

TRACTATENBLAD

VAN HET

KONINKRIJK DER NEDERLANDEN

JAARGANG 2024 Nr. 132

A. TITEL

1. *Statuut van de Wereldgezondheidsorganisatie;*
2. *Protocol nopens het Internationale Gezondheidsbureau, met Annex;*
3. *Overeenkomst, gesloten door de Regeringen, vertegenwoordigd op de Internationale Gezondheidsconferentie gehouden in de stad New York van 19 juni tot 22 juli 1946; New York, 22 juli 1946*

Voor een overzicht van de verdragsgegevens, zie verdragsnummers 006731, 011314, 013935 en 014037 in de Verdragenbank.

B. TEKST

De Wereldgezondheidsvergadering heeft tijdens haar zevenenzeventigste zitting (WHA77) op 1 juni 2024 te Genève in overeenstemming met artikel 55, derde lid, van de Internationale Gezondheidsregeling (2005), wijzigingen van artikelen 1, 2, 3, 4, 5, 6, 8, 10, 11, 12, 13, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 27, 28, 35, 37, 43, 44, 45, 48, 49, 50, 53, 54 en 60, toevoeging van nieuwe artikelen 44bis en 54bis, en wijzigingen van bijlagen 1, 2, 3, 4, 6, 7 en 8 bij de Internationale Gezondheidsregeling (2005) aangenomen. Op 19 september 2024 heeft de Directeur-Generaal van de Wereldgezondheidsorganisatie alle Partijen van deze wijzigingen in kennis gesteld. De Engelse tekst¹⁾ van de gewijzigde artikelen en bijlagen en van de toegevoegde nieuwe artikelen luidt als volgt, waarbij de toegevoegde tekst is onderstreept en de geschrapte tekst is doorgehaald:

INTERNATIONAL HEALTH REGULATIONS (2005)

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

¹⁾ De Arabische, de Chinese, de Franse, de Russische en de Spaanse tekst zijn niet opgenomen.

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

“container” means an article of transport equipment:

- a) of a permanent character and accordingly strong enough to be suitable for repeated use;
- b) specially designed to facilitate the carriage of goods by one or more modes of transport, without intermediate reloading;
- c) fitted with devices permitting its ready handling, particularly its transfer from one mode of transport to another; and
- d) 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 or on a product prepared for consumption or on other inanimate objects, including conveyances, that may constitute a public health risk;

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

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

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

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

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

“disease” means an illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans;

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

“disinsection” means the procedure whereby health measures are taken to control or kill the insect vectors of human diseases present in baggage, cargo, containers, conveyances, goods 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; permission for an aircraft, after landing, to embark or disembark, discharge or load cargo or stores; and permission for a ground transport 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 one 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 or contamination; a health measure does not include law enforcement or security measures;

“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;

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

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

“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” means possibly provoking discomfort through close or intimate contact or questioning;

“invasive” means the puncture or incision of the skin or insertion of an instrument or foreign material into the body or the examination of a body cavity. For the purposes of these Regulations, medical examination of the ear, nose and mouth, temperature assessment using an ear, oral or cutaneous thermometer, or thermal imaging; medical inspection; auscultation; external palpation; retinoscopy; external collection of urine, faeces or saliva samples; external measurement of blood pressure; and electrocardiography shall be considered to be non-invasive;

“isolation” means separation of ill or contaminated persons or affected baggage, containers, conveyances, 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 or by a person under the direct supervision of the competent authority, 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 Authority” means the entity designated or established by the State Party at the national level to coordinate the implementation of these Regulations within the jurisdiction of the State Party;

“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 these Regulations;

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

“pandemic emergency” means a public health emergency of international concern that is caused by a communicable disease and:

- (i) **has, or is at high risk of having, wide geographical spread to and within multiple States; and**
- (ii) **is exceeding, or is at high risk of exceeding, the capacity of health systems to respond in those States; and**
- (iii) **is causing, or is at high risk of causing, substantial social and/or economic disruption, including disruption to international traffic and trade; and**
- (iv) **requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches;**

