD

NOTE: We have no comments or suggested new language for the Foreword, so this section has been omitted in the interest of space.

PART I – DEFINITIONS, PURPOSE AND COMMUNICATIONS

Article 1 Definitions

1. For the purposes of these Regulations:

"affected area" means a geographical location within a State for which measures have been recommended by WHO under these Regulations;

"affected" with regard to conveyances, containers, cargo, goods or persons means those that are infected or contaminated, or carry sources of infection or contamination, so as to constitute a public health risk;

"aircraft" means an aircraft making an international voyage;

"airport" means any airport where international flights depart and arrive;

"arrival" of a conveyance means:

- (a) in the case of a seagoing vessel, arrival or anchoring at a port; (b) in the case of an aircraft, arrival at an airport;
- (c) in the case of an inland navigation vessel, arrival either at a port or at a frontier post; (d) in the case of a train or road vehicle, arrival at a frontier post;

"baggage" means the personal effects of a traveller;

SUGGESTED NEW DEFINITION: “bill of health” means an official certificate given by the authorities of a port from which a vessel departs, to the master of the ship, to show the state of the port, in respect to the public health, at the time of sailing, and exhibited to the authorities of the port at which the vessel next arrives, to demonstrate that the vessel does not bring disease.
"container" means an article of transport equipment:

(a) of a permanent character and accordingly strong enough to be suitable for repeated use;

(b) specially designed to facilitate the carriage of goods by one or more modes of transport, without intermediate reloading;

(c) fitted with devices permitting its ready handling, particularly its transfer from one mode of transport to another; and

(d) so designed as to be easy to fill and empty;

"container loading area" means a place or facility set aside for the loading and unloading of containers involved in international traffic;

"contamination" means a contamination that may constitute a public health risk;

"conveyance" means an aircraft, ship, train, road vehicle or other means of transport, on an international voyage;

"conveyance operator" means the person or entity in charge of a conveyance or his agent;

"Director-General" means the Director-General of the World Health Organization;

"disease" means an illness that presents a risk of significant harm to humans caused by biological, chemical or radio-nuclear sources;

"event" means a manifestation of disease or an occurrence that creates a potential for disease;

"free pratique" means permission for a ship to enter a port, disembark and commence operation, for an aircraft, after landing, to disembark and commence operation, or for a train or road vehicle upon arrival to disembark and commence operation;

COMMENT: What does WHO mean by “commence operation” in this context?

"goods" mean tangible products transported on an international voyage, including for consumption on board a conveyance;

"health administration" means the governmental authority responsible over the whole of a territory of a State to which these Regulations apply for the implementation of the health measures provided herein;

SUGGESTED NEW DEFINITION: "health authority" means the authority or entity immediately responsible for the implementation and application of appropriate health measures under these Regulations;

"infection" means an infection that may constitute a public health risk;

"inspection" means the examination of conveyances, containers, goods, baggage, areas or facilities, including relevant data, to determine if a public health risk exists;

"international voyage" means:

(a) in the case of a conveyance, a voyage between points of entry in the territories of more than one State, or a voyage between points of entry in the territory or territories of the same State if the
conveyance has contacts with the territory of any other State on its voyage but only as regards those contacts;

(b) in the case of a traveller, a voyage involving entry into the territory of a State other than the territory of the State in which that traveller commences his voyage;

SUGGESTED NEW DEFINITION: "isolation" means separation from others of suspect or affected conveyances, containers, goods, baggage or ill persons in such a manner as to avoid the spread of infection and/or contamination;

SUGGESTED NEW DEFINITION: "medical examination" means the preliminary examination of a person to determine his health status and potential public health risk to others, including scrutiny of health documents, and may include a physical examination or collection of specimens when justified by the circumstances of the individual case;

"National IHR Focal Point" means the national centre, designated by each State, as having the responsibility and the authority to communicate directly with the World Health Organization concerning the application and implementation of these Regulations;

"WHO" or "Organization" means the World Health Organization;

"point of entry" means an international point of entry or departure in a State;

"port" means a seaport or a port on an inland body of water;

SUGGESTED NEW DEFINITION: “public health emergency of international concern” means the occurrence or suspected occurrence of any of the listed diseases appearing in Annex 2 or a public health event determined by the health administration of a State or WHO to be a public health emergency of international concern using the algorithm in Annex 2.

SUGGESTED NEW DEFINITION: "public health risk" means an event posing a serious and direct threat to the health of human populations. (To determine whether the public health impact of an event is serious, please see Annex 2, Question 1);

SUGGESTED NEW DEFINITION: “quarantine” means separation or restriction of activities of well persons who are not ill but who are believed to have been exposed to a communicable disease and are therefore at high risk of becoming infected;

"recommendation" and "recommended" mean temporary or standing recommendations issued under these Regulations;

"ship" means a seagoing or an inland navigation vessel on an international voyage;

"standing recommendation" means advice issued by WHO pursuant to Article 12 of these Regulations regarding appropriate health measures for routine or periodic application needed for specific ongoing public health risks to prevent or reduce the international spread of disease and minimize interference with international traffic;

"suspect" means a conveyance, container, cargo, goods, baggage or person that is considered by the health authority as having been exposed to a public health risk and is a possible source for further spread of disease;
"temporary recommendation" means the advice issued by WHO pursuant to Article 11 of these Regulations for application on an ad hoc, time-limited, risk-specific basis, as a result of a public health emergency of international concern, to prevent or reduce the international spread of disease and minimize interference with international traffic;

"traveller" means a person undertaking an international voyage;

"vector" means an insect or other animal capable of transmitting a disease subject to these Regulations or to recommendations issued under these Regulations;

2. Unless otherwise specified or determined by the context, reference to these Regulations includes the annexes thereto.

3. The use in these Regulations of one gender shall be considered as including a reference to the other gender, unless the context otherwise requires.

Article 2 Purpose

The purpose of the International Health Regulations (hereinafter the "IHR" or "Regulations") is to provide security against the international spread of disease while avoiding unnecessary interference with international traffic.

Article 3 Communications

1. States shall designate a National IHR Focal Point and provide names and contact details of at least two (2) officials therein. The National IHR Focal Point shall remain accessible at all times by WHO for urgent communications.

2. WHO shall be accessible at all times for urgent communications from the National IHR Focal Point. WHO shall provide health administrations with contact details.

3. For the purposes of these Regulations, each State recognizes the right of WHO to communicate directly with the health administration, through the National IHR Focal Point. Information sent by WHO to the National IHR Focal Point shall be considered as having been sent to the health administration, and any notification or information sent by the National IHR Focal Point to WHO shall be considered as having been sent by the health administration.

4. Any information sent by WHO to the health administration shall be considered as having been sent to the State, and any notification or information sent by the health administration to WHO shall be considered as having been sent by the State.

COMMENT: Article 3.4—National IHR Focal Point issue: The reference to “health administration” in this provision but not the “National IHR Focal Point” is confusing. Doesn’t Article 3.3 set out the National IHR Focal Point and the health administration as one and the same? Why are they mentioned separately? In what situations would the health administration be involved, but not the National IHR Focal Point? This article states that if urgent communication is sent from the WHO Secretariat through the Focal Point, it shall be considered as having been sent to the health administration. However, it does not explicitly require ALL urgent communications to be sent through the Focal Point. Whether this is a requirement needs to be clarified. If it is not a requirement, then what is the role of a National IHR Focal Point? (see also Art. 5.3, 8.2)

PART II – SURVEILLANCE, NOTIFICATION, INFORMATION, VERIFICATION AND RESPONSE
Article 4  Surveillance

1. Each health administration shall develop and maintain the capacity to detect and report in accordance with these Regulations public health risks and events potentially constituting public health emergencies of international concern present in its territory, as specified in Annex 1.

2. In accordance with these Regulations, WHO, through its surveillance activities, shall collect information regarding events and assess their potential to cause international disease spread and possible interference with international traffic.

Article 5  Notification

SUGGESTED NEW LANGUAGE: 1. Health administrations shall notify WHO by the most rapid means of communications available, through the National IHR Focal Point, of all events potentially constituting a public health emergency of international concern within their territories according to the decision instrument contained in Annex 2, as well as any public health measure implemented in response to those events. The Health Administration shall use the decision instrument contained in Annex 2 PART A and the disease list contained in Annex 2 PART B to determine a public health emergency of international concern. The Health Administration shall immediately notify WHO through the national IHR Focal Point of all events within their territories that potentially constitute public health emergency of international concern, as well as public health measures implemented in response to those events.

2. WHO shall retain notifications under this article and other information provided to it under Article 6 for its use for verification and other purposes under these Regulations and not make it publicly available, until such time as:

(a) the event is determined to be a public health emergency of international concern in accordance with Article 9;

(b) the notifying or consulting health administration agrees to the public availability of the information;

(c) information evidencing the international spread of the infection or contamination has been confirmed by WHO in accordance with established epidemiological principles;

(d) there is evidence that:

(i) control measures against the international spread are unlikely to succeed because of the nature of the contamination, disease agent or vector; or

(ii) the health administration lacks the operational capacity to carry out necessary measures to prevent further spread of disease; or

(e) the nature and scope of the international movement of travellers, conveyances, containers, cargo or goods that may be affected by the infection or contamination requires the immediate application of international control measures.

COMMENT: Article 5.2—Did WHO intend to make ALL of the listed provisions (a-e) requirements for making information publicly available, or does the fulfillment of any of the 5 suffice? In other words, should there be an “and” or an “or” after each provision?
3. Following a notification, the health administration shall continue to communicate to WHO timely, accurate and sufficiently detailed epidemiological information, including: case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed.

**COMMENT:** Article 5.3—National IHR Focal Point issue: This provision states that WHO shall communicate with the health administration, but does not mention the IHR Focal Point. The text should clarify communication procedures, e.g. that communication shall take place through the IHR Focal Point—if not, then why not? (see also Art. 3.4, 8.2)

**Article 6 Consultation**

In the case of events occurring within its territory not requiring notification as provided in Article 5, in particular those events for which there is insufficient information available to complete the decision instrument, health administrations may nevertheless keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate measures. Such communications shall be treated in accordance with paragraph 2 of Article 5.

**Article 7 Information**

1. WHO may take into account reports from sources other than notifications or consultations and validate these reports in accordance with the verification procedures set forth in Article 8.

2. Health administrations shall immediately inform WHO no later than _____ after receipt/ [e.g. 48 hours] of evidence of a public health risk in another State that may cause international disease spread, as manifested by:

   (a) exported or imported cases or suspects related to a possible public health emergency of international concern; or

   (b) vectors which carry infection or contamination.

**NEW LANGUAGE:** 3. Subject to paragraph 2 of Article 5, WHO shall send to all health administrations as soon as possible and by the most efficient means available within ____ of verification [e.g. 48 hours], relevant public health information which it has received under Articles 4 to 8 inclusive.

**NEW LANGUAGE:** 4. States shall inform WHO of health measures they implement that significantly interfere with international traffic and which they are applying based on an unnotified event with potential for international spread of disease that is occurring in an area not covered by a temporary or standing recommendation. Significant interference with international traffic means refusal of entry or departure or delaying entry or departure for more than 24 hours, for ____ travellers and conveyances and ____ travellers (e.g. more than 13 travellers).

**COMMENT:** Article 7.4—We believe that the edit proposed above clarifies the drafters’ intent. We seek clarification that that is indeed the case.

**Article 8 Verification**

**NEW LANGUAGE:** 1. In accordance with these Regulations, WHO, in consultation with the health administration of the State concerned, shall verify rumors of public health risks unsubstantiated reports of events, including those based on media accounts, which may
involve or result in international spread of disease and/or possible interference with international traffic subject to these Regulations.

2. Each health administration, when requested by WHO, shall verify as rapidly as possible, and provide information on, the status of public health risks occurring in its territory. Each health administration shall continue to communicate to WHO such information, including relevant information as described in paragraph 3 of Article 5.

