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Review and approval of proposed amendments to the International Health Regulations

Proposal by the Chair

In response to requests from a very large number of Member States, and working closely with the Secretariat of the WHO, I have prepared a revised draft text for the consideration of the Intergovernmental Working Group on the Revision of the International Health Regulations. In preparing this text I have been mindful of the overwhelming support which was expressed for the general approach set out in document A/IHR/IGWG/3. In addition my proposal is based on a thorough consideration of the discussions which took place at our November meeting and the many submissions from Member States.

The proposal represents my views as Chair as to where a consensus may lie and, as such, all elements of the text are subject to further discussion. It is my hope that it will assist the Group's work. At the same time previous submissions from Member States will continue to be regarded as inputs into future deliberations of the IGWG.

The document contains bracketed text in areas where I believe that future discussions are particularly necessary in order to clarify or to develop a broader understanding of each other's concerns. The footnotes in the text are intended to assist in developing the text further. Where it was clear that a consensus could not emerge on any specific proposal it has not been included in my paper.

Three background documents have been produced by the Secretariat to accompany this text and provide more detail on the following issues raised during the November meeting: WHO's alert and response operations; the application of the Regulations at ground crossings and to ground transport and the regime of reservations applicable with respect to WHO regulations.

The numbering and placement of paragraphs was raised by a number of Member States in November. I would propose that, if considered necessary, this issue will be addressed when we have agreement on the text as a whole.

PART I – DEFINITIONS, PURPOSE AND SCOPE, PRINCIPLES AND RESPONSIBLE AUTHORITIES

Article 1 Definitions

1. For the purposes of the International Health Regulations (hereinafter the “IHR” or “Regulations”):

“adequate sanitary measure” means a measure which eliminates or controls a public health risk;

“affected” means persons, human remains, baggage, conveyances, containers, cargo, goods or postal parcels that are infected or contaminated, or carry sources of infection or contamination, so as to constitute a public health threat;

“affected area” means a geographical location within the territory of a State Party for which health measures have been recommended by WHO under these Regulations;

“aircraft” means an aircraft making an international voyage;

“airport” means any airport where international flights arrive or depart;

“arrival” of a conveyance means:

- (a) in the case of a seagoing vessel, arrival or anchoring in the defined area of a port;
- (b) in the case of an aircraft, arrival at an airport;
- (c) in the case of an inland navigation vessel on an international voyage, arrival at a point of entry;
- (d) in the case of a train or road vehicle, arrival at a point of entry;

“baggage” means the personal effects of a traveller;

“cargo” means goods carried on a conveyance or in a container;

“competent authority” means the authority responsible for the implementation and application of health measures under these Regulations;

“container”¹ 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;

¹ Having compared the use of this term in another international regime, it was felt that the above definition was more suitable for the purposes of these Regulations.

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

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

“container loading area” means a place or facility set aside for containers used in international traffic;

“contamination” means the presence of an infectious or toxic agent or matter on a human or animal body surface, in/on a product prepared for consumption or on other inanimate objects, including conveyances, that may constitute a public health risk or threat;

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

“conveyance operator” means a natural or legal person in charge of a conveyance or their agent;

“crew” means persons on board a conveyance who are not passengers;

“decontamination” means a procedure whereby measures are taken to eliminate an infectious or toxic agent or matter on a human or animal body surface, in/on a product prepared for consumption or on other inanimate objects, including conveyances, that may constitute a public health risk or threat;

“departure” means, for a person, conveyance, cargo, goods or baggage, the act of leaving a territory;

“deratting” means the procedure whereby measures are taken to control or kill rodent vectors of human disease present in conveyances, cargo, goods, baggage, containers and postal parcels;

“Director-General” means the Director-General of the World Health Organization;

[“disease” means an animal or human illness that presents a risk of significant harm to humans caused by biological, chemical or radionuclear sources;]

“disinfection” means the procedure whereby measures are taken to control or kill infectious agents on a human or animal body surface or in/on conveyances, cargo, goods, baggage, containers and postal parcels by direct exposure to chemical or physical agents;

“disinsection” means the procedure whereby measures are taken to control or kill the insect vectors of human diseases present in conveyances, cargo, goods, baggage, containers and postal parcels;

“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, embark or disembark, discharge or load cargo or stores; for an aircraft, after landing, to embark or disembark, discharge or load cargo or stores; and for a train or road vehicle, upon arrival, to embark or disembark, discharge or load cargo or stores;

“goods” mean tangible products, including animals and plants, transported on an international voyage, including for utilization on board a conveyance;

“ground crossing” means a point of land entry in a State Party, including those utilized by road vehicles and trains;

“ground transport vehicle” means a motorized conveyance for overland transport on an international voyage, including trains, coaches, lorries and automobiles;

“health measure” means procedures applied to prevent the spread of disease;

“ill person” means an individual suffering from or affected with a physical ailment that may pose a public health risk;

“infection” means the entry and development or multiplication of an infectious agent in the body of humans and animals, that may constitute a public health risk or threat;

“inspection” means the examination, by the competent authority or under its supervision, of conveyances, containers, goods, baggage, postal parcels, areas or facilities, including relevant data, to determine if a public health risk exists;

“international traffic” means the movement of persons, conveyances, containers, baggage, goods or postal parcels across an international border;

“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 the voyage;

“intrusive”;¹

“invasive” means the puncture or incision of the skin or insertion of an instrument or foreign material into the body;

“isolation” means separation of affected persons, baggage, conveyances, containers, goods or postal parcels from others in such a manner as to prevent the spread of infection or contamination;

“medical examination” means the preliminary assessment of a person by an authorized health worker, to determine the person’s health status and potential public health risk to others, and may include the scrutiny of health documents, and a physical examination when justified by the circumstances of the individual case;

“National IHR Focal Point” means the national centre, designated by each State Party, which shall be accessible at all times for communications with WHO IHR Contact Points under the Regulations;

¹ In light of the discussions on Articles 15, 21, 27 and 39, a definition of the term requires further consideration.

“Organization” or “WHO” means the World Health Organization;

“permanent residence” has the meaning as determined in the national legislation of the State Party concerned;

“personal data” means any information relating to an identified or identifiable natural person;

“point of entry” means an international point of arrival or departure in a State;

“port” means a seaport or a port on an inland body of water where ships on an international voyage arrive or depart;

“postal parcel” means an addressed article or package carried internationally by postal or courier services;

“public health emergency of international concern” means an extraordinary event which is determined, as provided in these Regulations,

(i) to constitute a public health threat to other States through the international spread of disease and

(ii) to potentially require a coordinated international response;

“public health observation” means the monitoring of the health status of a traveller over time for the purpose of determining the risk of disease transmission;

[“public health risk” means an event posing a probability of international spread of disease;]

[“public health threat” means a serious and direct danger to the health of human populations;]¹

“quarantine” means the restriction of activities and/or separation from others of suspect persons who are not ill or of suspect conveyances, containers, goods or baggage in such a manner as to prevent the possible spread of infection or contamination;

“recommendation” and “recommended” refer to temporary or standing recommendations issued under these Regulations;

“reservoir” means an animal, plant or substance in which an infectious agent normally lives and whose presence may constitute a public health risk;

“road vehicle” means a ground transport vehicle other than a train;

“scientific evidence” means information furnishing a level of proof based on the methods of science;

“scientific principles” means the fundamental laws and facts of nature known through the methods of science;

¹ The terms “public health risk” and “public health threat” require further discussion since a number of the sources checked did not reveal substantial differences between the two.

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

“standing recommendation” means non-binding advice issued by WHO for specific ongoing public health threats pursuant to Article 14 of these Regulations regarding appropriate health measures for routine or periodic application needed to prevent or reduce the international spread of disease and minimize interference with international traffic;

“sufficiently large” means having, in the judgement of a State Party, a magnitude justifying particular attention and the establishment of capacity to implement health measures;

“surveillance” means the systematic ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and action as necessary;

“suspect” means persons, conveyances, containers, cargo, baggage, goods or postal parcels considered by a State Party as having been exposed to a public health risk or threat and a possible source of further spread of disease;

“temporary recommendation” means non-binding advice issued by WHO pursuant to Article 13 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;

“temporary residence” has the meaning as determined in the national legislation of the State Party concerned;

“traveller” means a natural person undertaking an international voyage;

“vector” means an insect or animal which normally transports an infectious agent that constitutes a public health risk;

“verification” means the provision of information by a State Party to WHO confirming the status of an event within the territory or territories of that State Party;

“WHO IHR Contact Point” means the unit within WHO which shall be accessible at all times for communications with the National IHR Focal Point;

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

Article 2 Purpose and scope

The purpose and scope of these Regulations *are to prevent*, protect against, control, and provide public health responses to the international spread of disease in ways that are commensurate with risks and threats to public health, and which avoid unnecessary interference with international traffic.

Article 2bis Principles

1. The implementation of these Regulations shall be with full respect for the fundamental human rights and dignity of persons.

2. The implementation of these Regulations shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization.

Article 3 Responsible authorities

1. States Parties shall designate a National IHR Focal Point and the authorities responsible within their respective jurisdictions for the implementation of health measures under these Regulations.

2. National IHR Focal Points shall be accessible at all times for communications with the WHO IHR Contact Points provided for in paragraph 3 of this Article. The functions of National IHR Focal Points shall include:

(a) sending to WHO IHR Contact Points, on behalf of the State Party concerned, urgent communications concerning the implementation of these Regulations, in particular under Articles 5 to 10 [and 45]; and

(b) disseminating information to, and consolidating input from, relevant sectors of the administration of the State Party concerned, including those responsible for surveillance and reporting, points of entry, public health services, clinics and hospitals and other government departments.

3. WHO shall designate IHR Contact Points, which shall be accessible at all times for communications with National IHR Focal Points. WHO IHR Contact Points shall send urgent communications concerning the implementation of these Regulations, in particular under Articles 5 to 10 [and 45], to the National IHR Focal Point of the States Parties concerned. WHO IHR Contact Points may be designated by WHO at the Headquarters or at the regional level of the Organization.

4. States Parties shall provide WHO with contact details of their National IHR Focal Point and WHO shall provide States Parties with contact details of WHO IHR Contact Points. These contact details shall be continuously updated and annually confirmed. WHO shall make available to all States Parties the contact details of National IHR Focal Points it receives pursuant to this Article.