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

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

“point of entry” means a passage for international entry or exit of travellers, baggage, cargo, containers, conveyances, goods and postal parcels as well as agencies and areas providing services to them on entry or exit; “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 risk 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 a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger;

“quarantine” means the restriction of activities and/or separation from others of suspect persons who are not ill or of suspect baggage, containers, conveyances or goods 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;

“relevant health products” means those health products needed to respond to public health emergencies of international concern, including pandemic emergencies, which may include medicines, vaccines, diagnostics, medical devices, vector control products, personal protective equipment, decontamination products, assistive products, antidotes, cell- and gene-based therapies, and other health technologies;

“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 established and accepted methods of science;

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

“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 risks pursuant to Article 16 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;

“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 public health response as necessary;

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

“temporary recommendation” means non-binding advice issued by WHO pursuant to Article 15 for application on a time-limited, risk-specific basis, in response to a public health emergency of international concern, so as 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 law of the State Party concerned;

“traveller” means a natural person undertaking an international voyage;
“vector” means an insect or other 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, **prepare for**, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.

Article 3

Principles

1. The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons, **and shall promote equity and solidarity.**
2. The implementation of these Regulations shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization.
3. The implementation of these Regulations shall be guided by the goal of their universal application for the protection of all people of the world from the international spread of disease.
4. States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to legislate and to implement legislation in pursuance of their health policies. In doing so, they should uphold the purpose of these Regulations.

Article 4

Responsible authorities

1. Each State Party shall designate or establish ~~a~~, **in accordance with its national law and context, one or two entities to serve as National IHR Authority and** National IHR Focal Point ~~and~~, **as well as** the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations.

1 bis. **The National IHR Authority shall coordinate the implementation of these Regulations within the jurisdiction of the State Party.**

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 6 to 12; 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

2 bis. States Parties shall take measures to implement paragraphs 1, 1 bis and 2 of this Article, including, as appropriate, adjusting their domestic legislative and/or administrative arrangements.

National IHR Focal Points. WHO IHR Contact Points shall send urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12, 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 **Authority and 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 **the contact details** 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 5

Surveillance

1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the ~~capacity to~~ **core capacities to prevent**, detect, assess, notify and report events in accordance with these Regulations, as specified in **Part A of** Annex 1.
2. Following the assessment referred to in paragraph 2, ~~Part A~~ of Annex 1, a State Party may report to WHO on the basis of a justified need and an implementation plan and, in so doing, obtain an extension of two years in which to fulfil the obligation in paragraph 1 of this Article. In exceptional circumstances, and supported by a new implementation plan, the State Party may request a further extension not exceeding two years from the Director-General, who shall make the decision, taking into account the technical advice of the Committee established under Article 50 (hereinafter the "Review Committee"). After the period mentioned in paragraph 1 of this Article, the State Party that has obtained an extension shall report annually to WHO on progress made towards the full implementation.
3. WHO shall assist States Parties, upon request, to develop, strengthen and maintain the **core** capacities referred to in paragraph 1 of this Article.
4. 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 Articles 11 and 45 where appropriate.

Article 6

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 hours of assessment 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. If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA) **or other intergovernmental organization(s)**, WHO shall, **pursuant to paragraph 1 of Article 14**, immediately notify the IAEA **or, as appropriate, the other competent intergovernmental organization(s)**.
2. Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern.

Article 8

Consultation

In the case of events occurring within its territory not requiring notification as provided in Article 6, in particular those events for which there is insufficient information available to complete the decision instrument, a State Party ~~may~~**should** nevertheless keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate health measures **in a timely manner**. Such communications shall be treated in accordance with paragraphs 2 to 4 of Article 11. 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 10

Verification

1. WHO shall request, in accordance with Article 9, 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. Pursuant to the foregoing paragraph and to Article 9, each State Party, when requested by WHO, shall verify and provide:
 - a) within 24 hours, an initial reply to, or acknowledgement of, the request from WHO;
 - b) within 24 hours, available public health information on the status of events referred to in WHO's request; and
 - c) information to WHO in the context of an assessment under Article 6, including relevant information as described in that Article.
3. ~~When WHO receives~~**Upon receiving** information of an event that may constitute a public health emergency of international concern, ~~it~~**WHO** 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 activities may include collaboration with other standard-setting organizations and 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,~~**and** when justified by the magnitude of the public health risk, **WHO should** share with other States Parties the information **about the event** available to it, whilst encouraging the State Party to accept the offer of collaboration by WHO, taking into account the views of the State Party concerned.