COMMENT: Article 8.2—National IHR Focal Point issue: Not clear as to whether communication should be through the Focal Point. Clarify whether health administration should contact WHO through its Focal Point. (see also Art. 3.4, 5.3)

3. When WHO, through its surveillance activities, detects evidence of a possible public health emergency of international concern:

(a) WHO shall contact the health administration in whose territory the alleged event occurred or is occurring and request information thereon, which the health administration shall promptly provide;

NEW LANGUAGE: (b) the health administration in whose territory the alleged event occurred or is occurring shall collaborate with WHO in assessing the potential for international disease spread and possible interference with international traffic and the adequacy of control measures and, when necessary, in conducting on-the-spot studies by a team sent by WHO, with the purpose of ensuring that appropriate control measures are being employed.

COMMENT: This language gives the WHO Secretariat the authority to send WHO teams into a country - in the absence of a Member State's request - to conduct on-the-spot studies of the severity of a threat or the adequacy of a Member State's control measures to address a potential threat. We are concerned that any provision that purports to authorize the WHO Secretariat to conduct on-the-spot studies in a Member State in the absence of a Member State's request is an infringement on that Member State's sovereign prerogatives.

Article 9 Determination of a public health emergency of international concern

SUGGESTED NEW LANGUAGE: 1. WHO, in consultation with the health administration of the State concerned, shall determine whether an event constitutes a public health emergency of international concern in accordance with Annex 2 and Annex 3.

2. Where WHO determines that a public health emergency of international concern is occurring, it shall, in accordance with Annex 3:

(a) inform health administrations of the occurrence of the public health emergency of international concern and of the control measures taken by the health administration concerned; and

(b) make appropriate temporary recommendations.

SUGGESTED NEW LANGUAGE: In addition, WHO may make such information and recommendations available to other Member States and the general public.

SUGGESTED NEW LANGUAGE: 3. WHO, in consultation with the health administration of the State concerned, shall inform health administrations when it determines that a public health emergency of international concern has ended. The determination as to whether a
**Article 10 Response**

1. Health administrations shall develop and maintain the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern as set out in Annex 1.

2. At the request of a health administration of a State experiencing a public health emergency of international concern, WHO shall collaborate in the response by providing technical guidance and assistance and by verifying the effectiveness of the control and containment measures in place, including the mobilization of on-site teams of experts, if appropriate.

**SUGGESTED NEW LANGUAGE:** 3. In the absence of such a request, WHO may offer assistance to the health administration of a State in responding to the public health emergency of international concern, and the health administration shall collaborate with WHO in assessing the severity of the threat and the adequacy of control measures. If necessary, in conducting on-the-spot studies by a team sent by WHO, with the purpose of ensuring that appropriate control measures are being employed.

**COMMENT:** This language gives the WHO Secretariat the authority to require that Member States collaborate with WHO teams sent into a country - in the absence of a Member State's request - to conduct on-the-spot studies of the severity of a threat or the adequacy of a Member State's control measures to address a potential threat. We are concerned that any provision that purports to authorize the WHO Secretariat to conduct on-the-spot studies in a Member State in the absence of a Member State's request and/or requires that a Member State "collaborate with WHO in assessing the severity of the threat" in-country, in the absence of an invitation to the WHO, is an infringement on that Member State's sovereign prerogatives.

4. WHO shall provide appropriate guidance and assistance to other States impacted by the public health emergency of international concern.

**PART III – RECOMMENDATIONS**

**Article 11 Temporary Recommendations**

**SUGGESTED NEW LANGUAGE:** 1. If WHO, in consultation with the health administration of the State concerned, determines that a public health emergency of international concern is occurring, it shall make temporary recommendations in accordance with Annex 3, which may include health measures to be implemented by the State experiencing the public health emergency of international concern, or by other States, regarding conveyances, containers, cargo, goods, baggage and/or persons to prevent or reduce the international spread of disease and minimize interference with international traffic. WHO may, in accordance with Annex 3, modify or terminate its temporary recommendations, as appropriate, and may make such recommendations after it has determined that a public health emergency of international concern has ended, for the purpose of preventing or promptly detecting its re-occurrence.
2. WHO may make temporary recommendations concerning the application of measures by conveyance operators. WHO shall inform conveyance operators, through the relevant international agencies responsible for disseminating such information, of applicable temporary recommendations, including their modifications or termination.

Article 12 Standing recommendations

WHO may make standing recommendations of appropriate health measures in accordance with Annex 10 for routine or periodic application, which may be applied by States regarding conveyances, containers, goods, baggage and/or persons for specific, ongoing public health risks to prevent or reduce the international spread of disease and minimize interference with international traffic. WHO may, in accordance with Annex 10, modify or terminate such recommendations, as appropriate.

PART IV – POINTS OF ENTRY

Article 13 Health Administration

Each health administration shall, in addition to the other obligations provided for under these Regulations:

(a) ensure that points of entry develop and maintain the capacities set forth in Annex 1;

(b) designate the health authority responsible for each point of entry in its territory. Agencies designated to act for the health authority shall be considered the health authority within the scope of their designation for the purposes of the Regulations;

SUGGESTED NEW LANGUAGE: (c) furnish, at the request of WHO, relevant data on the extent to which its points of entry are kept free from sources of infection or contamination, including vectors, that have the potential to cause the international spread of disease or significantly interfere with international traffic.

Article 14 Airports and ports

SUGGESTED NEW LANGUAGE: 1. States shall designate the airports and ports that shall develop and maintain the capacities provided in Annex 1. Each health administration shall inform WHO of any changes which may occur to the status of the designated airports and ports.

2. Each health authority shall ensure that Ship Sanitation Control Exemption Certificates and Ship Sanitation Control Certificates are issued in accordance with the requirements and the model provided in Annex 4.

3. Each health administration shall send to WHO a list of ports authorized to offer:

(a) the issuance of Ship Sanitation Control Certificates and the provision of the services referred to in Annexes 1 and 4, in particular disinfection and decontamination services, including the control of vectors found on board; or

(b) the issuance of Ship Sanitation Control Exemption Certificates only.

Each health administration shall inform WHO of any changes which may occur to the status of the listed ports.

4. WHO shall publish the information received under this Article.
5. WHO shall, at the request of the health administration concerned, arrange to certify, after an appropriate investigation, that an airport or port in its territory meets the requirements referred to in paragraphs 1 and 3 of this Article. These certifications may be subject to periodic review by WHO in cooperation with the health administration.

**COMMENT:** Article 14.5 provides for WHO to investigate and, if warranted, certify that an airport or port meets the requirements of paragraphs 1 and 3 of Article 14. What are the implications of a health administration’s foregoing a request for certification? Does that mean that the airports and ports it designates under paragraph 1 and the list it sends to WHO under paragraph 3 are not recognized? If not, what is the rationale for having two categories of airports and ports - those that are certified by WHO and those that are not – if both categories otherwise will be treated similarly for purposes of these regulations?

**Article 15  Ground crossings**

**SUGGESTED NEW LANGUAGE:** Whenever the volume of international traffic is sufficiently large, health administrations shall designate ground crossings that shall within the territories of their respective States with the ability to develop and maintain the capacities provided in Annex 1.

**COMMENT:** Should this Article include a more concrete, volume-specific term than “sufficiently large/important”?

**Article 16  Health authority**

1. Health authorities shall be responsible for monitoring conveyances, containers, cargo, goods and baggage departing and arriving from affected areas, to ensure, insofar as possible, that they are maintained in such a condition that they are free of sources of infection or contamination, including vectors.

**SUGGESTED NEW LANGUAGE:** 2. The health authority shall ensure, insofar as possible, that facilities used by travellers at points of entry are maintained in a sanitary condition and are kept free of sources of infection or contamination, including vectors, that have the potential to cause the international spread of disease or interfere with international traffic.

3. The health authority shall be responsible for the supervision of any disinfection or decontamination of conveyances, containers, goods, baggage or persons, as required under these Regulations.

4. The health authority shall be responsible for the supervision of the removal and safe disposal of any contaminated water or food, human dejecta, waste water and any other contaminated matter from a conveyance.

5. Health authorities shall take all practicable measures consistent with these Regulations to monitor and control the discharge by ships of sewage, refuse, ballast water and other potentially disease-causing matter which might contaminate the waters of a port, river or canal.

**SUGGESTED NEW LANGUAGE:** 6. Measures recommended by WHO for conveyances, containers, goods, baggage or travellers arriving from an affected area may be re-applied by health authorities in the arriving State, if there is substantial evidence available to the health authority such health authorities have reason to believe that the measures applied on departure from the affected area were unsuccessful, or that new measures are otherwise warranted.
PART V – PUBLIC HEALTH MEASURES

Chapter I – General provisions

Article 17

Subject to applicable international agreements and Articles 33 and 36 of these Regulations, the health authority may for public health purposes:

(a) with regard to travellers on arrival or departure:

(i) require information concerning the traveller's destination so that he may be contacted for public health purposes;

(ii) require information concerning the traveller's itinerary in or near an affected area or other possible contacts with infection or contamination prior to arrival, as well as review the traveller's health documents if they are required under these Regulations;

SUGGESTED NEW LANGUAGE: (iii) require a non-invasive medical examination, which shall be the minimum necessary to achieve the public health purpose;

(b) require on arrival or departure inspection of conveyances, containers, cargo, goods and baggage on arrival.

Chapter II – Special provisions for conveyances and conveyance operators

Article 18 General provisions

1. Health authorities shall take all practicable measures consistent with these Regulations to ensure that conveyance operators comply with the measures recommended by WHO and adopted by health administrations.

2. Health authorities shall take all practicable measures consistent with these Regulations to ensure that conveyance operators inform travellers of the measures recommended by WHO and adopted by health administrations for application on board.

3. Health authorities shall take all practicable measures consistent with these Regulations to ensure that conveyance operators permanently keep conveyances for which they are responsible in such a condition that they are free of sources of infection or contamination, including vectors. The application of measures to control sources of infection or contamination may be required by a health authority if evidence is found on board during an inspection.

4. Specific provisions pertaining to conveyances and conveyance operators under this Article are provided for in Annex 4. Specific measures applicable to conveyances and conveyance operators with regard to vector-borne diseases are provided for in Annex 5.

Article 19 Ships in transit

SUGGESTED NEW LANGUAGE: 1. No health measure shall be applied to a ship not coming from an affected area [explanation for the deletion: if a ship comes from an affected area, it should be sufficient evidence of a public health risk] which passes through a maritime canal or waterway in the territory of a State on its way to a port in the territory of another State, unless based on evidence of a public health risk or authorized pursuant to applicable international agreements. A health authority shall permit any such ship to take on, under its control, fuel, water and
Supplies. Any such ship may take on fuel, water and supplies, under the supervision of
the health authority of the transit State.

**COMMENTS:** Article 19.1—Does the phrase, “under its control” in the original
language (deleted above) reference the health authority’s control, or the ship’s? The
above changes have been made based on the assumption that the “control” was meant to
refer to the health authority.

**SUGGESTED NEW LANGUAGE:** 2. Unless recommended by WHO or authorized
pursuant to applicable international agreements, no health measure shall be applied by a
health authority to any ship which passes through waters within its jurisdiction without
calling at a port or on the coast, unless based on evidence of a public health risk. If there
is evidence of a public health risk, the health administration should consult with WHO
regarding a health measure to be applied to any ship which passes through waters within
its jurisdiction. [explanation for the deletion: We are concerned about the implications
of this Article for a State’s ability to take measures other than those recommended by
WHO or authorized in yet to be defined applicable international agreements. To deny
States the right to take measures that they believe will protect the health of their
nationals or others residing in their territory because they have not been recommended
by WHO, or are not taken pursuant to yet to be defined “applicable international
agreements”, is an unacceptable infringement on the sovereignty of affected States.]

**Article 20** Affected conveyances

**SUGGESTED NEW LANGUAGE:** 1. Without prejudice to Article 17, if evidence of a public
health risk is found or suspected on board a conveyance, the health authority for the point of entry
shall consider the conveyance as affected and may proceed in the following manner:

**COMMENT:** Article 20.1—Presumably the “without prejudice to Article 17” refers to
the “subject to applicable international agreements” proviso in Article 17. If not, could
WHO clarify its significance?