PART II – INFORMATION AND PUBLIC HEALTH RESPONSE

Article 4 Surveillance

1. Each State Party shall develop and strengthen, as soon as possible [but no later than __ years from the entry into force of these Regulations for that State Party], the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1.

2. WHO shall assist States Parties to develop and strengthen the capacities referred to in paragraph 1 of this Article.

3. WHO shall collect information regarding events through its surveillance activities and assess their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Article 9.

Article 5 Notification

1. Each State Party shall assess events occurring within its territory by using the decision instrument in Annex 2. Each State Party shall notify WHO, by the most efficient means of communication available, by way of the National IHR Focal Point, and within [24]/[48]¹ hours of receipt of public health information, of all events which may constitute a public health emergency of international concern within its territory in accordance with the decision instrument, as well as any health measure implemented in response to those events.

2. Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it, including, where possible, 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; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern.

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, a State Party may nevertheless keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate health measures. Such communications shall be treated in accordance with paragraphs 2 to 4 of Article 9. The State Party in whose territory the event has occurred may request WHO assistance to assess any epidemiological evidence obtained by that State Party.

Article 7 Other reports

1. WHO may take into account reports from sources other than notifications or consultations and shall assess these reports according to established epidemiological principles.² Before taking any action based on such reports, WHO shall consult with the State Party in whose territory the event is allegedly occurring in accordance with the procedures set forth in Article 8.

2. States Parties shall inform WHO within 24 hours of receipt of evidence of a public health threat identified outside their territory that may cause international disease spread, as manifested by exported or imported:

- (a) human cases;
- (b) vectors which carry infection or contamination; or
- (c) goods that are contaminated.

¹ Further discussion is needed on the time period for notification.

² See resolution WHA56.28, adopted on 28 May 2003, which at paragraph 4(1) requests the Director-General “to take into account reports from sources other than official notifications, and to validate those reports according to established epidemiological principles”.

Article 8 Verification

1. WHO shall request, in accordance with paragraph 1 of Article 7, verification from a State Party of reports from sources other than notifications or consultations of events which may constitute a public health emergency of international concern allegedly occurring in the State's territory. In such cases, WHO shall inform the State Party concerned regarding the reports it is seeking to verify.
2. Each State Party, when requested by WHO, shall provide:
 - (a) within 24 hours, an initial reply to, or acknowledgement of the request from WHO;
 - (b) as soon as possible, available information on the status of events referred to in WHO's request; and
 - (c) information to WHO on a continuing basis, including relevant information as described in paragraph 2 of Article 5.
3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall offer to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.
4. If the State Party does not accept the offer of collaboration, WHO may share, with other States Parties, the information available to it.

Article 9 Provision of information by WHO

1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as appropriate, to relevant intergovernmental organizations, as soon as possible and by the most efficient means available, such public health information which it has received under Articles 4 to 8 inclusive and which is necessary to enable States Parties to respond to a public health threat.
2. WHO shall use information received under Articles 5 and 6 and paragraph 2 of Article 7 for verification, assessment and assistance purposes under these Regulations and, unless otherwise agreed with the States Parties referred to in those provisions, shall not make this information generally available to other States Parties, until such time as:
 - (a) the event is determined to constitute a public health emergency of international concern in accordance with Article 10; or
 - (b) information evidencing the international spread of the infection or contamination has been confirmed by WHO in accordance with established epidemiological principles; or
 - (c) there is evidence that
 - (i) control measures against the international spread are unlikely to succeed because of the nature of the contamination, disease agent, vector or reservoir; or

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

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

3. WHO shall consult with the State Party in whose territory the event is occurring as to its intent to make information available under this Article.

4. When information received by WHO under paragraph 2 of this Article is made available to States Parties in accordance with these Regulations, WHO may also make it available to the public if other information about the same event has already become publicly available and there is a need for the dissemination of authoritative and independent information.

Article 10 Determination of a public health emergency of international concern

1. The Director-General shall determine, on the basis of the information received, in particular from the State Party within whose territory an event is occurring, whether an event constitutes a public health emergency of international concern in accordance with the criteria and the procedure set out in these Regulations.

2. If the Director-General considers, based on an assessment under these Regulations, that a public health emergency of international concern is occurring, the Director-General shall consult with the State Party in whose territory the event arises regarding this preliminary determination. If the Director-General and the State Party are in agreement regarding this determination, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the "Emergency Committee") on appropriate temporary recommendations.

3. If, following the consultation in paragraph 2 above, the Director-General and the State Party in whose territory the event arises do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern, a determination shall be made, in accordance with the procedure set forth in Article 49.

4. In determining whether an event constitutes a public health emergency of international concern, the Director-General shall consider:

(a) information provided by the State Party;

(b) the decision instrument contained in Annex 2;

(c) the advice of the Emergency Committee;

(d) scientific principles as well as the available scientific evidence and other relevant information; and

(e) an assessment of the risk to human health, of the risk of international spread of disease and of interference with international traffic.

5. If the Director-General, following consultations with the State Party within whose territory the public health emergency of international concern has occurred, considers that a public health emergency of international concern has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49.

Article 11 Public health response

1. Each State Party shall develop and strengthen, as soon as possible [but no later than ___ years from the entry into force of these Regulations for that State Party], the capacity to respond promptly and effectively to public health threats and public health emergencies of international concern as set out in Annex 1. When appropriate WHO shall publish guidelines to support States Parties in the development of public health response capacities.

2. At the request of a State Party, WHO shall collaborate in the response to public health threats and other events by providing technical guidance and assistance and by assessing the effectiveness of the control measures in place, including the mobilization of international teams of experts for on-site assistance, when necessary.

3. If WHO, in consultation with the States Parties concerned as provided in Article 10, determines that a public health emergency of international concern is occurring, it may offer, in addition to the support indicated in paragraph 2 of this Article, further assistance to the State Party, including an assessment of the severity of the international threat and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.

4. When requested by WHO, States Parties should provide, to the extent possible, support to WHO coordinated response activities.

5. When requested, WHO shall provide appropriate guidance and assistance to other States Parties affected or threatened by the public health emergency of international concern.

Article 12 Cooperation of WHO with intergovernmental organizations and bodies¹

1. WHO shall cooperate and coordinate its activities, as appropriate, with other competent intergovernmental organizations or bodies in the implementation of these Regulations, including through the conclusion of agreements and other similar arrangements.

2. In cases in which notification or verification of, or response to, an event is also within the competence of other intergovernmental organizations or bodies, WHO shall coordinate its activities with such organizations or bodies in order to ensure the application of adequate measures for the protection of public health.

3. Notwithstanding the foregoing, nothing in these Regulations shall preclude or limit the provision by WHO of advice, support, or technical or other assistance for public health purposes.

¹ The proposals to change the place of Article 12 may have to be discussed upon the finalization of the text.

PART III – RECOMMENDATIONS

Article 13 Temporary recommendations

1. If it has been determined in accordance with Article 10, that a public health emergency of international concern is occurring, the Director-General shall issue temporary recommendations in accordance with the procedure set out in Article 49. Such temporary recommendations may be modified or extended as appropriate, including after it has been determined that a public health emergency of international concern has ended, at which time other temporary recommendations may be issued as necessary for the purpose of preventing or promptly detecting its recurrence.
2. Temporary recommendations may include health measures to be implemented by the State Party experiencing the public health emergency of international concern, or by other States Parties, regarding persons, conveyances, containers, cargo, goods, baggage and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.
3. Temporary recommendations may be terminated in accordance with the procedures set out in Article 49 at any time and shall automatically expire 90 days after their issuance. They may be modified or extended for additional periods of up to 90 days. Temporary recommendations may not continue for a period exceeding a total of 2 years from the determination of the public health emergency of international concern to which they relate.

Article 14 Standing recommendations

WHO may make standing recommendations of appropriate health measures in accordance with Article 54 for routine or periodic application. Such measures may be applied by States Parties regarding persons, conveyances, containers, goods, cargo, baggage and/or postal parcels for specific, ongoing public health threats in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic. WHO may, in accordance with Article 54, modify or terminate such recommendations, as appropriate.

Article 15 Criteria for recommendations

When issuing, modifying or terminating temporary or standing recommendations, the Director-General shall consider:

- (a) the advice of the Emergency Committee or the Review Committee, as the case may be;
- (b) scientific principles as well as available scientific evidence and information;
- (c) health measures that, on the basis of a risk assessment appropriate to the circumstances, are not more restrictive of international traffic and are not more intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection;
- (d) relevant international standards and instruments;
- (e) activities undertaken by other relevant international organizations and bodies; and
- (f) other appropriate and specific information relevant to the event, including the views of the States Parties directly concerned.

With respect to temporary recommendations, the consideration by the Director-General of subparagraphs (d) and (e) of this Article may be subject to limitations imposed by urgent circumstances.

Article 16 Recommendations with respect to persons, conveyances, containers, goods, cargo, baggage and postal parcels

1. Recommendations issued by WHO to States Parties with respect to persons may include the following advice:

- no health measures are advised;
- review travel history in affected areas;
- review proof of medical examination;
- require medical examinations;
- review proof of vaccination or other prophylaxis;
- require vaccination or other prophylaxis;
- place suspects under public health observation;
- implement quarantine or other health measures for suspects;
- implement isolation and treatment where necessary of affected persons;
- implement tracing of contacts of suspects or affected persons;
- refuse entry of suspects and affected persons; and
- implement exit restrictions on persons from affected areas.

2. Recommendations issued by WHO to States Parties with respect to conveyances, containers, goods, cargo, baggage and postal parcels may include the following advice:

- no health measures are advised;
- review manifest and routing;
- implement inspections;
- review proof of measures taken on departure or in transit to eliminate infection or contamination;
- implement treatment of the conveyances, containers, goods or cargo to remove infection or contamination, including vectors and reservoirs;
- implement isolation or quarantine;

- seizure and destruction of infected or contaminated or suspect cargo, goods or baggage under controlled conditions if no available treatment or process will otherwise be successful; and
- refuse departure or entry.

PART IV – POINTS OF ENTRY

Article 17 General obligations

Each State Party shall, in addition to the other obligations provided for under these Regulations:

- (a) ensure that the capacities set forth in Annex 1 for designated points of entry are developed [within the timeframe provided in paragraph 1 of Article 4 and paragraph 1 of Article 11];
- (b) identify the competent authorities at each designated point of entry in its territory; and
- (c) furnish to WHO, when requested in response to a specific potential public health threat, relevant data concerning sources of infection or contamination, including vectors and reservoirs, at its points of entry, which could result in international disease spread.