Article 11

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, in confidence, such public health information which it has received under Articles 5 to 10 inclusive and which is necessary to enable States Parties to respond to a public health risk. WHO should communicate information to other States Parties that might help them in preventing the occurrence of similar incidents.
2. WHO shall use information received under Articles 6 and 8 and paragraph 2 of Article 9 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, **including a pandemic emergency**, in accordance with Article 12; 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 sufficient 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, baggage, cargo, containers, conveyances, goods or postal parcels 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 12

*Determination of a public health emergency of international concern, **including a pandemic emergency***

1. The Director-General shall determine, on the basis of the information received, in particular from the State(s) Party(ies) within whose territory(ies) an event is occurring, whether an event constitutes a public health emergency of international concern, **including, when appropriate, a pandemic emergency**, 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(s) Party(ies) in whose territory(ies) the event ~~arises~~ **is occurring** regarding this preliminary determination. If the Director-General and the State(s) Party(ies) 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(s) Party(ies) in whose territory(ies) the event ~~arises~~ **is occurring** 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, **including, when appropriate, a pandemic emergency**, the Director-General shall consider:

- a) information provided by the State(s) Party(ies);
- 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 the risk of interference with international traffic.

4 bis. If the Director-General, determines that an event constitutes a public health emergency of international concern, the Director-General shall further determine, having considered the matters contained in paragraph 4, whether the public health emergency of international concern also constitutes a pandemic emergency.

5. If the Director-General, **having considered the matters contained in subparagraphs (a), (c), and (e) of paragraph 4 of this Article, and** following consultations with the State(s) Party(ies) within whose territory ~~the~~ **(ies) a public health emergency of international concern, including a pandemic emergency, has occurred, considers that a public health emergency of international concern, including a pandemic emergency, has ended, because it no longer meets the relevant definition in Article 1,** the Director-General shall take a decision in accordance with the procedure set out in Article 49.

Article 13

Public health response, including equitable access to relevant health products

1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity **core capacities to prevent, prepare for, and respond promptly and effectively to public health risks and public health emergencies of international concern, including a pandemic emergency, including in fragile and humanitarian settings**, as set out in **Part A of Annex 1**. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response **core** capacities.
2. Following the assessment referred to in paragraph 2, ~~Part A~~ of Annex 1, a State Party may report to WHO on the basis of a justified need and an implementation plan and, in so doing, obtain an extension of two years in which to fulfil the obligation in paragraph 1 of this Article. In exceptional circumstances and supported by a new implementation plan, the State Party may request a further extension not exceeding two years from the Director-General, who shall make the decision, taking into account the technical advice of the Review Committee. After the period mentioned in paragraph 1 of this Article, the State Party that has obtained an extension shall report annually to WHO on progress made towards the full implementation.
3. At the request of a State Party **or following its acceptance of an offer by WHO**, WHO shall collaborate in the response to public health risks 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.
4. If WHO, in consultation with the ~~States Parties~~ **State(s) Party(ies)** concerned as provided in Article 12, determines that a public health emergency of international concern, **including a pandemic emergency**, is occurring, it may offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the ~~State(s) Party(ies)~~ **State(s) Party(ies)**, including an assessment of the severity of the international risk 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.
5. When requested by WHO, States Parties should provide, to the extent possible, support to WHO-coordinated response activities.
6. When requested, WHO shall provide appropriate guidance and assistance to other States Parties affected or threatened by the public health emergency of international concern, **including a pandemic emergency**.
7. **WHO shall support States Parties, upon their request or following acceptance of an offer from WHO, and coordinate international response activities during public health emergencies of international concern, including pandemic emergencies, after their determination pursuant to Article 12 of these Regulations.**
8. **WHO shall facilitate, and work to remove barriers to, timely and equitable access by States Parties to relevant health products after the determination of and during a public health emergency of international concern, including a pandemic emergency, based on public health risks and needs. To that effect, the Director-General shall:**