(a) the health authority may disinfect, decontaminate, disinsect or derat the conveyance, as
appropriate, or cause these measures to be carried out under its direction and control;

(b) the health authority may decide in each case the technique employed to secure an adequate
level of control of the public health risk. Where there are methods or procedures advised by WHO,
these should be employed.

2. If the health authority for the point of entry is not equipped to carry out the control measures required
under this Article, the affected conveyance may nevertheless be allowed to depart, subject to the following
conditions:

(a) the evidence found and the control measures required shall be noted in the appropriate
certificate; and

(b) the health authority shall provide the health authority for the next known point of entry with
the information referred to under paragraph (a) above.

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1 Advice regarding methods and procedures for carrying out public health measures for conveyances can be found in "Guide to
Hygiene and Sanitation in Aviation" and the "Guide to Ship Sanitation", published by WHO.
SUGGESTED NEW LANGUAGE: 3. A conveyance that has been considered as suspect shall cease to be regarded as such when:

(a) the measures recommended by WHO have been effectively carried out; or

(b) the health authority is satisfied that there are no conditions on board that could constitute a public health risk.

Article 21  Conveyances at points of entry

SUGGESTED NEW LANGUAGE: 1. Unless otherwise recommended by WHO, or authorized pursuant to applicable international agreements, a conveyance shall normally should not be prevented for public health reasons from calling at any point of entry. If the point of entry is not equipped for applying measures under these Regulations, the conveyance may be ordered to proceed at its own risk to the nearest suitable point of entry convenient to the conveyance, unless the conveyance has an operational problem which would make this diversion unsafe.

COMMENT: Article 21.1—Sovereignty issue: The revision proposed above addresses one of the concerns we outline in our general comments: the need for the IHRs to recognize that there are certain prerogatives that States will want to retain. The provision with the word “shall” instead of “normally should” would prohibit a State from denying a conveyance that it deems a public health concern access to its territory unless such denial is pursuant to a recommendation by WHO or authorized by yet to be defined/identified applicable international agreements. (see also Art. 10.3, 14, 21.2, 22, 23, 24, 26, 34) As discussed in our general comments, we consider such a provision to constitute an inappropriate infringement on a State’s sovereign prerogatives to protect its nationals or others residing within its territory if it wants to take actions that go beyond those prescribed by this provision.

SUGGESTED NEW LANGUAGE: 2. Except in case of an event which may constitute a public health emergency of international concern., or unless otherwise recommended by WHO or authorized under applicable international agreements, a conveyance shall not be refused free pratique by the health authority for a point of entry; in particular it shall not be prevented from embarking or disembarking, discharging or loading cargo or stores, or taking on fuel or water. Health authorities may subject the granting of free pratique to the carrying out of disinfection, decontamination, disinsection or deratting, if a source of infection or contamination is found or suspected on board.

COMMENT: Article 21.2—Sovereignty issue: This provision may not be appropriate insofar as it prohibits a State from denying a conveyance that it deems a public health concern “free pratique” unless such denial is pursuant to a recommendation by WHO or authorized by yet to be defined/identified applicable international agreements. (see also Art. 10.3, 14, 21.1, 22, 23, 24, 26, 34)

3. Whenever practicable and subject to the previous paragraph, health authorities shall provisionally authorize the granting of free pratique by radio or other communication means to a conveyance on the basis of information received from the conveyance prior to its arrival.

SUGGESTED NEW LANGUAGE: 4. Officers in command of ships or aircraft, or their agents, shall make known to the port or airport control as long as possible before arrival at the port or airport of destination any cases of illness on board as soon as possible before arrival at the port or airport and as soon thereafter as such cases develop or are made known. This information must be immediately provided to the health authority for the port or airport.
5. The following shall apply if a suspect or affected aircraft, for reasons beyond the control of the pilot in command or its agent, lands elsewhere than at the airport at which the aircraft was due to land:

(a) the pilot in command or the agent of the aircraft shall make every effort to communicate without delay with the nearest health authority or any other public authority;

(b) as soon as the health authority has been informed of the landing it may apply measures recommended by WHO or other measures referred to in Article 22.1;

(c) unless required for emergency purposes or for communication, no traveller on board the aircraft shall leave its vicinity and no cargo shall be removed from that vicinity, unless authorized by the health authority or other public authority;

(d) when all measures required by the health authority have been completed, the aircraft may, so far as health measures are concerned, proceed either to the airport at which it was due to land, or, if for technical reasons it cannot do so, to a conveniently situated airport.

6. Notwithstanding the provisions contained in this Article, the officers in command of a ship or aircraft may take such emergency measures as may be necessary for the health and safety of travelers on board.

**Chapter III – Special provisions for persons**

**Article 22 Surveillance of travellers**

**SUGGESTED NEW LANGUAGE:** 1. A suspect traveller who on arrival is placed under surveillance may be allowed to continue his voyage, if, in the opinion of the health authority, the traveller does not pose an immediate public health risk and the health authority at the airport or port of destination is informed of his arrival. On arrival, the traveller shall report to that health authority.

**COMMENT:** Article 22.1—This is a sovereignty issue: Implicit in this provision is the right of a State to deny a suspect traveler who is placed under surveillance the right to continue his/her voyage if the traveler does not pose an immediate public health risk. Article 38 of these draft IHRs provides that “Persons enjoying diplomatic status shall not be exempt from the provisions of the Regulations or recommendations made under these Regulations.” Article 22 and Article 38 if read together could authorize the detention of or impediment of travel by diplomats. If so, this could create problems under agreements governing the privileges and immunities of diplomats including, for example, the Vienna Convention on Diplomatic Relations and various host country agreements. Would appreciate clarification from the drafters as to whether this is indeed the intent. If not, this provision and/or Article 38 should be revised to make clear that the IHRs are not attempting to interfere with privileges and immunities enjoyed by diplomats under relevant agreements. (see also Art. 10.3, 14, 21.1, 21.2, 23, 24, 26, 34)

**Article 23 Medical examination, vaccination or other prophylaxis**

**SUGGESTED NEW LANGUAGE:** 1. Unless recommended by WHO or otherwise provided in these Regulations, medical examination, vaccination or other prophylaxis shall not be required as a condition of admission of any traveller to a State, except for travellers and those seeking temporary or permanent residence. Travelers may be required as a condition of admission to a State to undergo a medical examination, vaccination or other prophylaxis when necessary to determine whether a public health risk exists or when recommended by WHO or otherwise provided in these Regulations.
2. Persons to be vaccinated or offered prophylaxis pursuant to these Regulations shall be informed of any risk associated with vaccination or with non-vaccination and with the use or non-use of prophylaxis. The health administration shall inform medical practitioners of this requirement.

Chapter IV – Special provisions for goods, containers and container loading areas

Article 24  Goods in transit

SUGGESTED NEW LANGUAGE: Without prejudice to the rights of states to impose measures to protect the public health and subject to Article 16, goods, other than live animals, in transit without transhipment, shall not be subject to measures under these Regulations or detained for public health reasons, except in case of an event which may constitute a public health emergency of international concern or unless when recommended by WHO or authorized pursuant to applicable international agreements.

COMMENT: WHO should clarify the intent of this provision. We seek clarification as to the relationship between Article 16 and what is being provided for under Article 24 (i.e., the implications of making Article 24, subject to Article 16).

COMMENT: This is a sovereignty issue: Article 24 prohibits Member State’s from detaining goods at point of entry without a recommendation from WHO. This conflicts with laws of Member States that provide for detention of products based on public health reasons. Under some circumstances, detention of adulterated products is necessary to prevent the distribution of product that could cause food borne illness. Member States should not be required to wait for a recommendation from WHO before taking such an action. (see also Art. 10.3, 14, 21.1, 21.2, 22, 23, 26, 34)

Article 25  Container and container loading areas

SUGGESTED NEW LANGUAGE: 1. Insofar as possible, containers used in international traffic shall be kept free of infection or contamination, including vectors, particularly during the course of packing.

SUGGESTED NEW LANGUAGE: 2. Insofar as possible, container loading areas shall be kept free from sources of infection or contamination.

SUGGESTED NEW LANGUAGE: 3. Whenever the volume of international traffic is sufficiently important large, health authorities shall take all practicable measures consistent with these Regulations, including carrying out inspections, to assess the sanitary condition of suspect container loading areas and containers, to ensure that the obligations contained in these Regulations are implemented.

COMMENT: Article 25.3—Should this provision include a more concrete, volume-specific term than “sufficiently large/important”?

PART VI – HEALTH DOCUMENTS

Article 26  General provisions

SUGGESTED NEW LANGUAGE: No health documents, other than those provided for under these Regulations, or in recommendations issued by WHO, shall be required in international traffic, except when necessary to determine when a public health risk exists provided however that this Article shall not apply to persons seeking temporary or permanent residence, nor
shall it apply to routine document requirements concerning or to ascertain the public health status of goods or cargo in international trade pursuant to applicable international agreements.

**Article 27  Certificates of vaccination or other prophylaxis**

1. Vaccines and prophylaxis for travellers administered pursuant to these Regulations or recommendations, and certificates relating thereto, shall conform to the provisions of Annex 6 and, when applicable, Annex 7 with regard to specific diseases.

**SUGGESTED NEW LANGUAGE:**

2. Unless recommended by WHO, a traveller in possession of a certificate of vaccination or other prophylaxis issued in conformity with Annex 6 and, when applicable, Annex 7 shall not be denied entry as a consequence of the disease to which the certificate refers, even if coming from an affected area, unless the health authority has reason to believe that the vaccination or other prophylaxis was not effective.

**Article 28  Maritime Declaration of Health**

1. The master of a ship, before arrival at its first port of call in a territory, shall ascertain the state of health on board, and, except when a health administration does not require it, the master shall, on arrival, complete and deliver to the health authority for that port a Maritime Declaration of Health which shall be countersigned by the ship's surgeon, if one is carried.

2. The master of a ship, or the ship's surgeon if one is carried, shall supply any information required by the health authority as to health conditions on board during the voyage.

3. A Maritime Declaration of Health shall conform with the model specified in Annex 8.

4. A health administration may decide:

   (a) to dispense with the submission of the Maritime Declaration of Health by all arriving ships; or

   (b) to require it under a recommendation concerning ships arriving from affected areas or to require it from ships which might otherwise carry infection or contamination.

The health administration shall inform shipping operators or their agents of these requirements.

**Article 29  Health Part of the Aircraft General Declaration**

**SUGGESTED NEW LANGUAGE:**

1. The pilot in command of an aircraft or his agent, in flight, orally, or upon landing at the first airport in a territory, shall, except when a health administration does not require it, complete and deliver to the health authority for that airport the Health Part of the Aircraft General Declaration which shall conform with the model specified in Annex 9.

2. The pilot in command of an aircraft or his agent, shall supply any information required by the health authority as to health conditions on board during the voyage and any health measure applied to the aircraft.

**COMMENT:** Article 29.2—Does the requirement for the pilot in command of an aircraft to report “any health measure applied” on board refer to measures applied under the IHRs, or any health measure at all, including the provision of first aid, drugs, defibrillation, etc.? This needs to be clarified, preferably to refer only to measures related to the IHRs.

3. A health administration may decide:
(a) to dispense with the submission of the Health Part of the Aircraft General Declaration by all arriving aircraft; or

(b) to require it under a recommendation concerning aircraft arriving from affected areas or to require it from aircraft that might otherwise carry infection or contamination.

The health administration shall inform aircraft operators or their agents of these requirements.

Article 30 Bills of health

SUGGESTED NEW LANGUAGE: Bills of health, with or without consular visa, or any certificate, however designated, concerning health conditions of a previous point of entry, shall not be routinely required from any conveyance.