Article 18 Airports and ports

1. States Parties shall designate the airports and ports that shall develop the capacities provided in Annex 1.
2. States Parties shall ensure that Ship Sanitation Control Exemption Certificates and Ship Sanitation Control Certificates are issued in accordance with the requirements in Article 35 of these Regulations and the model provided in Annex 3.
3. Each State Party 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 3; or
 - (b) the issuance of Ship Sanitation Control Exemption Certificates only; and
 - (c) extension of the Ship Sanitation Control Exemption Certificate for a period of one month until the arrival of the ship in the port at which the Certificate may be received.

Each State Party shall inform WHO of any changes which may occur to the status of the listed ports. WHO shall publish the information received under this paragraph.

4. WHO may, at the request of the State Party 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 consultation with the State Party.¹

5. WHO, in collaboration with competent international and intergovernmental organizations, shall develop and publish the certification requirements for airports and ports under this Article. WHO shall also publish a list of certified airports and ports.

Article 19 Ground crossings²

1. Whenever, in the opinion of a State Party, the volume of international traffic is sufficiently important, and where justified by public health considerations, that State Party may designate ground crossings that shall develop the capacities provided in Annex 1.

2. States Parties may take into consideration the following criteria in designating ground crossings under paragraph one of this Article:

- (a) the volume and frequency of the various types of international traffic, as compared to other points of entry, at a State Party's ground crossings which might be designated; and
- (b) the public health risks or threats existing in areas in which the international traffic originates, or through which it passes, prior to arrival at a particular ground crossing.

3. States Parties sharing common borders should consider:

- (a) entering into bilateral or multilateral agreements or arrangements concerning prevention or control of international transmission of disease at ground crossings in accordance with Article 58; and
- (b) joint designation of adjacent ground crossings for the capacities in Annex 1 in accordance with paragraph one of this Article.

Article 20 Role of competent authorities

1. The competent authorities shall:

- (a) be responsible for monitoring conveyances, containers, cargo, goods and baggage and postal parcels departing and arriving from affected areas, to ensure that they are maintained in such a condition that they are free of sources of infection or contamination, including vectors and reservoirs;
- (b) ensure 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 and reservoirs;

¹ It is noted that Article 21(1) of the current Regulations (1969) provides that WHO shall arrange to certify sanitary airports at the request of a Member State.

² See Information note "Ground Crossings and Ground Transport Conveyances in the International Health Regulations" prepared by the Secretariat (A/IHR/IGWG/2/INF.DOC./3).

- (c) be responsible for the supervision of any deratting, disinfection, disinsection or decontamination of conveyances, containers, goods, cargo, postal parcels, baggage, animals or sanitary measures for persons, as appropriate under these Regulations;
 - (d) advise conveyance operators, as far in advance as possible, of their intent to apply control measures to a conveyance, and shall provide, where available, written information concerning the methods to be employed;
 - (e) be responsible for the supervision of the removal and safe disposal of any contaminated water or food, human or animal dejecta, wastewater and any other contaminated matter from a conveyance;
 - (f) 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 [¹] waters of a port, river or canal, lake or other international waterway;
 - (g) be responsible for supervision of agencies and persons providing services concerning travellers, conveyances, containers, cargo, goods, baggage and postal parcels at points of entry, including the conduct of periodic inspections and medical examinations;
 - (h) have effective contingency arrangements to deal with an unexpected public health event; and
 - (i) communicate with the national IHR Focal Point on the relevant public health measures taken pursuant to these Regulations.
2. Health measures recommended by WHO for travellers, conveyances, containers, goods, cargo, baggage or postal parcels arriving from an affected area may be reapplied on arrival, if there are indications that the measures applied on departure from the affected area were unsuccessful.
3. Disinsection, deratting, disinfection, decontamination and other sanitary procedures shall be carried out so as to avoid as far as possible injury or discomfort to persons or damage to conveyances, containers, cargo, goods or baggage.

PART V – PUBLIC HEALTH MEASURES

Chapter I – General provisions

Article 21 Health measures on arrival and departure

1. Subject to applicable international agreements and relevant articles of these Regulations, a State Party may require for public health purposes, on arrival or departure:
- (a) with regard to travellers:

¹ Brackets inserted pending clarification of references to particular bodies of water.

- (i) information concerning the traveller's destination so that the traveller may be contacted;
 - (ii) information concerning the traveller's itinerary to ascertain if there was any travel 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; and/or
 - (iii) a non-invasive¹ medical examination which is the least intrusive examination that would achieve the public health objective.
- (b) inspection of conveyances, containers, cargo, goods, postal parcels, baggage and human remains.
2. On the basis of evidence of a public health threat obtained through the measures provided in paragraph 1 of this Article, or through other means, States Parties may apply additional health measures, in accordance with these Regulations, in particular with regard to a suspect or affected traveller, the least intrusive and invasive medical examination that would achieve the public health objective.
3. No medical examination, vaccination or prophylaxis or health measure under these Regulations shall be carried out on travellers without their prior express informed consent or that of their parents or guardians, except as provided in paragraph 2 of Article 27, and in accordance with the laws and international obligations of the State Party.
4. Travellers to be vaccinated or offered prophylaxis pursuant to these Regulations, or their parents or guardians, shall be informed of any risk associated with vaccination or with non-vaccination and with the use or non-use of prophylaxis in accordance with the laws and international obligations of the State Party. States Parties shall inform medical practitioners of these requirements.
5. Any medical examination, medical procedure, vaccination or other prophylaxis which involves a risk of disease transmission shall only be performed on, or administered to, a traveller in accordance with established national or international safety guidelines and standards so as to minimize such a risk.

Chapter II – Special provisions for conveyances and conveyance operators

Article 22 Conveyance operators

1. States Parties shall take all practicable measures consistent with these Regulations to ensure that conveyance operators:
- (a) comply with the health measures recommended by WHO and adopted by the State Party;

¹ The following definition is put forward for discussion:

["For purposes of these Regulations, the following public health procedures are covered under subparagraph (iii): temperature assessment using an ear, oral or cutaneous thermometer, or thermal imaging; auscultation of heart or abdomen; abdominal palpation; retinoscopy; visualization of the oropharynx using a tongue depressor; external collection of urine, faeces or saliva samples; external measurement of blood pressure; electrocardiography."]

(b) inform travellers of the health measures recommended by WHO and adopted by the State Party for application on board; and

(c) permanently keep conveyances for which they are responsible free of sources of infection or contamination, including vectors and reservoirs. The application of measures to control sources of infection or contamination may be required if evidence is found on board during an inspection.

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

Article 23 Ships and aircraft in transit

Subject to Articles 24 and 39 or unless authorized by applicable international agreements, no health measure shall be applied by a State Party to:

(a) a ship not coming from an affected area which passes through a maritime canal or waterway in the territory of that State Party on its way to a port in the territory of another State. Any such ship shall be permitted to take on, under the supervision of the competent authority, fuel, water, food and supplies;

(b) a ship which passes through [¹] waters within its jurisdiction without calling at a port or on the coast; and

(c) an aircraft in transit at an airport within its jurisdiction, except that the aircraft may be restricted to a particular area of the airport with no embarking and disembarking or loading and discharging. However, any such aircraft shall be permitted to take on, under the supervision of the competent authority, fuel, water, food and supplies.

Article 24 Affected conveyances

1. If evidence or indications of a public health threat, including sources of infection and contamination, are found on board a conveyance during an inspection, the competent authority shall consider the conveyance as affected and may:

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

(b) decide in each case the technique employed to secure an adequate level of control of the public health threat as provided in these Regulations. Where there are methods or materials advised by WHO for these procedures, these should be employed, unless the competent authority determines that other methods are as safe and reliable.

¹ See footnote under Article 20(1)(f).

The competent authority may implement additional health measures, including isolation of the conveyances, as necessary, to prevent the spread of disease. Such additional measures should be reported to the National Focal Point.

2. If the competent 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 competent authority shall, at the time of departure, inform the competent authority for the next known point of entry of the type of information referred to under subparagraph (b); and
- (b) in the case of a ship, the evidence found and the control measures required shall be noted in the Ship Sanitation Control Certificate.

Any such conveyance shall be permitted to take on, under the supervision of the competent authority, fuel, water and supplies.

3. A conveyance that has been considered as affected shall cease to be regarded as such when the competent authority is satisfied that:

- (a) the measures provided in paragraph 1 of this Article have been effectively carried out; and
- (b) there are no conditions on board that could constitute a public health threat.

Article 25 Ships or aircraft at points of entry

1. Subject to Article 39 or as provided in applicable international agreements, a ship or an aircraft shall not be prevented for public health reasons from calling at any point of entry. However, if the point of entry is not equipped for applying health measures under these Regulations, the ship or aircraft may be ordered to proceed at its own risk to the nearest suitable point of entry available to it, unless the ship or aircraft has an operational problem which would make this diversion unsafe.

2. Subject to Article 39 or as provided in applicable international agreements, ships or aircraft shall not be refused *free pratique* by States Parties for public health reasons; in particular they shall not be prevented from embarking or disembarking, discharging or loading cargo or stores, or taking on fuel, water and supplies. States Parties may subject the granting of *free pratique* to inspection and, if a source of infection or contamination is found on board, the carrying out of necessary disinfection, decontamination, disinsection or deratting, or other measures necessary to prevent the spread of the infection or contamination.

3. Whenever practicable and subject to the previous paragraph, a State Party shall authorize the granting of *free pratique* by radio or other communication means to a ship or an aircraft when on the basis of information received from it prior to its arrival, the State Party is of the opinion that the arrival of the ship or aircraft will not result in the introduction or spread of disease.

4. Officers in command of ships or pilots in command of aircraft, or their agents, shall make known to the port or airport control as early as possible before arrival at the port or airport of destination any cases of illness indicative of a disease of an infectious nature or evidence of a public health threat on board as soon as such illnesses or public health threats are made known to the officer

or pilot. This information must be immediately relayed to the competent authority for the port or airport. In urgent circumstances, such information should be communicated directly by the officers or pilots to the relevant port or airport authority.