- a) conduct, and periodically review and update, assessments of the public health needs, as well as of the availability and accessibility including affordability of relevant health products for the public health response; publish such assessments; and consider the available assessments while issuing, modifying, extending or terminating recommendations pursuant to Articles 15, 16, 17, 18, and 49 of these Regulations;
 - b) make use of WHO-coordinated mechanism(s), or facilitate, in consultation with States Parties, their establishment as needed, and coordinate, as appropriate, with other allocation and distribution mechanisms and networks that facilitate timely and equitable access to relevant health products based on public health needs;
 - c) support States Parties, upon their request, in scaling up and geographically diversifying the production of relevant health products, as appropriate, through relevant WHO-coordinated and other networks and mechanisms, subject to Article 2 of these Regulations, and in accordance with relevant international law;
 - d) share with a State Party, upon its request, the product dossier related to a specific relevant health product, as provided to WHO by the manufacturer for approval and where the manufacturer has consented, within 30 days of receiving such request, for the purpose of facilitating regulatory evaluation and authorization by the State Party; and
 - e) support States Parties, upon their request, and, as appropriate, through relevant WHO-coordinated and other networks and mechanisms, pursuant to subparagraph 8(c) of this Article, to promote research and development and strengthen local production of quality, safe and effective relevant health products, and facilitate other measures relevant for the full implementation of this provision.
9. Pursuant to paragraph 5 of this Article and paragraph 1 of Article 44 of these Regulations, and upon request of other States Parties or WHO, States Parties shall undertake, subject to applicable law and available resources, to collaborate with, and assist each other and to support WHO-coordinated response activities, including through:
- a) supporting WHO in implementing actions outlined in this Article;
 - b) engaging with and encouraging relevant stakeholders operating in their respective jurisdictions to facilitate equitable access to relevant health products for responding to a public health emergency of international concern, including a pandemic emergency; and
 - c) making available, as appropriate, relevant terms of their research and development agreements for relevant health products related to promoting equitable access to such products during a public health emergency of international concern, including a pandemic emergency.

PART III

RECOMMENDATIONS

Article 15

Temporary recommendations

1. If it has been determined in accordance with Article 12 that a public health emergency of international concern, **including a pandemic emergency**, 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, **including a pandemic emergency**, 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(s) Party(ies) experiencing the public health emergency of international concern, **including a pandemic emergency**, or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods, **including relevant health products**, and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.

2 bis. The Director-General, when communicating to States Parties the issuance, modification or extension of temporary recommendations, should provide available information on any WHO-coordinated mechanism(s) concerning access to, and allocation of, relevant health products, as well as on any other allocation and distribution mechanisms and networks.

3. Temporary recommendations may be terminated in accordance with the procedure set out in Article 49 at any time and shall automatically expire three months after their issuance. They may be modified or extended for additional periods of up to three months. Temporary recommendations may not continue beyond the second World Health Assembly after the determination of the public health emergency of international concern, including a pandemic emergency, to which they relate.

Article 16

Standing recommendations

1. WHO may make standing recommendations of appropriate health measures in accordance with Article 53 for routine or periodic application. Such measures may be applied by States Parties regarding persons, baggage, cargo, containers, conveyances, goods, **including relevant health products**, and/or postal parcels for specific, ongoing public health risks in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic. WHO may, in accordance with Article 53, modify or terminate such recommendations, as appropriate.

2. The Director-General, when communicating to States Parties the issuance, modification or extension of standing recommendations, should provide available information on any WHO-coordinated mechanism(s) concerning access to, and allocation of, relevant health products as well as on any other allocation and distribution mechanisms and networks.