PART VII – CHARGES

Article 31 Charges for medical examination, vaccination or other prophylaxis

SUGGESTED NEW LANGUAGE: 1. Except for travellers seeking temporary or permanent residence, no charges other than those based on the actual cost to the health authority or fair market value (if actual cost cannot be determined) shall be made by a health authority for:

(a) any medical examination provided for in these Regulations, or any supplementary examination, micro-biological or otherwise, which may be required by the health authority to ascertain the state of health of the traveller examined; or

(b) any vaccination or other prophylaxis provided to a traveller on arrival, and any certificate thereof required by the health administration.

2. The provisions of Article 31 are without prejudice to the rights of private entities to charge for health services or to the rights of the health authority to require reimbursement for payments made to private entities for health services on behalf of travelers.

COMMENT: The United States Government agrees and supports the concept that travelers should not be charged unreasonably by health authorities for medical examinations and other services provided under the Regulations. Notwithstanding, health authorities should be able to recoup their expenses based on actual costs to the health authority or the fair market value of services provided to travelers, if actual costs cannot be determined.

Article 32 Certificates on measures applied to travellers and their baggage

SUGGESTED NEW LANGUAGE: A health authority shall, when so requested, after applying measures pursuant to these Regulations to travellers and their baggage, issue free of charge to any traveller a certificate specifying the date of his arrival or departure and the health measures applied.

PART VIII – GENERAL PROVISIONS

Article 33 General provisions
1. Measures taken pursuant to these Regulations shall be initiated forthwith, completed without delay, and applied without discrimination.

2. Health administrations shall facilitate the efficient and effective implementation of WHO's verification and response activities under these Regulations.

**Article 34 Excessive measures**

**SUGGESTED NEW LANGUAGE:** States should make every effort not to impose measures exceeding those **reasonably necessary to accomplish the public health objective or otherwise** recommended by WHO under these Regulations.

COMMENT: Article 34—Sovereignty issue: What if States want to impose measures different from those in the WHO regulations? What if a country has a higher or lower appropriate level of protection? We believe the edits made above (adding "reasonably necessary...") resolve these sovereignty concerns (see also Art. 10.3, 14, 21.1, 21.2, 22, 23, 24, 26)

**Article 35 Cessation or full implementation of measures**

1. WHO may request the cessation of measures applied by States in excess of the measures it has recommended, or of inappropriate measures.

2. In cases where recommended measures are not fully implemented by States, WHO may request the full implementation of these measures.

**Article 36 Rights of persons**

1. These Regulations are without prejudice to rights persons may have under applicable international agreements which provide for, or protect, the rights of persons.

**SUGGESTED NEW LANGUAGE:** 2. Without prejudice to the rights of States to impose quarantine and isolation measures, or other measures to respond to a public health emergency of international concern, no invasive medical examination, vaccination or prophylaxis under these Regulations shall be carried out on travellers without their prior express informed consent.

**Article 37 Migrants, nomads, seasonal workers or persons taking part in periodic mass congregations**

1. Migrants, nomads, seasonal workers or persons taking part in periodic mass congregations may be subjected to additional health measures conforming with the laws and regulations of each State concerned, and with any agreement concluded between any such States.

2. The standards of hygiene on conveyances carrying persons taking part in periodic mass congregations shall not be inferior to those applicable under these Regulations.

3. WHO may make recommendations for the persons and conveyances referred to in this Article.

**Article 38 Persons enjoying diplomatic status**

Persons enjoying diplomatic status shall not be exempt from the provisions of the Regulations or recommendations made under the Regulations.

COMMENT: Article 38—Sovereignty issue: Article 22 and Article 38 if read together could authorize the detention or impediment of travel of diplomats. If so, this could
create problems under agreements that govern the privileges and immunities of diplomats, including, for example, the Vienna Convention on Diplomatic Relations and various host country agreements. We seek clarification from the drafters as to whether this is indeed the intent. If not, this provision and/or Article 38 should be revised to make clear that the IHRs are not attempting to interfere with privileges and immunities enjoyed by diplomats under relevant agreements. (see also Art. 10.3, 21.1, 21.2, 22, 23, 24, 26, 34)

_SUGGESTED NEW LANGUAGE:_ Without prejudice to the rights of States to impose restrictions on the transfer of biologic materials, including cultures and specimens, for purposes of health, safety, security, or other reasons, health administrations shall expedite the transport, entry and processing of laboratory specimens, reagents and other diagnostic tools as requested by WHO for verification and response purposes under these Regulations.

_SUGGESTED NEW LANGUAGE:_ Health administrations shall develop and maintain effective infection control practices, especially in health care settings and provide guidance to others who have such responsibilities regarding the development and maintenance of effective infection-control practices, in those settings.

COMMENT: Article 40—To what health care settings does Article 40 apply?

_SUGGESTED NEW LANGUAGE:_ In the context of a suspected intentional release of a biological, chemical or radionuclear agent, States shall immediately provide to WHO all relevant public health information, materials and samples, for verification and response purposes. Public health emergencies of international concern that are suspected or confirmed to be the result of an intentional act should be immediately reported to WHO by the State(s) where the event occurs or where affected persons are identified. If requested by the affected Member State(s), WHO will provide consultative and technical assistance, as would be the case in the event of a naturally occurring public health emergency of international concern. In situations where States do not request WHO assistance, the State shall keep WHO apprised in a timely manner of the steps taken to mitigate the effects of the intentional release and to prevent further spread of those effects internationally. [NOTE: Language of Annex 2 may need to be modified to coordinate with any new language for Article 41]

COMMENT: Article 41—Note the concerns listed under Annex 2 regarding possible areas in the decision algorithm where States might avoid reporting suspected intentional releases.

_SUGGESTED NEW LANGUAGE:_ Special treaties or arrangements may be concluded between two or more States having certain interests in common owing to their health, geographical, social or economic conditions, in order to facilitate the application of these Regulations, and in particular with regard to:

(a) the direct and rapid exchange of public health information between neighbouring territories;
(b) the health measures to be applied to international coastal traffic and to international traffic on inland waterways, including lakes;

(c) the health measures to be applied in contiguous territories at their common frontier;

(d) the combination of two or more territories into one territory for the purposes of any of the health measures to be applied in accordance with these Regulations;

(e) arrangements for carrying affected persons by means of transport specially adapted for the purpose; and

(f) disinfection, decontamination or other treatment designed to render merchandise free of disease-causing agents.

2. The treaties or arrangements referred to in paragraph 1 of this Article shall not be in conflict with the provisions of these Regulations.

3. States shall inform WHO of any such treaty or arrangement which they may conclude. WHO shall send immediately to all health administrations information concerning any such treaty or arrangement.

4. The provisions of this Article shall also apply to decisions taken by regional economic integration organizations constituted by sovereign States, Members of WHO, to which their Member States have transferred competence over matters governed by these Regulations, including the competence to enter into internationally legally binding regulations.

Article 43 Armed forces

States should ensure that military conveyances, containers, cargo and personnel meet the requirements of the Regulations and that the measures recommended by WHO are applied.

PART IX – FINAL PROVISIONS

Article 44 Reporting

1. The Director-General shall report to the World Health Assembly on the functioning of these Regulations and its implementation by States.

2. States shall forward to the Director-General at his request relevant information on issues selected by him for inclusion in the report to the World Health Assembly referred to in paragraph I of this Article.

Article 45 Review

The Director-General shall establish a committee (hereinafter the "Review Committee") which shall carry out the following functions:

(a) review and monitor the functioning of the Regulations, including the annexes;

(b) provide advice with respect to the application or implementation of the Regulations, including the annexes, as well as possible amendments thereof, in accordance with Article 46 of the Regulations;

(c) provide advice to the Director-General with respect to standing recommendations, and any modifications or termination thereof;
(d) advise the World Health Assembly, the Executive Board and the Director-General on any matter referred to it by them;

(e) consider disputes concerning the interpretation or application of the Regulations referred to it by the Director-General under Article 47 of the Regulations.

The Committee shall operate in accordance with the terms of reference and arrangements set out in Annex 10.

COMMENT: Article 45—WHO should list the qualifications for membership on the Review Committee.

Article 46 Amendments and additional annexes

1. Amendments to these Regulations, including its annexes, as well as the adoption of additional annexes, may be proposed by any State to which these Regulations apply or by the Director-General. Such amendments shall, subject to paragraph 2 of this Article, be submitted to the World Health Assembly for adoption.

SUGGESTED NEW LANGUAGE: 2. Amendments to the annexes may, at the request of the proposing State or the Director-General, be submitted to the Review Committee pursuant to Annex 10. If the Review Committee favours adoption of the amendment, the Director-General shall submit it to the Executive Board, which shall make its recommendation to the World Health Assembly for adoption.

3. Amendments to these Regulations and its annexes, as well as additional annexes, adopted pursuant to this Article shall come into force for all States to which these Regulations apply on the same terms, and subject to the same rights and obligations as provided for in Article 22 of the Constitution of WHO and Articles 49-53 of these Regulations.

Article 47 Settlement of disputes

1. Any dispute concerning the interpretation or application of these Regulations may be referred by any State party to such dispute to the Director-General, who shall make every effort to settle it. If such dispute is not thus settled, the Director-General on his own initiative, or at the request of a State party to such dispute, may refer the matter to the Review Committee for its views and advice pursuant to Annex 10.

2. The Review Committee shall forward its views and advice to the States parties to the dispute and the Director-General shall make them publicly available. Such views and advice shall not bind the States parties to the dispute, unless the parties so elect prior to the commencement of the proceedings of the Review Committee and inform it accordingly.

SUGGESTED NEW LANGUAGE: 3. A State may at any time declare in writing that, for a dispute not resolved in accordance with paragraph 1 of this Article, it accepts arbitration as compulsory with regard to all disputes to which it is a party or with regard to a specific dispute. Only States that accept arbitration as compulsory must participate in the arbitration of a dispute. The arbitration shall be conducted in accordance with the Permanent Court of Arbitration Optional Rules for
Arbitrating Disputes between States applicable at the time a request for arbitration is made. The States parties to the dispute shall accept the arbitral award as binding and final.

**SUGGESTED NEW LANGUAGE:** 4. The parties to the dispute resolved in accordance with paragraphs 2 or 3 shall report to the Director-General on the action taken to implement the views and advice of the Review Committee or the arbitral award. The Director-General shall inform the World Health Assembly regarding such actions as appropriate.

*Article 48 Existing conventions, regulations and similar agreements*

1. These Regulations, subject to the provisions of Article 50 and the exceptions hereinafter provided, replace, as between the States bound by these Regulations and as between these States and WHO, the provisions of the following existing International Sanitary Conventions, Regulations and similar agreements:

   (a) International Sanitary Convention, signed in Paris, 3 December 1903;

   (b) Pan American Sanitary Convention, signed in Washington, 14 October 1905;

   (c) International Sanitary Convention, signed in Paris, 17 January 1912;

   (d) International Sanitary Convention, signed in Paris, 21 June 1926;

   (e) International Sanitary Convention for Aerial Navigation, signed at The Hague, 12 April 1933;

   (f) International Agreement for dispensing with Bills of Health, signed in Paris, 22 December 1934;

   (g) International Agreement for dispensing with Consular Visas on Bills of Health, signed in Paris, 22 December 1934;

   (h) Convention modifying the International Sanitary Convention of 21 June 1926, signed in Paris, 31 October 1938;


   (k) Protocol of 23 April 1946 to prolong the International Sanitary Convention, 1944, signed in Washington;

   (l) Protocol of 23 April 1946 to prolong the International Sanitary Convention for Aerial Navigation, 1944, signed in Washington;

   (m) International Sanitary Regulations, 1951, and the Additional Regulations of 1955, 1956, 1960, 1963 and 1965; and


2. The Pan American Sanitary Code, signed at Havana, 14 November 1924, remains in force with the exception of Articles 2, 9, 10, 11, 16 to 53 inclusive, 61 and 62, to which the relevant part of paragraph 1 of this Article shall apply.
Article 49  Period for rejection or reservations

1. The period provided in execution of Article 22 of the Constitution of WHO for rejection or reservation shall be six months from the date of the notification by the Director-General of the adoption of these Regulations by the World Health Assembly.