5. The following shall apply if a suspect or affected aircraft or ship, for reasons beyond the control of the pilot in command or the officer in command of the ship, lands elsewhere than at the airport at which the aircraft was due to land or berths elsewhere than at the port at which the ship was due to berth:

- (a) the pilot in command or the officer in command of the ship or other person in charge shall make every effort to communicate without delay with the nearest competent authority;
- (b) as soon as the competent authority has been informed of the landing it may apply health measures recommended by WHO or other health measures provided in these Regulations;
- (c) unless required for emergency purposes or for communication with the competent authority, no traveller on board the aircraft or ship shall leave its vicinity and no cargo shall be removed from that vicinity, unless authorized by the competent authority; and
- (d) when all health measures required by the competent authority have been completed, the aircraft or ship may, so far as such health measures are concerned, proceed either to the airport or port at which it was due to land or berth, or, if for technical reasons it cannot do so, to a conveniently situated airport or port.

6. Notwithstanding the provisions contained in this Article, the officer in command of a ship or pilot in command of an aircraft may take such emergency measures as may be necessary for the health and safety of travellers on board. He or she shall inform the competent authority as early as possible concerning any measures taken pursuant to this paragraph.

Chapter III – Special provisions for travellers

Article 26 Travellers under public health observation

Subject to Article 39 or as authorized in applicable international agreements, a suspect traveller who on arrival is placed under public health observation may continue an international voyage, if the traveller does not pose an imminent public health risk and the State Party informs the competent authority of the point of entry at destination, if known, of the traveller's expected arrival. On arrival, the traveller shall report to that authority.

Article 27 Health measures relating to entry of travellers

1. Invasive medical examination, vaccination or other prophylaxis shall not be required as a condition of entry of any traveller to the territory of a State Party, except that, subject to Articles 28, 38 and 42, these Regulations do not preclude States Parties from requiring medical examination, vaccination or other prophylaxis:

- (a) as a condition of entry for any travellers seeking temporary or permanent residence;
- (b) as a condition of entry for any travellers pursuant to Article 39 or Annexes 6 and 7; or

- (c) which may be carried out pursuant to Article 21.

2. If a traveller for whom a State Party may require medical examination, vaccination or other prophylaxis under paragraph 1 of this Article fails to consent to any such measure, or refuses to provide the information or the documents referred to in paragraph 1(a) of Article 21, the State Party concerned may, subject to Articles 28, 38, and 42, deny entry to that traveller, or if there is evidence of an imminent public health threat and to the extent necessary to control such a threat, it may compel the traveller to undergo:

- (a) the least invasive and intrusive medical examination that would achieve the public health objective;
- (b) vaccination or other prophylaxis; or
- (c) additional established health measures that prevent or control the spread of disease, including isolation, quarantine or placing the traveller under public health observation.

Article 28 Treatment of travellers

In implementing health measures under these Regulations, States Parties shall treat travellers with respect for their dignity and fundamental human rights and minimize any discomfort or distress associated with such measures, including by:

- (a) treating all travellers with courtesy and respect;
- (b) taking into consideration the gender, socio-cultural or religious concerns of travellers; and
- (c) providing or arranging for adequate food and water, appropriate accommodation and clothing, protection for baggage and other possessions, appropriate medical treatment, means of necessary communication and other appropriate assistance for travellers who are quarantined, isolated or subject to medical examinations or other procedures for public health purposes.

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

Article 29 Goods in transit

Subject to Article 39 or unless authorized by applicable international agreements, goods, other than live animals, in transit without transshipment, shall not be subject to health measures under these Regulations or detained for public health purposes.

Article 30 Container and container loading areas

1. States Parties shall ensure, as far as practicable, that container shippers use international traffic containers that are kept free from sources of infection or contamination, including vectors and reservoirs, particularly during the course of packing.
2. States Parties shall ensure, as far as practicable, that container loading areas are kept free from sources of infection or contamination, including vectors and reservoirs.

3. Whenever in the opinion of a State Party, the volume of international container traffic is sufficiently large, the competent authorities shall take all practicable measures consistent with these Regulations, including carrying out inspections, to assess the sanitary condition of container loading areas and containers, to ensure that the obligations contained in these Regulations are implemented.
4. Facilities for the inspection and isolation of containers shall, as far as practicable, be available at container loading areas.
5. Container consignees and consignors shall make every effort to avoid cross contamination when multiple-use loading of containers is employed.

PART VI – HEALTH DOCUMENTS

Article 31 General rule

[Subject to Article 39,] no health documents, other than those provided for under these Regulations or in recommendations issued by WHO, shall be required in international traffic, provided however that this Article shall not apply to travellers seeking temporary or permanent residence, nor shall it apply to document requirements concerning the public health status of goods or cargo in international trade pursuant to applicable international agreements.

Article 32 Certificates of vaccination or other prophylaxis

1. Vaccines and prophylaxis for travellers administered pursuant to these Regulations or to recommendations, and certificates relating thereto, shall conform to the provisions of Annex 6 and, when applicable, Annex 7 with regard to specific diseases.
2. 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 competent authority has indications or evidence that the vaccination or other prophylaxis was not effective.

Article 33 Maritime Declaration of Health

1. The master of a ship, before arrival at its first port of call in the territory of a State Party, shall ascertain the state of health on board, and, except when that State Party does not require it, the master shall, on arrival, or in advance of the vessel's arrival if the vessel is so equipped and the State Party requires such advance delivery, complete and deliver to the competent 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 that authority as to health conditions on board during an international voyage.
3. A Maritime Declaration of Health shall conform to the model provided in Annex 8.

4. A State Party 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 State Party shall inform shipping operators or their agents of these requirements.

Article 34 Health Part of the Aircraft General Declaration

1. The pilot in command of an aircraft or the pilot's agent, in flight or upon landing at the first airport in the territory of a State Party, shall, except when that State Party does not require it, complete and deliver to the competent authority for that airport the Health Part of the Aircraft General Declaration which shall conform to the model specified in Annex 9.¹
2. The pilot in command of an aircraft or the pilot's agent shall supply any information required by the State Party as to health conditions on board during an international voyage and any health measure applied to the aircraft.
3. A State Party 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 which might otherwise carry infection or contamination.

The State Party shall inform aircraft operators or their agents of these requirements.

Article 35 Ship sanitation certificates

1. 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.
2. If a valid Ship Sanitation Control Exemption Certificate or Ship Sanitation Control Certificate is not produced or evidence of a public health threat is found on board a ship, the State Party may proceed as provided in paragraph 1 of Article 24 of these Regulations.
3. The certificates referred to in this Article shall conform to the model in Annex 3.
4. Whenever possible, control measures shall be carried out when the ship and holds are empty. In the case of a ship in ballast, it shall be done before loading.

¹ Annex 9 is part of the General Declaration for aircraft promulgated by the International Civil Aviation Organization (ICAO).

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

6. The competent authority may issue a Ship Sanitation Control Exemption Certificate at any port specified under Article 18 of these Regulations if it is satisfied that the ship is free of infection and contamination, including vectors and reservoirs. Such a certificate shall normally be issued only if the inspection of the ship has been carried out when the ship and 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.

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

[Article 35bis Ground Transport Health Document¹]

PART VII – CHARGES

Article 36 Charges for health measures

1. Except for travellers seeking temporary or permanent residence, no charge [other than those based on the actual cost to the competent authority or fair market value (if actual cost cannot be determined)] shall be made by a State Party for:

- (a) any medical examination provided for in these Regulations, or any supplementary examination, microbiological or otherwise, which may be required by that State Party to ascertain the health status of the traveller examined;
- (b) any vaccination or other prophylaxis provided to a traveller on arrival, and any certificate thereof required by the State Party; or
- (c) any isolation or quarantine requirement of travellers.

2. Where charges are made for applying the health measures provided for in these Regulations, [other than those referred to in paragraph 1 of this Article,] there shall be in each State Party only one tariff for such charges and every charge shall:

- (a) conform to this tariff;
- (b) not exceed the actual cost of the service rendered; and
- (c) be levied without distinction as to the nationality, domicile, or residence of the traveller concerned, or as to the nationality, flag, registry or ownership of conveyances, containers,

¹ See Information note “Ground Crossings and Ground Transport Conveyances in the International Health Regulations” prepared by the Secretariat (A/IHR/IGWG/2/INF.DOC./3).

cargo, goods, baggage or postal parcels. In particular, there shall be no distinction made between national and foreign travellers, conveyances, containers, cargo, goods or baggage.

3. The tariff, and any amendment thereto, shall be published at least ten days in advance of any levy thereunder.

Article 37 Charges for certificates

The State Party shall, when so requested, after applying health measures pursuant to these Regulations to travellers and their baggage, issue [free of charge] to any traveller a certificate specifying the date of the traveller's arrival or departure and the health measures applied.

PART VIII – GENERAL PROVISIONS

Article 38 Implementation of health measures

Health measures taken pursuant to these Regulations shall be initiated and completed without delay, and applied in a transparent and non-discriminatory manner.

Article 39 Additional health measures

1. These Regulations shall not preclude States Parties from implementing health measures, in accordance with their national health legislation and obligations under international law, which differ from those recommended under the Regulations or are otherwise prohibited under Article 23, paragraphs 1 and 2 of Article 25, Article 26, paragraph 1 of Article 27, [or] Article[s] 29 [or 31] in response to specific public health threats or public health emergencies of international concern provided such measures are not otherwise inconsistent with these Regulations. In determining whether to implement any such measures, States Parties shall base their determinations upon scientific principles and scientific evidence of a risk to human health, or where such evidence is insufficient, the available information including from WHO and other relevant international organizations. Such measures shall not be more restrictive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection.

2. Upon request by WHO, a State Party implementing such a measure shall provide to WHO the public health rationale and scientific information for it. WHO may share this information with other States Parties.

3. After assessing information provided pursuant to paragraph 2 of this Article and other relevant information, WHO may request that the State Party concerned ceases the application of that measure or fully implements the recommended measure.

- [4. States Parties shall inform WHO within 48 hours of implementation of health measures they implement that significantly interfere with international traffic and which they are applying based on an event in an area not covered by a temporary or standing recommendation. Significant interference means refusal of entry or departure or delaying, for more than 24 hours, the entry or departure of conveyances or of travellers.]

5. A State Party implementing a health measure pursuant to paragraph 1 of this Article shall within 90 days review such a measure taking into account the advice of WHO and new scientific evidence.
6. Without prejudice to their rights under Article 57, any State Party impacted by a measure taken pursuant to paragraph 1 of this Article may request the State Party implementing such a measure to consult with it. The purpose of such consultations is to clarify the scientific information and public health rationale underlying the measure and to find a mutually acceptable solution.
7. Health measures implemented by a State Party which conform to WHO recommendations shall be deemed to comply with these Regulations.
8. The provisions of this Article may apply to implementation of measures concerning travellers taking part in periodic mass congregations.