Article 17

Criteria for recommendations

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

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

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

Article 18

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

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

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

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

- no specific 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 baggage, cargo, containers, conveyances, goods, postal parcels or human remains to remove infection or contamination, including vectors and reservoirs;
- the use of specific health measures to ensure the safe handling and transport of human remains;
- implement isolation or quarantine;
- seizure and destruction of infected or contaminated or suspect baggage, cargo, containers, conveyances, goods or postal parcels under controlled conditions if no available treatment or process will otherwise be successful; ~~and~~
- refuse departure or entry.

3. **Recommendations issued by WHO to State Parties shall, as appropriate, take into account the need to:**
 a) **facilitate international travel, particularly of health and care workers and persons in life-threatening or humanitarian situations. This provision is without prejudice to Article 23 of these Regulations; and**
 b) **maintain international supply chains, including for relevant health products and food supplies.**

PART IV

POINTS OF ENTRY

Article 19

General obligations

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

- a) ensure that the **core** capacities set forth in **Part B** of Annex 1 for designated points of entry are developed within the time_frame provided in paragraph 1 of Article 5 and paragraph 1 of Article 13;
- b) identify the competent authorities at each designated point of entry in its territory; and
- c) furnish to WHO, as far as practicable, when requested in response to a specific potential public health risk, 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 20

Airports and ports

1. States Parties shall designate the airports and ports that shall develop the **core** capacities provided in **Part B** of 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 39 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.

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

Article 21

Ground crossings

1. Where justified for public health reasons, a State Party may designate ground crossings that shall develop the **core** capacities provided in **Part B of Annex 1**, taking into consideration:

- 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 existing in areas in which the international traffic originates, or through which it passes, prior to arrival at a particular ground crossing.

2. 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 57; and
- b) joint designation of adjacent ground crossings for the **core** capacities in **Part B of Annex 1** in accordance with paragraph 1 of this Article.

PART V

PUBLIC HEALTH MEASURES

CHAPTER I

GENERAL PROVISIONS

Article 23

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:
 - (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 of the traveller's health documents if they are required under these Regulations; and/or
 - (iii) a non-invasive medical examination which is the least intrusive examination that would achieve the public health objective; **and**
- b) inspection of baggage, cargo, containers, conveyances, goods, postal parcels and human remains.

2. On the basis of evidence of a public health risk 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, on a case-by-case basis, the least intrusive and invasive medical examination that would achieve the public health objective of preventing the international spread of disease.

3. No medical examination, vaccination, 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 31, and in accordance with the law 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 law and international obligations of the State Party. States Parties shall inform medical practitioners of these requirements in accordance with the law of the State Party.

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 24

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, **including for application on board as well as during embarkation and disembarkation;**
- b) inform travellers of the health measures recommended by WHO and adopted by the State Party, **including for application on board as well as during embarkation and disembarkation;** 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.

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 25

Ships and aircraft in transit

Subject to Articles 27 and 43 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 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 27

Affected conveyances

1. If clinical signs or symptoms and information based on fact or evidence of a public health risk, including sources of infection and contamination, are found on board a conveyance, 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 risk 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.

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

2. If the competent authority for the point of entry is not able 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, food 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 risk.

Article 28

Ships and aircraft at points of entry

1. Subject to Article 43 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 43 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, food 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~~ **2 of this Article**, 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 risk on board, as soon as such illnesses or public health risks 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 of the aircraft 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 of the aircraft 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.

PART VI
HEALTH DOCUMENTS

Article 35

General rule

1. 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. The competent authority may request travellers to complete contact information forms and questionnaires on the health of travellers, provided that they meet the requirements set out in Article 23.

2. Health documents under these Regulations may be issued in non-digital format or digital format, subject to the obligations of any State Party regarding the format of such documents deriving from other international agreements.

3. Regardless of the format in which health documents under these Regulations have been issued, said health documents shall conform to the Annexes, referred to in Articles 36 to 39, as applicable, and their authenticity shall be ascertainable.

4. WHO, in consultation with States Parties, shall develop and update, as necessary, technical guidance, including specifications or standards related to the issuance and ascertainment of authenticity of health documents, both in digital format and non-digital format. Such specifications or standards shall be in accordance with Article 45 regarding treatment of personal data.