2. Such period may, by notification to the Director-General, be extended to twelve months with respect to overseas or other outlying territories for whose international relations the State may be responsible.

3. Any rejection or reservation received by the Director-General after the expiry of the periods referred to in paragraph 1 or 2 of this Article shall have no effect.

Article 50  Reservations

1. If any State makes a reservation to these Regulations or to an additional annex, or to an amendment to the Regulations or to an existing annex, such reservation shall not be valid unless it is accepted by the World Health Assembly, and these Regulations or the annex or amendment concerned shall not enter into force with respect to that State until such reservation has been accepted by the Assembly or, if the Assembly objects to it on the grounds that it substantially detracts from the character and purpose of these Regulations, until it has been withdrawn. Any existing conventions, regulations and similar agreements listed in Article 48 to which such State is already a party consequently remain in force as far as such State is concerned.

2. A rejection in part of the Regulations, an annex or an amendment to the Regulations or an annex shall be considered as a reservation.

3. The World Health Assembly may, as a condition of its acceptance of a reservation, request the State making such reservation to undertake that it will continue to fulfill any obligation or obligations corresponding to the subject matter of such reservation, which such State has previously accepted under the existing conventions, regulations and similar agreements listed in Article 48.

4. If a State makes a reservation which in the opinion of the World Health Assembly detracts to an insubstantial extent from an obligation or obligations previously accepted by that State under the existing conventions, regulations and similar agreements listed in Article 48, the Assembly may accept such reservation without requiring as a condition of its acceptance an undertaking of the kind referred to in paragraph 3 of this Article.

Article 51  Withdrawal of rejection or reservation

A rejection, or the whole or part of any reservation, may at any time be withdrawn by notifying the Director-General.

Article 52  Entry into force

1. These Regulations shall enter into force on the first day of June 2006.

COMMENT: Article 52.1—WHO needs to confirm that the entry into force date provided for in this provision does not undercut the six-month period for execution of rejections or reservations provided for in Article 22. How, as a practical matter, can the six-month rejection or reservation period be implemented if the World Health Assembly has to accept a reservation and will not convene within the six-month period following the Assembly to be held in May 2005?

2. Any State which becomes a Member of WHO after the date of the notification by the Director-General referred to in paragraph 1 of Article 49, and which is not already a party hereto, may notify its rejection of, or any reservation to, these Regulations within a period of six months from the date of the notification to it
by the Director-General after becoming a Member of WHO. Unless rejected, these Regulations shall enter into force with respect to that State, subject to the provisions of Article 50, upon expiry of that period.

Article 53 States not Members of WHO

1. Any State not a Member of WHO, which is a party to any conventions, regulations and similar agreements listed in Article 48 or to which the Director-General has notified the adoption of these Regulations by the World Health Assembly, may become a party hereto by notifying its acceptance to the Director-General and, subject to the provisions of Article 50, such acceptance shall become effective upon the date of entry into force of these Regulations, or, if such acceptance is notified after that date, three months after the date of receipt by the Director-General of the notification of acceptance.

2. For the purpose of the application of these Regulations Articles 23, 33, 62, 63 and 64 of the Constitution of WHO shall apply to any State not a Member of WHO which becomes a party to these Regulations.

3. Any State not a Member of WHO which has become a party to these Regulations may at any time withdraw from participation in these Regulations, by means of a notification addressed to the Director-General which shall take effect six months after he has received it. The State which has withdrawn shall, as from that date, resume application of the provisions of any conventions, regulations and similar agreements listed in Article 48 to which it was previously a party.

Article 54 Notifications by the Director-General

The Director-General shall notify all States Members and Associate Members of WHO, and also other parties to any conventions, regulations and similar agreements listed in Article 48 of the adoption by the World Health Assembly of these Regulations. The Director-General shall also notify these States, as well as any other State which has become a party to these Regulations or any additional annex, to any amendment to these Regulations or to any existing annex, of any notification received by WHO under Articles 49, 51, 52 and 53 respectively, as well as of any decision taken by the World Health Assembly under Article 50.

Article 55 Original texts

1. The Arabic, Chinese, English, French, Russian and Spanish texts of these Regulations shall be equally authoritative.

2. The original texts of these Regulations shall be deposited in the archives of WHO. Certified true copies shall be sent by the Director-General to all Members and Associate Members, and also to other parties to one of the conventions, regulations and similar agreements listed in Article 48. Upon the entry into force of these Regulations, certified true copies shall be delivered by the Director-General to the Secretary-General of the United Nations for registration in accordance with Article 102 of the Charter of the United Nations.
ANNEX 1

A. CORE CAPACITY REQUIREMENTS FOR SURVEILLANCE AND RESPONSE

1. At the community level:

The capacities:

(a) To detect events involving illness or death above expected levels for the particular time and place in all areas within the territory of the Health Administration; and

(b) To report all available essential information immediately to the appropriate local health personnel (e.g. emergency room, village health care worker, etc.).

2. At the first and intermediate public health response levels

The capacities:

(a) To verify reported events and to implement preliminary control measures immediately; and

(b) To assess reported events immediately, and if found urgent, to report all essential information to the national level.

3. At the national level

Assessment and notification. The capacities:

(a) To assess all reports of urgent events within 24 hours; and

(b) To notify WHO immediately through the National IHR Focal Point when the assessment indicates the event is notifiable pursuant to Article 5.1 and Annex 2.

Response. The capacities:

(a) To rapidly determine the control measures required to prevent international spread;

(b) To provide support through specialized staff skills, laboratory analysis of samples (domestically or through collaborating centres), and logistical assistance (e.g. equipment, supplies and transport);

(c) To provide on-site assistance as required to supplement local investigations;

(d) To provide a direct operational link with senior health and other officials to rapidly approve and implement containment and control measures;

(e) To provide direct liaison with other key government ministries, such as transport, customs and agriculture;

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1 See generally the following WHO publications: Guideline for the Implementation of Early Warning Systems in Disease Surveillance (in preparation) and Essential Laboratory Functions for Epidemic Alert and Response at National Level (in preparation).

2 Essential information includes the following types of information: clinical descriptions, laboratory results, sources and type of risk, numbers of cases and deaths, conditions affecting the spread of the disease and the health measures employed. Such information is further described in Guideline for the Implementation of Early Warning Systems in Disease Surveillance.

3 Criteria for urgent events include serious public health impact and/or unusual or unexpected nature with high potential for spread.
To provide rapid communications links with hospitals, clinics, airports, ports, laboratories and other key operational areas, for the dissemination of information and recommendations received from WHO regarding events both in countries and inside other countries;

**COMMENT:** How is the “rapid communications” requirement to be applied in countries that might not have highly developed communication capabilities?

(g) To establish, operate and maintain a national public health emergency response plan; and

(h) To provide the foregoing on a 24-hour basis.

**B. CORE CAPACITY REQUIREMENTS FOR DESIGNATED AIRPORTS, PORTS AND GROUND CROSSINGS**

1. **At all times**

The capacities:

(a) To provide access to an organized medical service, located so as to allow the prompt assessment and care of ill travellers, and to adequate staff, equipment and premises;

(b) To provide access to equipment and personnel for the transport of ill travellers to an appropriate medical facility;

(c) To provide trained personnel for the inspection of conveyances;

(d) To conduct regular inspection programmes to ensure a safe environment for travellers using point of entry facilities, including potable water supplies, eating establishments, flight catering facilities, public washrooms, appropriate solid and liquid waste disposal services and other potential risk areas; and

(e) To provide a programme and trained personnel for the control of vectors in and near points of entry.

**COMMENT:** Please clarify what is meant by “near points of entry?” Existing IHRs use a radius of 10 kilometers. Thus, not defining this in the revision would be a departure from current practice.

2. **For responding to possible public health emergencies of international concern**

The capacities:

(a) To provide appropriate public health emergency response, by establishing and maintaining a public health emergency contingency plan, including the nomination of a coordinator and contact points for relevant point of entry, public health and other agencies and services;

**SUGGESTED NEW LANGUAGE:** (b) To provide assessment and care for suspect or affected travellers by establishing arrangements with local medical facilities for their isolation and treatment;

(c) To provide for the isolation of suspect travellers who are not ill, preferably in facilities away from the point of entry;

(d) To provide appropriate space, separate from other travellers, to interview them or other persons who may have been in proximity to a suspect or affected person;
(e) To apply recommended measures to disinfect, decontaminate or otherwise treat conveyances, containers, cargo, goods or baggage;

(f) To apply entry or exit controls for arriving and departing travellers during public health emergencies of international concern; and

(g) To provide access to specially designated equipment, and to trained personnel with appropriate personal protection, for the transfer of travellers who may carry infection or contamination.
ANNEX 2

SUGGESTED NEW LANGUAGE: [call this section: PART A, with PART B being the proposed disease list]

**PART A: DECISION INSTRUMENT FOR STATES TO ASSESS AND NOTIFY EVENTS POTENTIALLY CONSTITUTING A PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN**

Is the public health impact of the event serious?

- Yes
  - Is the event unusual or unexpected?
    - Yes
      - Is there a significant risk of international spread?
        - Yes
          - Is there a risk for international restrictions?
            - Yes
              - Event should be notified to WHO under the International Health Regulations
            - No
              - Not notified at this stage. Reassess if more information becomes available
        - No
          - Event should be notified to WHO under the International Health Regulations
    - No
      - Is there a significant risk of international spread?
        - Yes
          - Is there a risk for international restrictions?
            - Yes
              - Event should be notified to WHO under the International Health Regulations
            - No
              - Not notified at this stage. Reassess if more information becomes available
        - No
          - Event should be notified to WHO under the International Health Regulations
  - No
    - Is the event unusual or unexpected?
      - Yes
        - Is there a significant risk of international spread?
          - Yes
            - Is there a risk for international restrictions?
              - Yes
                - Event should be notified to WHO under the International Health Regulations
              - No
                - Not notified at this stage. Reassess if more information becomes available
          - No
            - Event should be notified to WHO under the International Health Regulations
      - No
        - Event should be notified to WHO under the International Health Regulations
## 1. Is the public health impact of the event serious?

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>Is the number of cases and/or the number of deaths for this type of event large for the given place and time?</td>
</tr>
<tr>
<td>2.</td>
<td>Has the event the potential to have a high public health impact?</td>
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<td></td>
<td><strong>THE FOLLOWING ARE EXAMPLES OF CIRCUMSTANCES THAT CONTRIBUTE TO HIGH PUBLIC HEALTH IMPACT:</strong></td>
</tr>
<tr>
<td></td>
<td>✓ Event caused by a pathogen with high potential to cause epidemic (infectiousness of the agent, high case fatality rate, multiple transmission routes, healthy carrier, possibility of preventing spread with vaccine, drugs or other means).</td>
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<tr>
<td></td>
<td>✓ Indication of treatment failure (new or emerging antibiotic resistance, new strains, vaccine failure, antidote resistance or failure).</td>
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<td></td>
<td>✓ Event represents a significant public health risk even if no or very few human cases have yet been identified.</td>
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<td></td>
<td>✓ Cases reported amongst health staff.</td>
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<td>✓ The population at risk is especially vulnerable (refugees, low level of immunization, children, elderly, low immunity, undernourished, etc).</td>
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<td>✓ Concomitant factors that may hinder or delay the response (natural catastrophes, armed conflicts, unfavourable weather conditions, multiple foci in the country).</td>
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<tr>
<td></td>
<td>✓ Event in an area with high population density.</td>
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<tr>
<td></td>
<td>✓ Release into the environment of a chemical or radiological agent that has contaminated or has the potential to contaminate a population and/or a large geographical area.</td>
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</tbody>
</table>

3. Is external assistance needed to detect, investigate, respond and control the current event, or prevent new cases?  

**THE FOLLOWING ARE EXAMPLES OF WHEN ASSISTANCE MAY BE REQUIRED:**  
 ✓ Inadequate human, financial, material or technical resources – in particular:  
   - Insufficient laboratory or epidemiological capacity to investigate the event (equipment, personnel, financial resources)  
   - Insufficient antidotes, drugs and/or vaccine and/or protective equipment, decontamination equipment, or supportive equipment to cover estimated needs  
   - Existing surveillance system is inadequate to detect new cases

### IS THE PUBLIC HEALTH IMPACT OF THE EVENT SERIOUS?  
**Answer “yes” if you have answered “yes” to 1, 2 or 3 above.**
### 2. Is the event unusual or unexpected?