Article 40 Cessation or full implementation of health measures

[merged with Article 39]

Article 41 Collaboration and assistance

1. States Parties undertake to collaborate with each other, to the extent possible, in:
 - (a) the detection and assessment of, and response to, events as provided under these Regulations;
 - (b) the provision or facilitation of technical cooperation and logistical support, particularly in the development and strengthening of the public health capacities required under these Regulations;
 - (c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and
 - (d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations.
2. WHO shall collaborate with States Parties, to the extent possible, in:
 - (a) the evaluation and assessment of their public health capacities in order to facilitate the effective implementation of these Regulations;
 - (b) the provision or facilitation of technical cooperation and logistical support to States Parties; and
 - (c) the mobilization of financial resources to support developing countries in building and strengthening of the capacities provided for in Annex 1.
3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through international organizations.

Article 42 Treatment of personal data

1. Health information collected or received pursuant to these Regulations by States Parties or by WHO, which refers to an identified or identifiable person shall be kept confidential except to the extent necessary to disclose or transmit it for public health purposes or as required by national legislation.

[2. Where the processing of personal data is essential for the purposes of assessing and managing a public health emergency of international concern or a public health threat, the States Parties and WHO must ensure that personal data is:

- (a) processed lawfully; and not further processed in a way incompatible with that purpose;
- (b) relevant and not excessive in relation to that purpose;
- (c) accurate and, where necessary, kept up to date, every reasonable step must be taken to ensure that data which are inaccurate or incomplete are erased or rectified; and
- (d) not kept longer than necessary for that purpose.^{1]}

Article 43 Travellers enjoying immunities under international law

Nothing in these Regulations shall affect the rights and obligations of States Parties under international law in respect to diplomatic agents and other representatives enjoying immunities under international law. States Parties shall require that their diplomatic agents and other representatives enjoying immunities under international law comply with health measures adopted pursuant to these Regulations, without prejudice to such immunities.

Article 44 Transport and handling of diagnostic materials

States Parties shall, subject to national regulatory requirements and taking into account relevant international guidelines, facilitate the transport, entry, exit, processing and disposal of specimens, reagents and other diagnostic materials for verification and response purposes under these Regulations.

Article 44bis Armed forces

States Parties shall² ensure that their military personnel, conveyances, containers, cargo, goods, baggage and postal parcels meet the requirements of these Regulations.

[Article 45 Information sharing during a suspected intentional release]

[If a State Party has evidence that there has been an intentional release of a biological, chemical or radionuclear agent within its territory, it shall, consistent with its national and international security

¹ The provision may require further discussion.

² Under the current Regulations (1969) no exception is made for armed forces.

and law enforcement requirements, provide to WHO all relevant public health information, materials and samples, for verification and response purposes.]

Article 46 Armed forces

[moved as new Article 44bis]

**PART IX – THE IHR ROSTER OF EXPERTS, THE EMERGENCY
COMMITTEE AND THE REVIEW COMMITTEE**

Chapter I – The IHR Roster of Experts

Article 47 Composition

1. The Director-General shall establish a roster composed of experts in all relevant fields of expertise (hereinafter the “IHR Expert Roster”). In establishing the membership of the IHR Expert Roster, the Director-General shall follow, unless otherwise provided in these Regulations, the WHO Regulations for Expert Advisory Panels and Committees (hereinafter the “WHO Advisory Panel Regulations”). The Director-General shall periodically inform the States Parties, the Executive Board and the Health Assembly of the composition of the IHR Expert Roster.
2. The Director-General shall appoint the members of the IHR Expert Roster in accordance with the WHO Advisory Panel Regulations. In addition, the Director-General shall appoint one member at the request of each State Party and, where appropriate, experts proposed by relevant intergovernmental and regional economic integration organizations. Interested States Parties shall notify the Director-General of the qualifications and field of expertise of each of the experts they propose for membership.

Chapter II - The Emergency Committee

Article 48 Terms of reference and composition

1. The Director-General shall establish an Emergency Committee to advise on whether an event constitutes a public health emergency of international concern, on the termination of a public health emergency of international concern, as well as on the issuance, modification, extension and termination of temporary recommendations, at the request of the Director-General.
2. The Emergency Committee shall be composed of experts selected by the Director-General from the IHR Expert Roster and, when appropriate, other expert advisory panels of the Organization. The Director-General shall determine the duration of membership with a view to ensuring its continuity in the consideration of a specific event and its consequences. The Director-General shall select the members of the Emergency Committee on the basis of the expertise and experience required for any particular session and with due regard to the principles of equitable geographical representation.
3. The Director-General may, on his or her own initiative or at the request of the Emergency Committee, appoint one or more technical experts to advise the Committee.

Article 49 Procedure

1. The Director-General shall convene meetings of the Emergency Committee by selecting a number of experts from among those referred to in paragraph 2 of Article 48, according to the fields of expertise and experience most relevant to the specific event that is occurring. For the purpose of this Article, “meetings” of the Emergency Committee may include teleconferences, videoconferences or electronic communications.
2. The Director-General shall provide the Emergency Committee with the agenda and any relevant information concerning the event, including information provided by the States Parties, as well as any temporary recommendation that the Director-General proposes for issuance.
3. The Emergency Committee shall elect its Chairperson and prepare following each meeting a brief summary report of its proceedings and deliberations, including any recommendations.
4. The Director-General shall invite the State Party in whose territory the event arises to present its views to the Emergency Committee. To that effect, the Director-General shall notify it the dates and the agenda of the meeting of the Emergency Committee with as much advance notice as necessary. The State Party concerned, however, may not seek a postponement of the meeting of the Emergency Committee for the purpose of presenting its views thereto.
5. The Emergency Committee shall provide its views on:
 - (a) whether an event constitutes a public health emergency of international concern;
 - (b) the termination of a public health emergency of international concern; and
 - (c) the proposed adoption, modification, extension or termination of temporary recommendations.

The views of the Emergency Committee shall be forwarded to the Director-General for consideration.

6. The Director-General shall make the final determination on these matters.
7. The Director-General shall communicate to States Parties the determination and the termination of a public health emergency of international concern, any health measure taken by the State Party concerned, any temporary recommendation, as well as the modification, extension and termination of such recommendations, together with the views of the Emergency Committee. The Director-General shall inform conveyance operators through States Parties and the relevant international agencies of such temporary recommendations, including their modification, extension or termination. The Director-General may subsequently make such information and recommendations available to the general public.
8. States Parties in whose territories the event has occurred may propose to the Director-General the termination of a public health emergency of international concern and/or the temporary recommendations, and may request to make a presentation to that effect to the Emergency Committee.

Chapter III – The Review Committee

Article 50 Terms of reference and composition

1. The Director-General shall establish a Review Committee, which shall carry out the following functions:
 - (a) at the request of the Health Assembly review the functioning of these Regulations;
 - (b) make technical recommendations to the Director-General regarding amendments to these Regulations;
 - (c) provide technical advice to the Director-General with respect to standing recommendations, and any modifications or termination thereof;
 - (d) provide technical advice to the Health Assembly or the Executive Board on any matter referred to it by them regarding implementation of these Regulations; and
 - (e) provide technical advice to the Director-General on any matter referred to it by the Director-General regarding the implementation of these Regulations.
2. The Review Committee shall be considered an expert committee and shall be subject to the WHO Advisory Panel Regulation, unless otherwise provided in this Article.
3. The Members of the Review Committee shall be selected and appointed by the Director-General from among the persons serving on the IHR Expert Roster and, when appropriate, other expert advisory panels of the Organization.
4. The Director-General shall establish the number of members to be invited to a meeting of the Review Committee, determine its date and duration, and convene the Committee.
5. The Director-General shall appoint members to the Review Committee for the duration of the work of a session only. The Director-General shall select the members of the Review Committee on the basis of the principles of equitable geographical representation, gender balance, a balance of experts from developed and developing countries, representation of different trends of thought, approaches and practical experience in various parts of the world, and an appropriate interdisciplinary balance.

Article 51 Conduct of business

1. Decisions of the Review Committee shall be taken by a majority of the members present and voting.
2. The Director-General shall invite Member States, the United Nations and its specialized agencies and other relevant intergovernmental organizations or nongovernmental organizations in official relations with WHO to designate representatives to attend the Committee sessions. 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.

Article 52 Reports

1. For each session, the Review Committee shall draw up a report setting forth the Committee's views and advice. This report shall be approved by the Review 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.
2. If the Review Committee is not unanimous in its findings, any member shall be entitled to express personal opinions 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.
3. Except for advice under Article 56, the Review Committee's report shall be submitted to the Director-General, who shall communicate its views and advice to the Health Assembly or the Executive Board for their consideration and action.

Article 53 Consideration of disputes

[deleted]

Article 54 Standing recommendations

When the Director-General considers that a standing recommendation is necessary and appropriate for a specific public health threat, the Director-General shall seek the views of the Review Committee. In addition to the relevant paragraphs of Articles 50 to 52, the following provisions shall apply:

- (a) proposals for standing recommendations, their modification or termination may be submitted to the Review Committee by the Director-General or by States Parties through the Director-General;
- (b) any State Party may submit relevant information for consideration by the Review Committee;
- (c) the Director-General may request any State Party, intergovernmental organization or nongovernmental organization in official relations with WHO to place at the disposal of the Review Committee information in its possession concerning the subject of the proposed standing recommendation as specified by the Review Committee;
- (d) the Director-General may, at the request of the Review Committee or on the Director-General's own initiative, appoint one or more technical experts to advise the Review Committee. They shall not have the right to vote;
- (e) any report containing the views and advice of the Review Committee regarding standing recommendations shall be forwarded to the Director-General for consideration and decision. The Director-General shall communicate the Review Committee's views and advice to the Health Assembly;
- (f) the Director-General shall communicate to States Parties any standing recommendation, as well as the modifications or termination of such recommendations, together with the views of the Review Committee;

- (g) standing recommendations shall be submitted by the Director-General to the subsequent Health Assembly for its consideration.

PART X – FINAL PROVISIONS

Article 55 Reporting and review

1. States Parties shall report to the Health Assembly on the implementation of these Regulations as decided by the Health Assembly.
2. The Health Assembly shall periodically review the functioning of these Regulations. To that end it may request the advice of the Review Committee pursuant to Article 50(1)(a). The first such review shall take place no later than five years after the entry into force of these Regulations.