Article 37

MaritimeShip 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 **MaritimeShip** Declaration of Health, which shall be countersigned by the ship's surgeon, if one is carried.

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

3. A **MaritimeShip** 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 **MaritimeShip** Declaration of Health by all arriving ships; or
- b) to require the submission of the **MaritimeShip** Declaration of Health 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.

PART VIII
GENERAL PROVISIONS

Article 43

Additional health measures

1. These Regulations shall not preclude States Parties from implementing health measures, in accordance with their relevant national law and obligations under international law, in response to specific public health risks or public health emergencies of international concern, which:

- a) achieve the same or greater level of health protection than WHO recommendations; or

b) are otherwise prohibited under Article 25, Article 26, paragraphs 1 and 2 of Article 28, Article 30, paragraph 1(c) of Article 31 and Article 33,

provided such measures are otherwise consistent with these Regulations.

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. In determining whether to implement the health measures referred to in paragraph 1 of this Article or additional health measures under paragraph 2 of Article 23, paragraph 1 of Article 27, paragraph 2 of Article 28 and paragraph 2(c) of Article 31, States Parties shall base their determinations upon:

a) scientific principles;

b) available scientific evidence of a risk to human health, or where such evidence is insufficient, the available information, including from WHO and other relevant intergovernmental organizations and international bodies; and

c) any available specific guidance or advice from WHO.

3. A State Party implementing additional health measures referred to in paragraph 1 of this Article which significantly interfere with international traffic shall provide to WHO the public health rationale and relevant scientific information for it. WHO shall share this information with other States Parties and shall share information regarding the health measures implemented. For the purpose of this Article, significant interference generally means refusal of entry or departure of international travellers, baggage, cargo, containers, conveyances, goods, and the like, or their delay, for more than 24 hours.

4. After assessing information provided pursuant to paragraphs 3 and 5 of this Article and other relevant information, WHO may request that the State Party concerned reconsider the application of the measures.

5. A State Party implementing additional health measures referred to in paragraphs 1 and 2 of this Article that significantly interfere with international traffic shall inform WHO, within 48 hours of implementation, of such measures and their health rationale unless these are covered by a temporary or standing recommendation.

6. A State Party implementing a health measure pursuant to paragraph 1 or 2 of this Article shall within three months review such a measure taking into account the advice of WHO and the criteria in paragraph 2 of this Article.

7. Without prejudice to its rights under Article 56, any State Party impacted by a measure taken pursuant to paragraph 1 or 2 of this Article may request the State Party implementing such a measure to consult with it, **either directly, or through the Director-General, who may also facilitate consultations between the States Parties concerned.** 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. **Unless otherwise agreed with the State Parties involved in the consultation, information shared during the consultation must be kept confidential.**

8. The provisions of this Article may apply to implementation of measures concerning travellers taking part in mass congregations.

Article 44

Collaboration and assistance and financing

1. States Parties shall undertake to collaborate with each other, to the extent possible, in:
 - a) the detection and assessment of, **preparedness for** and response to, events as provided under these Regulations;
 - b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the ~~public health~~**core** capacities required under **Annex 1 of** these Regulations;
 - c) the mobilization of financial resources, **including through relevant sources and funding mechanisms** to facilitate **the** implementation of their obligations under these Regulations, **in particular to address the needs of developing countries**; and
 - d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations.
2. WHO shall collaborate with, **and assist**, States Parties, upon **their** request, to the extent possible, in:
 - a) the evaluation and assessment of their ~~public health~~**core** 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~~**developing**, strengthening and maintaining the **core** capacities provided for in Annex 1.; **and**
 - d) **the facilitation of access to relevant health products, in accordance with paragraph 8 of Article 13.**
- 2 bis. **States Parties, subject to applicable law and available resources, shall maintain or increase domestic funding, as necessary, and collaborate, including through international cooperation and assistance, as appropriate, to strengthen sustainable financing to support the implementation of these Regulations.**
- 2 ter. **Pursuant to subparagraph (c) of paragraph 1 of this Article, States Parties shall undertake to collaborate, to the extent possible, to:**
 - a) **encourage governance and operating models of existing financing entities and funding mechanisms to be regionally representative and responsive to the needs and national priorities of developing countries in the implementation of these Regulations;**
 - b) **identify and enable access to financial resources, including through the Coordinating Financial Mechanism, established pursuant to Article 44 bis, necessary to equitably address the needs and priorities of developing countries, including for developing, strengthening and maintaining core capacities.**
- 2 quater. **The Director-General shall support the collaboration work in paragraph 2 bis of this Article, as appropriate. States Parties and the Director-General shall report on its outcomes as part of the reporting to the Health Assembly.**
3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies.