<p>| | |</p>
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</table>
| 4. | Is the event unusual?  
**THE FOLLOWING ARE EXAMPLES OF UNUSUAL EVENTS:**  
✓ The event is caused by an unknown agent (biological, chemical or nuclear) or the source, vehicle, route of transmission is unusual or unknown.  
✓ Evolution of cases more severe than expected (including case-fatality rates) or with unusual symptoms.  
✓ Occurrence of the event itself unusual for the area or season. |
| 5. | Is the event unexpected?  
**THE FOLLOWING ARE EXAMPLES OF UNEXPECTED EVENTS:**  
✓ Event caused by a disease/agent that had already been eliminated or eradicated from the country or not previously reported, or chemical that has been nationally/internationally banned or restricted.  
✓ Is the event known or suspected to be the result of an intentional or accidental release of chemical, radiological or biological agent. |

**IS THE EVENT UNUSUAL OR UNEXPECTED?**  
*Answer “yes” if you have answered “yes” to 4 or 5 above.*

### 3. Is there a significant risk of international spread?

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<tbody>
<tr>
<td>6.</td>
<td>Is there evidence of an epidemiological link to similar events in other countries?</td>
</tr>
</tbody>
</table>
| 7. | Is there any factor that should alert us to the potential for cross border movement of the agent, vehicle or host?  
**THE FOLLOWING ARE EXAMPLES OF CIRCUMSTANCES THAT MAY PREDISPOSE TO INTERNATIONAL SPREAD:**  
✓ Where there is evidence of local spread, an index case (or other linked cases):  
  - with history of international travel within the previous month (or time equivalent to the incubation period if the pathogen is known) or  
  - with history of participation in an international gathering (pilgrimage, sports event, conferences, etc.) or  
  - with close contact with an international traveller or a highly mobile population.  
✓ Event caused by release into the environment e.g. air, water, that has the potential to spread across international borders.  
✓ Event in an area of intense international traffic with limited capacity for sanitary control or environmental detection or decontamination. |

**IS THERE A SIGNIFICANT RISK OF INTERNATIONAL SPREAD?**  
*Answer “yes” if you have answered “yes” to 6 or 7 above.*
<table>
<thead>
<tr>
<th>Risk of international restrictions?</th>
<th>4. Is there a significant risk of travel or trade restrictions?</th>
</tr>
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<tbody>
<tr>
<td>8.</td>
<td>Have similar events in the past resulted in international restriction on trade and/or travel against the affected country?</td>
</tr>
<tr>
<td>9.</td>
<td>Is the source suspected or known to be a food product, water or any other goods that might be contaminated that has been exported/imported to/from other countries?</td>
</tr>
<tr>
<td>10.</td>
<td>Has the event occurred in association with an international gathering or in an area of intense international tourism?</td>
</tr>
<tr>
<td>11.</td>
<td>Has the event caused requests for more information by foreign officials or international media?</td>
</tr>
</tbody>
</table>

**IS THERE A SIGNIFICANT RISK FOR INTERNATIONAL TRADE OR TRAVEL RESTRICTIONS?**

*Answer “yes” if you have answered “yes” to 8, 9, 10 or 11 above.*

*Answering Yes to any 2 of the 4 main questions above will result in a notification under the revised International Health Regulations.*
SUGGESTED NEW LANGUAGE FOR ANNEX 2 PART B:
PART B: LIST OF DISEASES THAT SHOULD BE REPORTED IN ALL CIRCUMSTANCES

The following diseases should be reported in all circumstances:

- Anthrax
- Botulism
- Cholera
- Influenza caused by non-human subtypes with pandemic potential A (H4-15)
- Nipah Viruses
- Plague (pneumonic)
- Polio
- SARS
- Smallpox
- Tularemia
- Viral hemorrhagic fevers (Lassa, Marburg, Ebola, Crimean-Congo, South American, and others not yet isolated or named)
- Yellow Fever

NOTE: The diseases listed above are included because they fall within one or more of the following categories. However, not all diseases that fall into these categories are included in the list.

- Communicable diseases that can be spread through the droplet or aerosol route and have life-threatening or severe consequences;
- Selected communicable diseases among those eradicated or targeted for eradication by the WHO;
- Communicable diseases without an effective control strategy or for which isolation is deemed an essential part of the control strategy, which are transmitted easily from person to person and which, if spread in the population, would have severe public health consequences, including potentially high case fatality rates;
- Selected vector-borne diseases that can be translocated to non-endemic countries with compatible vectors;
- Selected zoonotic diseases that occur in humans and which pose a potential public health risk to human populations.

This list will be reviewed on a periodic basis for relevance and currency by the “IHR Advisory Panel” to be convened by the WHO Director-General as outlined in Annex 3. The World Health Assembly will consider any changes to the list, as recommended by
the Executive Board. Changes will be made only through the adoption of a resolution or decision by the World Health Assembly.

**COMMENT:** Annex 2 Part A might be revised to ensure reporting of suspected intentional release. As it is drafted right now, there are two questions in the algorithm that are vague enough for a Member State to not report an intentional release:

1) **Question 1:** "Is the public health impact of the event serious?" The concern is with intentional releases of agents that do not bring about mass casualties or are easily contained (not a serious threat to international spread; i.e., 2001 anthrax attacks). It appears that the closest question that would force a "yes" answer out of this is on page 29, "Event represents a significant public health risk even if no or very few human cases have yet been identified." Then again, "significant public health risk" is vague. The point is that there is nothing in this first question that compels reporting of an intentional release unless a State judges that the answer to this question is yes and would thereby be compelled to report per Question 2, which explicitly lists intentional release as a reportable incident.

2) **Question 3:** "Is there a significant risk of international spread?" In cases where there was an intentional release that brought about few casualties and was easily contained, the answer to this would appear to be "No", in which case the event would likely not be reportable. An argument can be made that if the release was deemed to be caused by a State Actor or international terrorist organization, that the attack could take place elsewhere.

Because of these two areas where States might avoid reporting suspected intentional releases, the following questions need to be addressed:

Does WHO need to participate in intentional biological, chemical, or radiological releases where assistance is not requested and there is little threat to the overall public health or international spread (e.g., 2001 anthrax attacks in the U.S.) or should they just be involved in attacks that are not easily contained and have the potential to cross borders? If it is the latter, Annex 2 as drafted would require reporting of the incident because of its similarity to a naturally occurring outbreak with high potential to cause epidemic. If it is the former, then the possibility of deliberate attack should be included as a justification for reporting under the Questions 1 and 3.

**SUGGESTED NEW LANGUAGE:** In the Figure on page 28 (Annex 2, Part A), we suggest text to direct readers to the question-tables on the following pages for appropriate decision points. (For example, in first box insert: refer to Annex 2 Part A Table 1)
ANNEX 3

PROCESSES TO BE FOLLOWED BY WHO IN THE DETERMINATION OF A PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN AND ISSUANCE OF TEMPORARY RECOMMENDATIONS

Section I. Public health emergency of international concern

1. If the Director-General, based on his assessment under these Regulations, considers that a public health emergency of international concern is occurring, he shall consult further with the health administration in whose territory the event arises, and inform it of his preliminary determination. If the Director-General and the health administration are in agreement regarding this determination, the Director-General shall, in accordance with the procedure set forth in the following section, seek the views of the Committee established under this Annex on appropriate temporary recommendations.

2. If the Director-General and the health administration of the territory where the event arises do not come to a consensus in a timely manner on whether the event constitutes a public health emergency of international concern, the Director-General shall seek the views of the Committee, in accordance with the procedure set forth in the following section.

Section II. The Emergency Committee

A. Composition and terms of reference

3. The Director-General shall establish an expert advisory panel composed of senior public health experts in all relevant fields of expertise (hereinafter the "IHR Advisory Panel"). Experts from the IHR Advisory Panel and, when appropriate, other expert advisory panels of the Organization, shall be selected by the Director-General to serve on the Emergency Committee. The Director-General shall follow, whenever applicable and as far as practicable, the principles and rules applicable to expert advisory panels and committees.

4. The Emergency Committee shall be competent to advise the Director-General on whether an event constitutes a public health emergency of international concern and on the issuance of temporary recommendations, at his request.

5. The Emergency Committee shall deliberate and provide its views at meetings convened by the Director-General, or, if so decided by the Director-General in urgent cases, through teleconferences, facsimile communications or electronic communications.

B. Procedure

6. The Director-General shall convene the Emergency Committee by selecting a number of experts from among those referred to in paragraph 3 above, according to the fields of expertise most relevant to the specific event that is occurring.

7. The Director-General shall provide the Committee with the agenda and any relevant information concerning the event, as well as temporary recommendation(s) that the Director-General proposes for issuance.

8. When so requested by the Director-General in accordance with paragraph 2 above, the Emergency Committee shall provide its views as to whether the event constitutes a public health emergency of international concern, which shall be forwarded to the Director-General for his consideration. The Director-General shall make the final determination as to the occurrence of a public health emergency of international concern.
9. If in accordance with paragraph 1 or 8 the Director-General determines that a public health emergency of international concern is occurring, he shall seek the views of the Emergency Committee on appropriate temporary recommendations. The views of the Emergency Committee shall be forwarded to the Director-General for his consideration. The Director-General shall make the final determination as to the temporary recommendations that shall be issued under these Regulations.

10. If the Director-General considers that a public health emergency of international concern has ended or that a temporary recommendation should be modified or is no longer needed, he shall seek the views of the Emergency Committee on the termination of the public health emergency of international concern and/or appropriate modifications. The views of the Emergency Committee shall be forwarded to the Director-General for his consideration. The Director-General shall make the final determination on these matters.

11. The Director-General shall communicate to health administrations the occurrence and the ending of a public health emergency of international concern and appropriate temporary recommendations, as well as the modifications and termination of such recommendations, together with the views of the Emergency Committee.

COMMENT: Annex 3 and Annex 10—These Annexes contain information with regard to the creation of an “Emergency Committee” (Annex 3) and the terms or reference for a “Review Committee” (Annex 10) as outlined in Articles 45-47. The Review Committee, among other things, monitors and reviews the “functioning of the regulations”, provides advice on the application and implementation of the regulations, and advises the Director-General on standing recommendations and modifications. The Emergency Committee advises on whether an event constitutes a public health emergency of international concern. The membership of both Committees, however, is to be drawn from the “IHR Advisory Panel” which is referred to as an expert advisory panel composed of senior public health experts in all relevant fields of expertise as outlined in Annex 3 (Section II.A.3) and Annex 10 (Section I.3). We question why the IHR Advisory Panel, from which members of the two Committees are to be drawn, is not mentioned in the text of the IHRs itself. The Emergency Committee also has no mention in the text of the IHRs. The IHRs should include an appropriate direct reference with regards to the proposed Panel and Committees and their interrelationship. WHO should consider supplying specific timeframes for the actions outlined in this annex, such as the convening of the Emergency Committee, the Director-General’s final determination as to the occurrence of a public health emergency of international concern, and what temporary recommendations should be issued.
ANNEX 4

TECHNICAL REQUIREMENTS PERTAINING TO CONVEYANCES AND CONVEYANCE OPERATORS

Section 1. Conveyance operators

1. Conveyance operators shall facilitate:
   
   (a) inspections of the conveyance and its cargo;
   
   (b) medical examinations of persons on board;
   
   (c) application of public health measures under these Regulations.

2. Conveyance operators shall provide public health certificates required for international voyages, when requested by a health authority. In the case of ships, a valid Ship Sanitation Control Exemption Certificate or Ship Sanitation Control Certificate and a Maritime Declaration of Health; in the case of aircraft, an Aircraft General Declaration, Health Part.