Article 56 Amendments

1. Amendments to these Regulations may be proposed by any State Party or by the Director-General. Such proposals for amendments shall be submitted to the Health Assembly for its consideration.
2. The text of any proposed amendment shall be communicated to all States Parties by the Director-General at least four months before the Health Assembly at which they are proposed for consideration.
3. Amendments to these Regulations adopted by the Health Assembly pursuant to this Article shall come into force for all States Parties 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 60 to 65 of these Regulations.

Article 57 Settlement of disputes between States Parties

1. In the event of a dispute between two or more States Parties concerning the interpretation or application of these Regulations, the States Parties concerned shall seek to settle the dispute through negotiation or any other peaceful means of their own choice, including good offices, mediation, or conciliation. Failure to reach agreement shall not absolve the parties to the dispute from the responsibility of continuing to seek to resolve it.
2. The States Parties concerned may refer the dispute to the Director-General, who shall make every effort to settle it.
3. A State Party may at any time declare in writing to the Director-General that it accepts arbitration as compulsory with regard to all disputes concerning the interpretation or application of these Regulations to which it is a party or with regard to a specific dispute in relation to any other State Party accepting the same obligation. The arbitration shall be conducted in accordance with the Permanent Court of Arbitration Optional Rules for Arbitrating Disputes between Two States applicable at the time a request for arbitration is made. The States Parties that have agreed to accept arbitration as compulsory shall accept the arbitral award as binding and final.

4. Nothing in these Regulations shall impair the rights of States Parties under any international agreement to which they may be parties to resort to the dispute settlement mechanisms of other intergovernmental organizations or established under any international agreement.

Article 58 Relationship with other international agreements

1. States Parties recognize that the IHR and other relevant international agreements should be interpreted so as to be compatible. The provisions of the IHR shall not affect the rights and obligations of any State Party deriving from other international agreements, [provided they do not represent a direct conflict with these Regulations].

2. Subject to paragraph 1 of this Article, nothing in these Regulations shall prevent States Parties having certain interests in common owing to their health, geographical, social or economic conditions, from concluding special treaties or arrangements 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 or affected human remains by means of transport specially adapted for the purpose; and
- (f) disinfection, decontamination or other treatment designed to render goods free of disease-causing agents.

3. Without prejudice to their obligations under these Regulations, States Parties that are members of a regional economic integration organization shall apply in their mutual relations the common rules in force in that regional economic integration organization.

Article 59 International sanitary agreements and regulations

1. These Regulations, subject to the provisions of Article 62 and the exceptions hereinafter provided, shall replace as between the States bound by these Regulations and as between these States and WHO, the provisions of the following international sanitary agreements and regulations:

- (a) International Sanitary Convention, signed in Paris, 21 June 1926;
- (b) International Sanitary Convention for Aerial Navigation, signed at The Hague, 12 April 1933;
- (c) International Agreement for dispensing with Bills of Health, signed in Paris, 22 December 1934;

- (d) International Agreement for dispensing with Consular Visas on Bills of Health, signed in Paris, 22 December 1934;
 - (e) Convention modifying the International Sanitary Convention of 21 June 1926, signed in Paris, 31 October 1938;
 - (f) International Sanitary Convention, 1944, modifying the International Sanitary Convention of 21 June 1926, opened for signature in Washington, 15 December 1944;
 - (g) International Sanitary Convention for Aerial Navigation, 1944, modifying the International Sanitary Convention of 12 April 1933, opened for signature in Washington, 15 December 1944;
 - (h) Protocol of 23 April 1946 to prolong the International Sanitary Convention, 1944, signed in Washington;
 - (i) Protocol of 23 April 1946 to prolong the International Sanitary Convention for Aerial Navigation, 1944, signed in Washington;
 - (j) International Sanitary Regulations, 1951, and the Additional Regulations of 1955, 1956, 1960, 1963 and 1965; and
 - (k) the International Health Regulations of 1969 and the amendments of 1973 and 1981.
2. The Pan American Sanitary Code, signed at Havana, 14 November 1924, shall remain 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 60 Entry into force; period for rejection or reservations

1. The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, these Regulations or an amendment thereto, shall be [__]¹ from the date of the notification by the Director-General of the adoption of these Regulations or of an amendment to these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.
2. These Regulations shall enter into force [__]¹ after the date of notification referred to in paragraph 1 of this Article, except for:
- (a) a State that has rejected the Regulations or an amendment thereto in accordance with Article 61;
 - (b) a State that has made a reservation, for which the Regulations shall enter into force as provided in Article 62;

¹ The period proposed by the Secretariat in document A/IHR/IGWG/3 was twelve months. A proposal was made to change it to three years.

- (c) a State that becomes a Member of WHO after the date of the notification by the Director-General referred to in paragraph 1 of this Article, and which is not already a party to these Regulations, for which the Regulations shall enter into force as provided in Article 60bis; and
- (d) a State not a Member of WHO that accepts these Regulations, for which they shall enter into force in accordance with paragraph 1 of Article 65.

Article 60bis New Member States of WHO

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 60, and which is not already a party to these Regulations, may communicate its rejection of, or any reservation to, these Regulations within a period of twelve 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 62, upon expiry of that period.

Article 61 Rejection

If a State notifies the Director-General of its rejection of these Regulations or of an amendment thereto within the period provided in paragraph 1 of Article 60, these Regulations or the amendment concerned shall not enter into force with respect to that State. Any international sanitary agreement or regulations listed in Article 59 to which such State is already a party shall remain in force as far as such State is concerned.

Article 62 Reservations¹

1. If any State makes a reservation to these Regulations, such reservation shall not be valid unless it is accepted by the Health Assembly, and these Regulations shall not enter into force with respect to that State until such reservation has been accepted by the Health Assembly or until it has been withdrawn if the Health Assembly objects to it on the grounds that it is incompatible with the object and purpose of these Regulations.
2. If, pursuant to paragraph 1 of this Article, a State does not become bound by these Regulations, any international sanitary agreement or regulations listed in Article 59 to which that State is already a party shall remain in force as far as such State is concerned.
3. If any State makes a reservation to an amendment to these Regulations, such reservation shall not be valid unless it is accepted by the Health Assembly, and the amendment concerned shall not enter into force with respect to that State until such reservation has been accepted by the Health Assembly or until it has been withdrawn if the Health Assembly objects to it on the grounds that it is incompatible with the object and purpose of these Regulations.
4. A rejection in part of these Regulations or an amendment to the Regulations shall be considered as a reservation.

¹ The provision should be considered in light of the information document prepared by the Secretariat on reservations (A/IHR/IGWG/2/INF.DOC./2). The first of the two alternatives is based on Article 88 of the current Regulations (1969).

5. If the Health Assembly accepts a reservation, the reserving State shall be bound by these Regulations or the amendment concerned as of the date of the acceptance of the reservation by the Health Assembly, subject to the reservation.

6. The 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 fulfil any obligations corresponding to the subject matter of such reservation, which such State has previously accepted under any international sanitary agreement or regulations listed in Article 59.

7. If a State makes a reservation which in the opinion of the Health Assembly detracts to an insubstantial extent from an obligation or obligations previously accepted by that State under any international sanitary agreement or regulations listed in Article 59, the Health Assembly may accept such reservation without requiring as a condition of its acceptance an undertaking of the kind referred to in paragraph 6 of this Article.]

or

[1. WHO Member States may make reservations to these Regulations or any amendment thereof within twelve months from the date on which the Director-General communicates the acceptance by the Health Assembly of these Regulations or of any such amendment. Non-Member States may make reservations to these Regulations or any amendment thereof when notifying the Director-General of their acceptance of these Regulations or amendments.

2. The reserving State shall be bound by these Regulations or the amendment concerned, subject to the reservation.

3. The reserving State shall continue to fulfil any obligations corresponding to the subject matter of such reservation, which the State has accepted under any of the international sanitary agreements or regulations listed in Article 59.]

Article 63 Withdrawal of rejection or reservation

1. A rejection made under Article 61 may at any time be withdrawn by a State by notifying the Director-General. In such cases, the Regulations will come into force with regard to that State upon receipt by the Director-General of the notification [, except where the State makes a reservation when withdrawing its rejection, in which case the Regulations shall enter into force as provided in Article 62]. [In no case shall the Regulations enter into force in respect to that State earlier than [] after the date of notification referred to in paragraph 1 of Article 60.]

2. The whole or part of any reservation may at any time be withdrawn by the State Party concerned by notifying the Director-General. In such cases, the withdrawal will be effective from the date of receipt by the Director-General of the notification.

Article 64 New Member States of WHO

[moved to Article 60bis]

Article 65 States not Members of WHO

1. Any State not a Member of WHO, which is a party to any international sanitary agreement or regulations listed in Article 59 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 62, 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. 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 the Director-General has received it. The State which has withdrawn shall, as from that date, resume application of the provisions of any international sanitary agreement or regulations listed in Article 59 to which it was previously a party.

Article 66 Notifications by the Director-General

1. The Director-General shall notify all States Members and Associate Members of WHO, and also other parties to any international sanitary agreement or regulations listed in Article 59 of the adoption by the Health Assembly of these Regulations.

2. The Director-General shall also notify these States, as well as any other State which has become a party to these Regulations or to any amendment to these Regulations, of any notification received by WHO under Articles 61 to 65 respectively, as well as of any decision taken by the Health Assembly under Article 62.

Article 67 Authentic texts

1. The Arabic, Chinese, English, French, Russian and Spanish texts of these Regulations shall be equally authentic. The original texts of these Regulations shall be deposited with WHO.

2. The Director-General shall send, with the notification provided in paragraph 1 of Article 60, certified copies of these Regulations to all Members and Associate Members, and also to other parties to any of the international sanitary agreements or regulations listed in Article 59.

3. Upon the entry into force of these Regulations, the Director-General shall deliver certified copies thereof 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. States Parties shall utilize existing national structures and resources to meet their core capacity requirements under these Regulations, including with regard to:
 - (a) their surveillance, reporting, notification, verification, response and collaboration activities; and
 - (b) their activities concerning designated airports, ports and ground crossings.
2. Each State Party shall assess, within two years following the entry into force of these Regulations, the ability of existing national structures and resources to meet the minimum requirements described in this Annex. As a result of such assessment, States Parties shall develop and implement plans of action to ensure that these core capacities are present and functioning throughout their territories as set out in paragraph 1 of Article 4 and paragraph 1 of Article 11.
3. States Parties and WHO shall support assessments, planning and implementation processes under this Annex.