Article 44 bis

Coordinating Financial Mechanism

1. **A Coordinating Financial Mechanism (hereinafter “the Mechanism”) is hereby established to:**
 - a) **promote the provision of timely, predictable, and sustainable financing for the implementation of these Regulations in order to develop, strengthen, and maintain core capacities as set out in Annex 1 of these Regulations, including those relevant for pandemic emergencies;**
 - b) **seek to maximize the availability of financing for the implementation needs and priorities of States Parties, in particular of developing countries; and**
 - c) **work to mobilize new and additional financial resources, and increase the efficient utilization of existing financing instruments, relevant to the effective implementation of these Regulations.**
2. **In support of the objectives set out in paragraph 1 of this Article, the Mechanism shall, inter alia:**
 - a) **use or conduct relevant needs and funding gap analyses;**
 - b) **promote harmonization, coherence and coordination of existing financing instruments;**

- c) identify all sources of financing that are available for implementation support and make this information available to States Parties;
 - d) provide advice and support, upon request, to States Parties in identifying and applying for financial resources for strengthening core capacities, including those relevant for pandemic emergencies; and
 - e) leverage voluntary monetary contributions for organizations and other entities supporting States Parties to develop, strengthen and maintain their core capacities, including those relevant for pandemic emergencies.
3. The Mechanism shall function, in relation to the implementation of these Regulations, under the authority and guidance of the Health Assembly and be accountable to it.

Article 45

Treatment of personal data

1. Health information collected or received by a State Party pursuant to these Regulations from another State Party or from WHO which refers to an identified or identifiable person shall be kept confidential and processed anonymously, as required by national law.
2. Notwithstanding paragraph 1, States Parties may **process and** disclose ~~and process~~ personal data where essential for the purposes of assessing and managing a public health risk, but State Parties, in accordance with national law, and WHO must ensure that the personal data are:
 - a) processed fairly and lawfully, and not further processed in a way incompatible with that purpose;
 - b) adequate, 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.
3. Upon request, WHO shall as far as practicable provide an individual with his or her personal data referred to in this Article in an intelligible form, without undue delay or expense and, when necessary, allow for correction.

PART IX

THE IHR ROSTER OF EXPERTS, THE EMERGENCY COMMITTEE AND THE REVIEW COMMITTEE

CHAPTER II

THE EMERGENCY COMMITTEE

Article 48

Terms of reference and composition

1. The Director-General shall establish an Emergency Committee that at the request of the Director-General shall provide its views on:
 - a) whether an event constitutes a public health emergency of international concern, **including a pandemic emergency;**
 - b) the termination of a public health emergency of international concern, **including a pandemic emergency;** and
 - c) the proposed issuance, modification, extension or termination of temporary recommendations.

1 bis. **The Emergency Committee shall be considered an expert committee and shall be subject to the WHO Advisory Panel Regulations, unless otherwise provided for in this Article.**

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. ~~At least one member~~**Members** of the Emergency Committee should ~~be an~~ **include at least one** expert nominated by a-State(s) Party(ies) within whose territory the event ~~arises~~**is occurring**.

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 advice on recommendations.

4. The Director-General shall invite the State(s) Party(ies) in whose territory the event ~~arises~~**is occurring** to present its **(their)** views to the Emergency Committee. To that effect, the Director-General shall notify to it the dates and the agenda of the meeting of the Emergency Committee with as much advance notice as necessary. The State(s) Party(ies) concerned, however, may not seek a postponement of the meeting of the Emergency Committee for the purpose of presenting its views thereto.