3. Conveyance operators shall inform travellers of the measures recommended by WHO and adopted by States for application on board.

Section 2. Ships

4. Ship Sanitation Control Exemption and Ship Sanitation Control Certificates shall be valid for a maximum period of six months. This period may be extended by one month if the inspection or control measures required cannot be accomplished at the port.

5. If a valid Ship Sanitation Control Exemption Certificate or Ship Sanitation Control Certificate is not produced or evidence of a public health risk is found on board a ship, the health authority for a designated port under Article 14 may proceed as provided in Article 20, paragraph 1 of the Regulations.

6. Measures applied under the previous paragraph shall be carried out so as to avoid as far as possible injury or discomfort to persons or damage to the ship, baggage, containers or cargo. Wherever possible, public health measures shall be carried out when the holds are empty. In the case of a ship in ballast, it shall be done before loading.

7. When control measures are required and have been satisfactorily completed, the health authority shall issue a Ship Sanitation Control Certificate, noting the evidence found and the corrective measures taken.

8. The health authority may issue a Ship Sanitation Control Exemption Certificate at any port specified under Article 14 of the Regulations if it is satisfied that the ship is free of infection and contamination, including vectors. Such a certificate shall normally be issued only if the inspection of the ship has been carried out when the holds are empty or when they contain only ballast or other material, of such a nature or so disposed as to make a thorough inspection of the holds possible.

9. If the conditions under which sanitary control is carried out are such that, in the opinion of the health authority for the port where the operation was performed, a satisfactory result cannot be obtained, the health authority shall make a note to that effect on the Ship Sanitation Control Certificate.

Section 3. Aircraft
10. Measures applied under Article 20, paragraph 1 of the Regulations shall be carried out so as to avoid as far as possible injury or discomfort to persons or damage to the aircraft, baggage or cargo. Wherever possible, sanitary control measures shall be done when the aircraft holds are empty.

11. When the control measures have been satisfactorily completed, the health authority shall note on the Health Part of the Aircraft General Declaration the evidence found and the corrective measures taken.

Section 4. General provisions for conveyances

12. Any measures requiring treatment of a conveyance, cargo or baggage shall be communicated in writing to the master, pilot in command or person in charge of the conveyance, before implementation.

13. A health authority shall indicate in writing the measures applied to a conveyance or its cargo, the parts treated, the methods employed, and the reasons for their application. In the case of aircraft, this information shall be provided in writing to the person in charge of the aircraft for entry in the Health Part of the Aircraft General Declaration. In the case of ships, the health authority shall indicate this information on the “Ship Sanitation Control Certificate”. For other conveyances, cargo or containers, the health authority shall issue to consignors, consignees, carriers or their respective agents, in writing, proof of treatment indicating the parts treated, the methods employed and the reasons for application of measures.

14. Facilities for the inspection and isolation of containers shall be available at container loading areas.

15. Container consignees and consignors shall make every effort to avoid cross contamination when multiple-use loading of containers is employed.

Section 5. Measures that may be recommended with respect to conveyances, containers, goods and cargo

Measures that may be recommended by WHO with respect to conveyances, containers, goods and cargo could include the following:

- no measures required;
- require manifest and routing;
- require inspection;
- require proof of measures taken on departure or in transit to eliminate infection or contamination;
- require treatment of the conveyances, containers, goods or cargo to remove infection or contamination, including vectors;
- require isolation until disinfection or decontamination has been successfully completed;
- require destruction of infected or contaminated cargo, goods or baggage if no treatment or process will otherwise be successful;
- refuse departure or entry.

The measures will be recommended by WHO based on an assessment of the public health risk.
Model Ship Sanitation Control Exemption Certificate

Ship Sanitation Control Exemption Certificate

<table>
<thead>
<tr>
<th>Areas inspected</th>
<th>Evidence found¹</th>
<th>Sample results²</th>
<th>Documents reviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Galley</td>
<td>Medical log</td>
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<tr>
<td>Pantry</td>
<td>Ship’s log</td>
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<tr>
<td>Stores</td>
<td>Other</td>
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<td>Quarters:</td>
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<td>- crew</td>
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<td>- passengers</td>
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<td>- deck</td>
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<tr>
<td>Potable water</td>
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<td>Sewage</td>
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<tr>
<td>Ballast tanks</td>
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<td>Solid waste</td>
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<tr>
<td>Standing water</td>
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<td></td>
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<tr>
<td>Engine room</td>
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</tbody>
</table>

No evidence found. Ship/vessel is exempted from control measures.

Signature......................... Date.................. Signature......................... Date..................

¹Evidence of infection or contamination, including: vectors in all stages of growth, animal reservoirs for vectors, rodents or other species that could carry human disease, microbiological, chemical and other risks to human health, evidence of inadequate sanitary measures.

²Results from samples taken on board. Analysis to be provided to ship’s Master by most expedient means, and if re-inspection is required, to the next appropriate port of call coinciding with the re-inspection date specified in this certificate.

Note: Sanitation Control Exemption Certificates and Sanitation Control Certificates are valid for a maximum of six months, but the validity period may be extended by one month if inspection cannot be carried out at the port and there is no evidence of infection or contamination.
ANNEX 5

SPECIFIC MEASURES FOR VECTOR-BORN DISEASES

1. The Organization shall publish, on a regular basis, a list of areas where disinsection or other vector control measures are recommended for conveyances arriving from these areas. Determination of such areas shall be made pursuant to the procedures regarding temporary or standing recommendations, as appropriate.

2. Every conveyance leaving a point of entry situated in an area where vector control is recommended shall be disinfected and kept free of vectors. When there are methods and procedures advised by the Organization, these should be employed. The presence of vectors on board conveyances and the control measures used to eradicate them shall be included:

   (a) In the case of aircraft, in the Health Part of the Aircraft General Declaration, unless this part of the Declaration is waived by the health authority at the airport of arrival;

   (b) In the case of ships, on the Ship Sanitation Control Certificates;

   (c) In the case of other conveyances, on a written proof of treatment issued to the consignor, consignee, carrier or their agent, respectively.

3. Health authorities should accept disinsecting, deratting and other vector control measures for conveyances applied by health authorities of other States if methods advised by the Organization have been applied.

4. All airports, ports and container terminals shall be kept free of vectors to a minimum distance of 400 metres from the port or terminal boundaries, with extension if vectors with a greater range are present.

5. If a follow-up inspection is required to determine the success of the vector control measures applied, this should be noted on the Ship Sanitation Control Certificate or the Health Part of the Aircraft General Declaration as the case may be, and the health authorities for the next port or airport of call with a capacity to inspect should be informed of this requirement in advance by the health authority.

6. A conveyance may be regarded as suspect if:

   (a) it has a possible case of vector-borne disease on board;

   (b) a possible case of vector-borne disease has occurred on board during the voyage;

   (c) it has left an affected area within a period of time where on-board vectors could still carry disease, or when the introduction of vectors found on board would have serious public health consequences.

7. A State should not prohibit the landing of an aircraft at any airport in its territory if the control measures provided for in paragraph 3 of this Annex or otherwise recommended by the Organization are applied. However, in an area where vectors are present, aircraft coming from an affected area may be required to land at airports specified by the State for that purpose.

8. On arrival from an affected area of a conveyance, other than a ship or aircraft, or a container, in an area where vectors are present, vector control measures may be applied by the health authority.
ANNEX 6

VACCINATION, PROPHYLAXIS AND RELATED CERTIFICATES

1. Vaccines or other prophylaxis under the Regulations shall be of suitable quality; those vaccines and prophylaxis designated by WHO shall be subject to its approval. Upon request, the Health Administration shall provide appropriate evidence of the suitability of vaccines and prophylaxis administered within its territory under the Regulations.

COMMENT: Annex 6.1—We seek clarification as to the meaning of “Vaccines or other prophylaxis... under the Regulations.” Does this refer to all vaccines that might be administered to travelers or only to certain vaccines specified by the IHRs (e.g. yellow fever vaccine)?

2. Persons undergoing vaccination or other prophylaxis under the Regulations shall be provided with an international certificate of vaccination or prophylaxis (“certificate”) in the form specified in this Annex. No departure shall be made from the model of the certificate specified in this Annex, and no photograph shall be included.

3. Certificates under this Annex are valid only if the vaccine or prophylaxis used has been approved by WHO as it may designate.

4. Certificates must be signed in the hand of the medical practitioner or other clinician supervising the administration of the vaccine or prophylaxis; such person's official stamp is not an accepted substitute for the signature.

5. Certificates shall be fully completed in English or in French. They may also be completed in another language, in addition to either English or French.

6. Any amendment of this certificate, or erasure, or failure to complete any part of it, may render it invalid.

7. Certificates are individual and shall in no circumstances be used collectively. Separate certificates shall be issued for children.

8. A parent or guardian shall sign the certificate when the child is unable to write. The signature of an illiterate shall be indicated in the usual manner by the person's mark and the indication by another that this is the mark of the person concerned.

9. If the supervising clinician is of the opinion that the vaccination or prophylaxis is contraindicated on medical grounds he shall provide the person with reasons, written in English or French, underlying that opinion, which health authorities should take into account.

10. An equivalent document issued by the Armed Forces to an active member of those Forces shall be accepted in lieu of an international certificate in the form shown in this Annex if:

(a) it embodies medical information substantially the same as that required by such form; and

(b) it contains a statement in English or in French recording the nature and date of the vaccination or prophylaxis and to the effect that it is issued in accordance with this paragraph.
MODEL INTERNATIONAL CERTIFICATE OF VACCINATION OR PROPHYLAXIS

This is to certify that………………………date of birth sex whose signature follows

has on the date indicated been vaccinated or received prophylaxis against:

(name of disease or condition)…………………………………………………..

In accordance with the International Health Regulations.

<table>
<thead>
<tr>
<th>Vaccine or prophylaxis</th>
<th>Date</th>
<th>Signature and professional status of supervising clinician</th>
<th>Manufacturer and batch No. of vaccine or prophylaxis</th>
<th>Valid until: date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Official stamp of administering centre

This certificate is valid only if the vaccine or prophylaxis used has been approved by the World Health Organization as it shall designate.

This certificate must be signed in the hand of the medical practitioner or other clinician supervising the administration of the vaccine or prophylaxis; such person’s official stamp is not an accepted substitute for the signature.

Any amendment of this certificate, or erasure, or failure to complete any part of it, may render it invalid.

The validity of this certificate shall extend until the date indicated for the particular vaccination or prophylaxis.
ANNEX 7

REQUIREMENTS CONCERNING VACCINATION OR PROPHYLAXIS FOR SPECIFIC DISEASES

1. In addition to any recommendation concerning vaccination or prophylaxis, the following diseases are those for which proof of vaccination or prophylaxis may be required for travellers as a condition of entry to a State:

Vaccination against yellow fever.

2. Requirements for vaccination against yellow fever:

(a) For the purpose of this Annex, the incubation period of yellow fever is six days.

(b) Vaccination against yellow fever may be required of any traveller leaving an area where the Organization has determined a risk of yellow fever transmission is present. Determination of such areas shall be made pursuant to the procedures regarding temporary or standing recommendations, as appropriate.

(c) If a traveller is in possession of a certificate of vaccination against yellow fever which is not yet valid, the traveller may be permitted to depart, but the provisions of paragraph 2(g) of this Annex may be applied on arrival.

(d) A person in possession of a valid certificate of vaccination against yellow fever shall not be treated as a suspect, even if coming from an area where the Organization has determined a risk of yellow fever transmission is present.

(e) The yellow fever vaccine used must be approved by the Organization.

(f) Every person employed at a point of entry in an area where the Organization has determined a risk of yellow fever transmission is present, and every member of the crew of a conveyance using any such point of entry, shall be in possession of a valid certificate of vaccination against yellow fever.