1. At the local community level

The capacities:

- (a) to detect events involving disease or death above expected levels for the particular time and place in all areas within the territory of the State Party; and
- (b) to report all available essential information immediately to health-care institutions in the local community or the appropriate health personnel. For the purposes of this Annex, essential information includes the following: clinical descriptions, laboratory results, sources and type of risk, numbers of human cases and deaths, conditions affecting the spread of the disease and the health measures employed.

2. At the first and intermediate public health response levels

The capacities:

- (a) to confirm the status of 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. For the purposes of this Annex, the criteria for urgent events include serious public health impact and/or unusual or unexpected nature with high potential for spread.

3. At the national level

Assessment and notification. The capacities:

- (a) to assess all reports of urgent events within [twenty-four]/[forty-eight]¹ hours; and
- (b) to notify WHO immediately through the National IHR Focal Point when the assessment indicates the event is notifiable pursuant to paragraph 1 of Article 5 and Annex 2 and to inform WHO as required pursuant to paragraph 2 of Article 7 [and Article 45].

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 relevant government ministries;
- (f) to provide, by the most efficient means of communication available, links with hospitals, clinics, airports, ports, ground crossings, laboratories and other key operational areas, for the dissemination of information and recommendations received from WHO regarding events in the State Party's own territory and in the territories of other States Parties;
- (g) to establish, operate and maintain a national public health emergency response plan, including the creation of multidisciplinary/multisectoral teams to respond to events that may constitute a public health emergency of international concern; 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 (i) an appropriate medical service including diagnostic facilities located so as to allow the prompt assessment and care of ill travellers, and (ii) adequate staff, equipment and premises;

¹ The issue of time frames may need to be considered as a whole.

- (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 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, by conducting inspection programmes, as appropriate; and
- (e) to provide a programme and trained personnel for the control of vectors and reservoirs in and near points of entry.

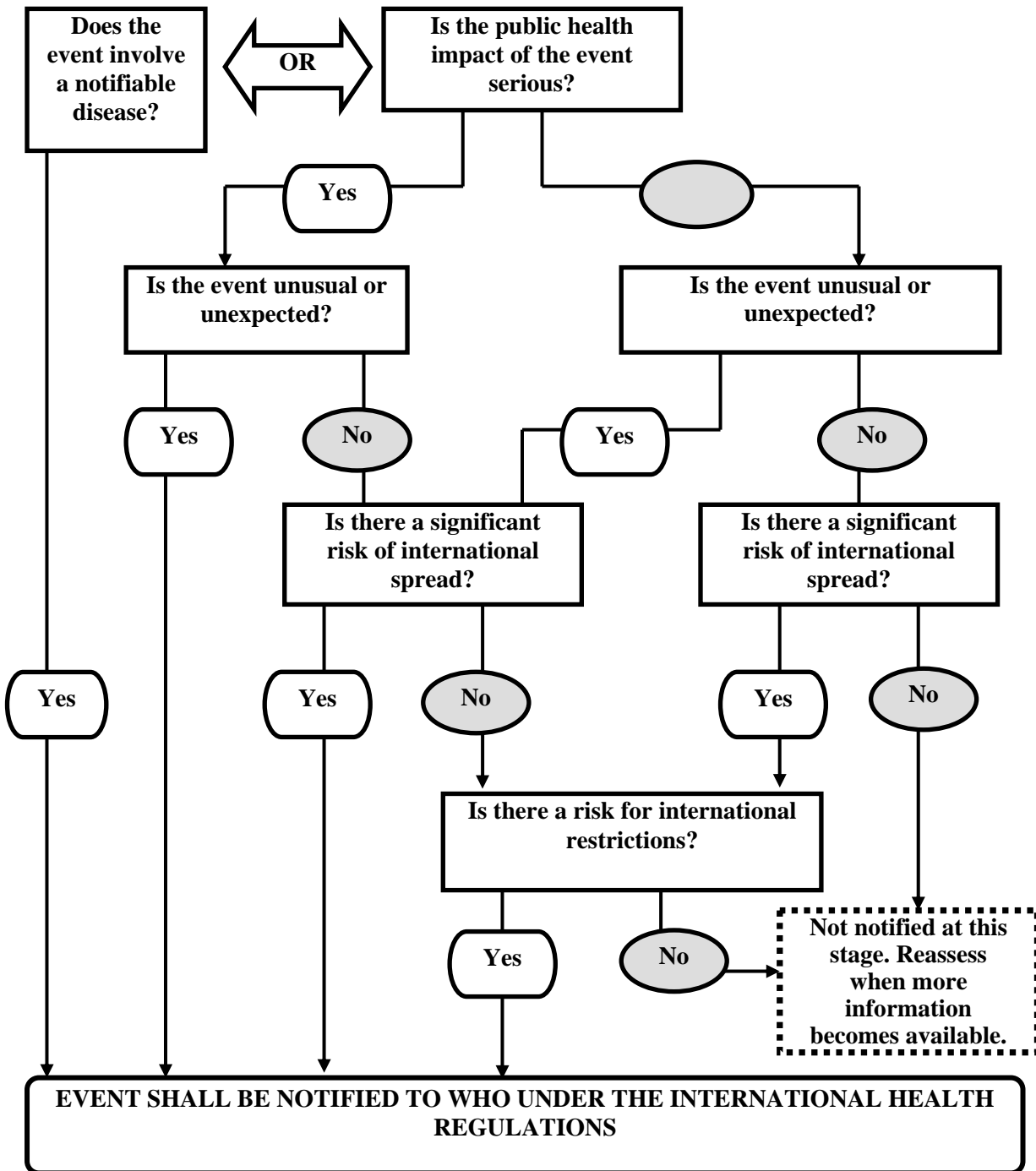
2. For responding to events that may constitute a public health emergency of international concern

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;
- (b) to provide assessment of and care for affected travellers or animals by establishing arrangements with local medical and veterinary facilities for their isolation, treatment and other support services that may be required;
- (c) to provide appropriate space, separate from other travellers, to interview suspects or affected persons;
- (d) to provide for the assessment and, if required, quarantine of suspect travellers, preferably in facilities away from the point of entry;
- (e) to apply recommended measures to disinfect, decontaminate or otherwise treat conveyances, containers, cargo, goods or baggage including, when appropriate, at locations specially designated and equipped for this purpose;
- (f) to apply entry or exit controls for arriving and departing travellers; 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 2¹

PART A DECISION INSTRUMENT FOR THE ASSESSMENT AND NOTIFICATION OF EVENTS THAT MAY CONSTITUTE A PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN*



¹ No change has been made to Annex 2 from the text proposed by the Secretariat (A/IHR/IGWG/3) pending the recommendations of the Ad Hoc Expert group which will report to the next session of the IGWG.

* The decision instrument shall be used by States Parties to assess the need to notify events irrespective of etiology, and, in addition, it shall be used to assess all events that involve, or are considered likely to involve, the diseases listed in Part B of this Annex.

DOES THE EVENT INVOLVE A NOTIFIABLE DISEASE?

A single diagnosed case of any of the following diseases is of international concern and shall therefore be notified to WHO:

- Smallpox
- Poliomyelitis (occurring in an area following eradication)
- Coronavirus-associated Severe Acute Respiratory Syndrome (SARS)

IF THE EVENT DOES NOT INVOLVE A NOTIFIABLE DISEASE, DOES IT MEET AT LEAST TWO OF THE FOLLOWING CRITERIA?

Is the public health impact of the event serious?	I. Is the public health impact of the event serious?
	1. <i>Is the number of cases and/or number of deaths for this type of event large for the given place and time?</i>
	2. <i>Has the event the potential to have a high public health impact?</i> THE FOLLOWING ARE EXAMPLES OF CIRCUMSTANCES THAT CONTRIBUTE TO HIGH PUBLIC HEALTH IMPACT: <ul style="list-style-type: none"> ✓ Event caused by a pathogen with high potential to cause epidemic (infectiousness of the agent, high case fatality, multiple transmission routes or healthy carrier). ✓ Indication of treatment failure (new or emerging antibiotic resistance, vaccine failure, antidote resistance or failure). ✓ Event represents a significant public health threat even if no or very few human cases have yet been identified. ✓ Cases reported among health staff. ✓ The population at risk is especially vulnerable (refugees, low level of immunization, children, elderly, low immunity, undernourished, etc.). ✓ Concomitant factors that may hinder or delay the response (natural catastrophes, armed conflicts, unfavourable weather conditions, multiple foci in the country). ✓ Event in an area with high population density. ✓ Release into the environment of a chemical or radionuclear agent that has contaminated or has the potential to contaminate a population and/or a large geographical area.
	3. <i>Is external assistance needed to detect, investigate, respond and control the current event, or prevent new cases?</i> THE FOLLOWING ARE EXAMPLES OF WHEN ASSISTANCE MAY BE REQUIRED: <ul style="list-style-type: none"> ✓ Inadequate human, financial, material or technical resources – in particular: <ul style="list-style-type: none"> – 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 questions 1, 2 or 3 above.

II. Is the event unusual or unexpected?	
Is the event unusual or unexpected?	<p>4. <i>Is the event unusual?</i></p> <p>THE FOLLOWING ARE EXAMPLES OF UNUSUAL EVENTS:</p> <ul style="list-style-type: none"> ✓ The event is caused by an unknown agent (biological, chemical or radionuclear) or the source, vehicle, route of transmission is unusual or unknown. ✓ Evolution of cases more severe than expected (including case-fatality) or with unusual symptoms. ✓ Occurrence of the event itself unusual for the area or season.
	<p>5. <i>Is the event unexpected?</i></p> <p>THE FOLLOWING ARE EXAMPLES OF UNEXPECTED EVENTS:</p> <ul style="list-style-type: none"> ✓ 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, radionuclear or biological agent?
	<p style="text-align: center;">IS THE EVENT UNUSUAL OR UNEXPECTED?</p> <p style="text-align: center;">Answer “yes” if you have answered “yes” to questions 4 or 5 above.</p>

III. Is there a significant risk of international spread?	
Is there a significant risk of international spread?	<p>6. <i>Is there evidence of an epidemiological link to similar events in other countries?</i></p>
	<p>7. <i>Is there any factor that should alert us to the potential for cross border movement of the agent, vehicle or host?</i></p> <p>THE FOLLOWING ARE EXAMPLES OF CIRCUMSTANCES THAT MAY PREDISPOSE TO INTERNATIONAL SPREAD:</p> <ul style="list-style-type: none"> ✓ Where there is evidence of local spread, an index case (or other linked cases): <ul style="list-style-type: none"> – with history of international travel within the previous month (or time equivalent to the incubation period if the pathogen is known) – with history of participation in an international gathering (pilgrimage, sports event, conferences, etc.) – 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.
	<p style="text-align: center;">IS THERE A SIGNIFICANT RISK OF INTERNATIONAL SPREAD?</p> <p style="text-align: center;">Answer “yes” if you have answered “yes” to questions 6 or 7 above.</p>

	IV. Is there a significant risk of international travel or trade restrictions?
Risk of international restrictions ?	8. <i>Have similar events in the past resulted in international restriction on trade and/or travel against the affected country?</i>
	9. <i>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?</i>
	10. <i>Has the event occurred in association with an international gathering or in an area of intense international tourism?</i>
	11. <i>Has the event caused requests for more information by foreign officials or international media?</i>
	IS THERE A SIGNIFICANT RISK OF INTERNATIONAL TRADE OR TRAVEL RESTRICTIONS? Answer “yes” if you have answered “yes” to questions 8, 9, 10 or 11 above.

States Parties that answer “yes” to the question whether the event meets any two of the four criteria (I-IV) above, shall notify WHO under Article 5 of the International Health Regulations.

PART B. PARTICULAR DISEASES REQUIRING UTILIZATION OF THE DECISION INSTRUMENT

1. The diseases in this list have demonstrated the ability to cause serious public health impact and have the potential to spread rapidly internationally.
2. States Parties shall use the decision instrument in Part A of this Annex to assess all events that involve, or are considered likely to involve, the following diseases in order to determine if notification is required under Article 5 of these Regulations and this Annex:

Cholera

Crimean-Congo haemorrhagic fever

Ebola haemorrhagic fever

Inhalational anthrax

Pneumonic plague

Nipah virus infection

Lassa fever

Marburg disease

Yellow fever

ANNEX 4

TECHNICAL REQUIREMENTS PERTAINING TO CONVEYANCES AND CONVEYANCE OPERATORS

Section 1. Conveyance operators

1. Conveyance operators shall facilitate:
 - (a) inspections of the conveyance, containers and cargo;
 - (b) medical examinations of persons on board;
 - (c) application of other health measures under these Regulations; and
 - (d) provision of relevant public health information requested by the State Party.
2. Conveyance operators shall provide to the competent authority a valid Ship Sanitation Control Exemption Certificate or a Ship Sanitation Control Certificate or a Maritime Declaration of Health, or the Health Part of an Aircraft General Declaration, as required under these Regulations.

Section 2. Conveyances

3. Control measures applied to conveyances, containers and cargo under these Regulations shall be carried out so as to avoid as far as possible injury or discomfort to persons or damage to the conveyance, container, cargo, goods or baggage. Whenever possible and appropriate, control measures shall be applied when the conveyance and holds are empty.
4. States Parties shall indicate in writing the measures applied to a conveyance, container or cargo, the parts treated, the methods employed, and the reasons for their application. This information shall be provided in writing to the person in charge of an aircraft and, in case of a ship, on the Ship Sanitation Control Certificate. For other conveyances, cargo or containers, States Parties shall issue such information in writing to consignors, consignees, carriers, the person in charge of the conveyance or their respective agents.

ANNEX 5

SPECIFIC MEASURES FOR VECTOR-BORNE DISEASES

1. WHO 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 should be disinfected and kept free of vectors. When there are methods and materials advised by the Organization for these procedures, 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 competent authority at the airport of arrival;
 - (b) in the case of ships, on the Ship Sanitation Control Certificates; and
 - (c) in the case of other conveyances, on a written proof of treatment issued to the consignor, consignee, carrier, the person in charge of the conveyance or their agent, respectively.
3. States Parties should accept disinsecting, deratting and other control measures for conveyances applied by other States if methods and materials advised by the Organization have been applied.
4. States Parties shall establish programmes to control vectors that may transport an infectious agent that constitutes a public health threat to a minimum distance of 400 metres from the boundaries of airports, ports or container loading areas in their territories, with extension of the minimum distance 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, the competent authorities for the next known port or airport of call with a capacity to make such an inspection shall be informed of this requirement in advance by the competent authority advising such follow-up. In the case of ships, this shall be noted on the Ship Sanitation Control Certificate.
6. A conveyance may be regarded as suspect and should be inspected for vectors and reservoirs, 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 an international voyage; or
 - (c) it has left an affected area within a period of time where on-board vectors could still carry disease.

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

8. A State Party may apply vector control measures to a conveyance arriving from an area affected by a vector-borne disease if the vectors for the foregoing disease are present in its territory.

ANNEX 6

VACCINATION, PROPHYLAXIS AND RELATED CERTIFICATES

1. Vaccines or other prophylaxis specified in Annex 7 or recommended under these Regulations shall be of suitable quality; those vaccines and prophylaxis designated by WHO shall be subject to its approval. Upon request, the State Party shall provide to WHO appropriate evidence of the suitability of vaccines and prophylaxis administered within its territory under these Regulations.
2. Persons undergoing vaccination or other prophylaxis under these Regulations shall be provided with an international certificate of vaccination or prophylaxis (hereinafter the “certificate”) in the form specified in this Annex. No departure shall be made from the model of the certificate specified in this Annex.
3. Certificates under this Annex are valid only if the vaccine or prophylaxis used has been approved by WHO.
4. Certificates must be signed in the hand of the clinician, who shall be a medical practitioner or other authorized health worker, supervising the administration of the vaccine or prophylaxis. The certificate must also bear the official stamp of the administering centre; however, this shall not be 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 the supervising clinician shall provide the person with reasons, written in English or French, and where appropriate in another language in addition to English or French, underlying that opinion, which the competent authorities on arrival should take into account. The supervising clinician and competent authorities shall inform such persons of any risk associated with non-vaccination and with the non-use of prophylaxis in accordance with paragraph 3 of Article 27.
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 and where appropriate in another language in addition to English or 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 [name], date of birth, sex,
nationality, 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.

Vaccine or prophylaxis	Date	Signature and professional status of supervising clinician	Manufacturer and batch No. of vaccine or prophylaxis	Certificate valid from - until
1.				
2.				

Official stamp of administering centre
1.

Official stamp of administering centre
2.

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

This certificate must be signed in the hand of the clinician, who shall be a medical practitioner or other authorized health worker, supervising the administration of the vaccine or prophylaxis. The certificate must also bear the official stamp of the administering centre; however, this shall not be 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. The certificate shall be fully completed in English or in French. The certificate may also be completed in another language on the same document, in addition to either English or French.

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 specifically designated under these Regulations 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:

(i) the incubation period of yellow fever is six days;

(ii) yellow fever vaccines approved by WHO provide protection against infection starting ten days following the administration of the vaccine; and

(iii) this protection continues for ten years.

(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(h) of this Annex may be applied on arrival.

(d) A traveller 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) In accordance with paragraph 1 of Annex 6 the yellow fever vaccine used must be approved by the Organization.

(f) States Parties may designate specific yellow fever vaccination centres within their territories in order to ensure the quality and safety of the procedures and materials employed.¹

(g) 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

¹ WHO does not designate, approve or list designated vaccination centres. The Member States designate such centres within their territories.

conveyance using any such point of entry, shall be in possession of a valid certificate of vaccination against yellow fever.

(h) A State Party, in whose territory 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 quarantined 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.

(i) Travellers who possess an exemption from yellow fever vaccination, signed by a medical practitioner or an authorized health worker, [shall]/[may] 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. Should the travellers not be quarantined, they may be required to report any feverish symptoms to the competent authority and be placed under surveillance.

ANNEX 8

MODEL OF MARITIME DECLARATION OF HEALTH

To be completed and submitted to the competent authorities by the masters of ships arriving from foreign ports.

Submitted at the port of Date.....
 Name of ship or inland navigation vessel..... Registration/IMO No.....arriving fromsailing to
 Nationality..... Master's name
 Gross 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:

Upon request of the competent authority at the port of arrival, list crew members, passengers or other persons who have joined ship/vessel since international 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) Namejoined from: (1).....(2).....(3).....
 (2) Namejoined 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.....
 If yes, state particulars in attached schedule. Total no. of deaths
- (2) Is there on board or has there been during the international voyage any case of disease which you suspect to be of an infectious nature? yes..... no..... If yes, state particulars in attached schedule.
- (3) Has the total number of ill passengers during the voyage been greater than normal/expected? yes.... no.....
 How many ill persons?
- (4) Is there any ill person on board now? yes..... no..... If yes, state particulars in attached schedule.
- (5) Was a medical practitioner consulted? yes..... no..... If yes, state particulars of medical treatment or advice provided in attached schedule.
- (6) Are you aware of any condition on board which may lead to infection or spread of disease? yes..... no.....
 If yes, state particulars in attached schedule.
- (7) Has any sanitary measure (e.g. quarantine, isolation, disinfection or decontamination) been applied on board? yes no.....
 If yes, specify type, place and date.....
- (8) Have any stowaways been found on board? yes no..... If yes, where did they join the ship (if known)?

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:

- (a) fever, persisting for several days or accompanied by (i) prostration; (ii) decreased consciousness; (iii) glandular swelling; (iv) jaundice; (v) cough or shortness of breath; (vi) unusual bleeding; or (vii) paralysis.
- (b) with or without fever: (i) any acute skin rash or eruption; (ii) severe vomiting (other than sea sickness); (iii) severe diarrhoea; or (iv) recurrent convulsions.

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.....

ATTACHMENT TO MODEL OF MARITIME DECLARATION OF HEALTH

Name	Class or rating	Age	Sex	Nationality	Port, date joined ship/vessel	Nature of illness	Date of onset of symptoms	Reported to a port medical officer?	Disposal of case*	Drugs or medicines given to patient	Comments

* State: (1) whether the person recovered, is still ill or died; and (2) whether the person is still on board, was evacuated (including the name of the port or airport), or was buried at sea.

ANNEX 9

**THIS DOCUMENT IS PART OF THE AIRCRAFT GENERAL DECLARATION,
PROMULGATED BY THE INTERNATIONAL CIVIL AVIATION ORGANIZATION¹**

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, diarrhoea) 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

= = =

¹ WHO will provide the recommended changes to this document to the International Civil Aviation Organization.