(g) A health authority in an area where vectors of yellow fever are present may require a traveller from an area where the Organization has determined a risk of yellow fever transmission is present, who is unable to produce a valid certificate of vaccination against yellow fever, to be isolated until the certificate becomes valid, or until a period of not more than six days, reckoned from the date of last possible exposure to infection has elapsed, whichever occurs first.

(h) Travellers who possess an exemption from yellow fever vaccination, signed by a medical practitioner, shall nevertheless be allowed entry, subject to the provisions of the foregoing paragraph of this Annex and to being provided with information regarding protection from yellow fever vectors.
ANNEX 8

MODEL OF MARITIME DECLARATION OF HEALTH

To be completed and submitted to health authorities by the masters of ships arriving from ports outside the territory, in particular when arriving from areas subject to World Health Organization (WHO) recommendations or other measures under the International Health Regulations.

Submitted at the port of……………………………… Date………………
Name of ship or inland navigation vessel…………………… arriving from………… sailing to…………………………
Nationality……………………………………………………… Master's name………………………………………………
Net registered tonnage (ship)…………………………………
Tonnage (inland navigation vessel)…………………………
Valid Sanitation Control Exemption/Control Certificate carried on board? yes…… no…… Issued at……… date……
Re-inspection required? yes…… no………
Has ship/vessel visited an affected area identified by WHO? yes…… no…… Port and date of visit……………………
List ports of call from commencement of voyage with dates of departure, or within past four weeks, whichever is shorter:
………………………………………………………………………………………………………………………………
………………………………………………………………………………………………………………………………
………………………………………………………………………………………………………………………………
List crewmembers, passengers or other persons who have joined ship/vessel since voyage began or within past four weeks, whichever is shorter, including all ports/countries visited in this period (add additional names to the attached schedule):

(1) Name……………………………………… joined from: (1)……………………………………(2)……………………(3) …………
(2) Name……………………………………… joined from: (1)……………………………………(2)……………………(3) …………
(3) Name……………………………………… joined from: (1)……………………………………(2)……………………(3) …………

Number of crew members on board……………………
Number of passengers on board…………………………

Health questions

(1) Has any person died on board during the voyage otherwise than as a result of accident? yes …… no…… State particulars in attached schedule.

(2) Is there on board or has there been during the voyage any case of disease which you suspect to be of an infectious or unusual nature? yes…… no…… State particulars in attached schedule.

(3) Is there any sick person on board now? yes…… no…… State particulars in attached schedule.

Note: In the absence of a surgeon, the Master should regard the following symptoms as grounds for suspecting the existence of a disease of an infectious nature: fever accompanied by prostration, persisting for several days, or attended with glandular swelling; any acute skin rash or eruption with or without fever; severe diarrhea with symptoms of collapse; jaundice accompanied by fever; unusual bleeding accompanied by fever; recurrent convulsions.

(4) Was a medical practitioner consulted? yes…… no…… State particulars of medical advice provided in attached schedule.

(5) Are you aware of any condition on board which may lead to infection or spread of disease? yes…… no…… State particulars in attached schedule.

I hereby declare that the particulars and answers to the questions given in this Declaration of Health (including the schedule) are true and correct to the best of my knowledge and belief.

Signed…………………………………………………………
Master

Countersigned……………………………………
Ship's Surgeon (if carried)

Date………………………………………………
* State: (1) whether the person recovered, is still ill, or died; and (2) whether the person is still in board, landed (include name of port), or was buried at sea

<table>
<thead>
<tr>
<th>Name</th>
<th>Class or rating</th>
<th>Age</th>
<th>Sex</th>
<th>Nationality</th>
<th>Port, date joined ship/vessel</th>
<th>Nature of illness</th>
<th>Date of onset</th>
<th>Reported to a port medical officer?</th>
<th>Disposal of case*</th>
<th>Comments</th>
</tr>
</thead>
</table>
ANNEX 9

HEALTH PART OF THE AIRCRAFT GENERAL DECLARATION

Declaration of Health

Persons on board with illnesses other than airsickness or the effects of accidents (including persons with symptoms or signs of illness such as rash, fever, chills, diarrhea) as well as those cases of illness disembarked during the flight

........................................................................................................................................
........................................................................................................................................
........................................................................................................................................

Any other condition on board which may lead to the spread of disease

........................................................................................................................................

Details of each disinsecting or sanitary treatment (place, date, time, method) during the flight. If no disinsecting has been carried out during the flight, give details of most recent disinsecting

........................................................................................................................................
........................................................................................................................................
........................................................................................................................................

Signature, if required: ........................................................................................................

Crew member concerned

NOTE: The Aircraft General Declaration has been adopted by the International Civil Aviation Organization and will be undergoing review.
ANNEX 10

THE REVIEW COMMITTEE

Section I  Terms of reference and composition

1. The functions of the Review Committee (hereinafter the "Committee") shall be:

(a) to review and monitor the functioning of the Regulations, including the annexes in accordance with Article 45 of the Regulations;

(b) to provide advice with respect to the application or implementation of the Regulations, including the annexes, as well as possible amendments thereof in accordance with Article 46 of the Regulations;

(c) to provide advice to the Director-General with respect to standing recommendations, and any modifications or termination thereof;

(d) to advise the World Health Assembly, the Executive Board and the Director-General on any matter referred to it by them;

(e) to consider disputes concerning the interpretation or application of the Regulations referred to it by the Director-General under Article 47 of the Regulations.

2. The Committee shall be considered an expert committee and shall be subject to the Regulations for Expert Advisory Panels and Committees, unless otherwise provided in this Annex.

3. The Director-General shall establish an Expert Advisory Panel composed of senior public health experts in all relevant fields of expertise (hereinafter the "IHR Advisory Panel"). The Members of the Committee shall be selected and appointed by the Director-General from amongst the persons serving on the IHR Advisory Panel and other appropriate expert advisory panels of the Organization.

4. The Director-General shall establish the number of experts to be invited to a meeting of the Committee, determine its date and duration, and convene the Committee.

5. The Director-General shall appoint members to the Committee for the duration of the work of a session only, except that members appointed to a session which considers a dispute shall continue to serve for any further deliberation on such dispute until the consideration thereof is terminated.

6. Members shall be eligible for reappointment.

Section II  Conduct of business

7. In respect of decisions other than on disputes, such decisions shall be taken by a majority of the members present and voting.

8. In respect of decisions on disputes under Section IV, such decisions shall be taken by a majority of the members present, each member casting an affirmative or negative vote. If the votes are equally divided, the chairman shall, in addition, cast the deciding vote.

9. For meetings of the Committee other than those dealing with disputes under Section IV of this Annex, the Director-General shall invite Member States, the United Nations, specialized agencies and other relevant intergovernmental or non-governmental organizations to designate representatives to attend the Committee sessions if the subjects on the agenda so require. Such representatives may submit memoranda and, with the consent of the chairman, make statements on the subjects under discussion. They shall not have the right to vote.
Section III  Reports on sessions of the Committee

10. This Section shall not apply to matters dealt with under Section IV.

11. For each session, the Committee shall draw up a report setting forth the Committee's views and advice. This report shall be approved by the Committee before the end of the session. Its views and advice shall not commit the Organization and shall be formulated as advice to the Director-General. The text of the report may not be modified without the Committee's consent.

12. If the Committee is not unanimous in its findings, any member shall be entitled to express his/her personal opinion in an individual or group report, which shall state the reasons why a divergent opinion is held and shall form part of the Committee's report.

13. Except for advice under Sections IV and V, the Committee's report shall be submitted to the Director-General, who shall communicate its views and advice, as appropriate, to the Health Assembly or to the Executive Board for their consideration and action.

Section IV  Consideration of disputes under Article 47 of the International Health Regulations

14. If a dispute is referred to the Committee for consideration under Article 47 of the International Health Regulations and subparagraph (e) of paragraph 1 of this Annex, the procedure shall be as follows:

(a). The Director-General shall forthwith communicate with the States parties to the dispute informing them of such reference and inviting them to submit, within a prescribed period, any observations they deem appropriate.

(b). As soon as all observations are received or the prescribed period expires, or if no reply which would put an end to the dispute is received within the prescribed period, the Director-General shall convene the Committee. No member who is a national of any State party to the dispute may sit on the Committee.

(c). The States parties to the dispute may appoint one or more representatives in order to state their cases to the Committee. Each State party to the dispute shall be responsible for its own costs and expenses arising from its participation in the proceedings. Should two or more parties be presenting a common case, they shall, for the purposes of this paragraph, be considered as one party only; the Committee shall decide any questions which may arise regarding this issue.

(d). The Director-General may request any State, intergovernmental organization, nongovernmental organization or individual to place at the disposal of the Committee any information in its possession concerning the subject of the dispute as specified by the Committee.

(e) The Director-General, taking into account the nature of the problems involved in the consideration of the dispute, may at the request of the Committee or on the Director-General's own initiative, appoint one or more technical experts to advise the Committee. Such technical experts shall normally be drawn from the expert advisory panels or the Organization. They shall not have the right to vote.

(f) The Committee, after inviting the parties to present their arguments and examine any evidence submitted to it, shall give its reasoned views and advice and specify any conclusions which it deems appropriate. The Director-General shall communicate the Committee's views and advice to the States parties to the dispute. States parties to the dispute shall, in accordance with paragraph 4 of Article 47 of the Regulations, report to the Director-General on the action taken to implement the views and advice of the Committee. Members of the Committee who dissent from the views and advice shall be entitled to append their dissenting views.
(g) The views and advice of the Committee shall not bind the States parties to the dispute, unless the parties so elect prior to the commencement of the proceedings of the Committee and inform the Committee accordingly.

Section V  Standing recommendations

15. Under Article 12 of the Regulations, the Director-General may issue standing recommendations of appropriate measures for adoption by States and routine or periodic application by health authorities for specific, ongoing public health risks to prevent or reduce the international spread of disease and minimize interference with international traffic.

16. When the Director-General considers that a standing recommendation is necessary and appropriate for a specific public health risk, he shall seek the views of the Committee in accordance with the provisions of this Annex. In addition to the relevant paragraphs in Sections I-III of this Annex, the following provisions shall also apply:

(a) Proposals for standing recommendations, their modification or termination may be submitted to the Committee by the Director-General or by States which are parties to the Regulations through the Director-General.

(b) Any State which is a party to the Regulations may submit relevant information for consideration by the Committee.

(c) The Director-General may request any State, intergovernmental organization, nongovernmental organization or individual with relevant technical expertise to place at the disposal of the Committee information in its possession concerning the subject of the proposed standing recommendation as specified by the Committee.

(d) The Director-General may, at the request of the Committee or on his own initiative, appoint one or more technical experts to advise the Committee. Such technical experts shall normally be drawn from the expert advisory panels or the Organization. They shall not have the right to vote.

(e) Any report containing the Committee's views and advice regarding standing recommendations shall be forwarded to the Director-General for his consideration and decision. The Director-General shall communicate the Committee's views and advice to the World Health Assembly and, if appropriate, to the Executive Board.

(f) The Director-General shall communicate to health administrations standing recommendations, as well as any related modifications or their termination, together with the views of the Committee.

COMMENT: Annex 3 and Annex 10—These Annexes contain information with regard to the creation of an “Emergency Committee” (Annex 3) and the terms or reference for a “Review Committee” (Annex 10) as outlined in Articles 45-47. The Review Committee, among other things, monitors and reviews the “functioning of the regulations”, provides advice on the application and implementation of the regulations, and advises the Director-General on standing recommendations and modifications. The Emergency Committee advises on whether an event constitutes a public health emergency of international concern. The membership of both Committees, however, is to be drawn from the “IHR Advisory Panel” which is referred to as an expert advisory panel composed of senior public health experts in all relevant fields of expertise as outlined in Annex 3 (Section II.A.3) and Annex 10 (Section I.3). We question why the IHR Advisory Panel, from which members of the two Committees are to be drawn, is not mentioned in the IHR Articles. The Emergency Committee also has no mention in the IHR Articles.
The IHR Articles should include an appropriate direct reference with regards to the proposed Panel and Committees and their interrelationship.