5. The views of the Emergency Committee shall be forwarded to the Director-General for consideration. The Director-General shall make the final determination on these matters.

6. The Director-General shall communicate to **all** States Parties the determination and the termination of a public health emergency of international concern, **including a pandemic emergency**, any health measure taken by the State(s) Party(ies) concerned, any temporary recommendations, **including the supporting evidence**, and the modification, extension and termination of such recommendations, together with the **composition and** 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 shall subsequently make such information and recommendations available to the general public.

7. 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, **including a pandemic emergency**, and/or the temporary recommendations, and may 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) make technical recommendations to the Director-General regarding amendments to these Regulations;
b) provide technical advice to the Director-General with respect to standing recommendations, and any modifications or termination thereof; **and**

- c) provide technical advice to the Director-General on any matter referred to it by the Director-General regarding the functioning of these Regulations.
2. The Review Committee shall be considered an expert committee and shall be subject to the WHO Advisory Panel Regulations, unless otherwise provided in this Article.
3. The ~~M~~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.
6. 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 a diversity of scientific opinion, approaches and practical experience in various parts of the world, and an appropriate interdisciplinary balance.

Article 53

Procedures for standing recommendations

When the Director-General considers that a standing recommendation is necessary and appropriate for a specific public health risk, 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; **and**
- g) standing recommendations shall be submitted by the Director-General to the subsequent Health Assembly for its consideration.

PART X

FINAL PROVISIONS

Article 54

Reporting and review

1. States Parties and the Director-General 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, **including financing for their effective implementation**. To that end it may request the advice of the Review Committee, through the Director-General. The first such review shall take place no later than five years after the entry into force of these Regulations.
3. WHO shall periodically conduct studies to review and evaluate the functioning of Annex 2. The first such review shall commence no later than one year after the entry into force of these Regulations. The results of such reviews shall be submitted to the Health Assembly for its consideration, as appropriate.

Article 54 bis

States Parties Committee for the Implementation of the International Health Regulations (2005)

1. The States Parties Committee for the Implementation of the International Health Regulations (2005) is hereby established to facilitate the effective implementation of these Regulations, in particular of Article 44 and 44 bis. The Committee shall be facilitative and consultative in nature only, and function in a non-adversarial, non-punitive, assistive and transparent manner, guided by the principles set out in Article 3. To this effect:

- a) **the Committee shall have the aim of promoting and supporting learning, exchange of best practices, and cooperation among States Parties for the effective implementation of these Regulations;**
- b) **the Committee shall establish a Subcommittee to provide technical advice and report to the Committee.**

2. The Committee shall be comprised of all States Parties and shall meet at least once every two years. Terms of reference for the Committee, including the way that the Committee conducts its business, and for the Subcommittee shall be adopted at the first meeting of the Committee by consensus.

3. The Committee shall have a Chair and a Vice-Chair, elected by the Committee from among its State Party members, who shall serve for two years and rotate on a regional basis.¹⁾

4. The Committee shall adopt, at its first meeting, by consensus, terms of reference for the Coordinating Financial Mechanism, established in Article 44 bis, and modalities for its operationalization and governance and may adopt necessary working arrangements with relevant international bodies, which may support its operation as appropriate.

Article 60

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 59, 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~~¹² 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 Articles 62 and 63, upon expiry of that period. In no case shall these Regulations enter into force in respect to that State earlier than 24 months after the date of notification referred to in paragraph 1 of Article 59.

¹⁾ **For the purposes of this provision, the Holy See and Liechtenstein shall be regarded as belonging to the European Region of WHO, it being understood that this arrangement is without prejudice to their status as States Parties to the International Health Regulations (2005) that are not Members of WHO.**

ANNEX 1

A. CORE CAPACITY REQUIREMENTS FOR SURVEILLANCE AND RESPONSE

CORE CAPACITIES

1. States Parties shall utilize existing national structures and resources to meet their core capacity **capacities** requirements under these Regulations, including with regard to:
 - a) their **prevention**, surveillance, reporting, notification, verification, **preparedness**, 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 for that State Party, 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 5 and, paragraph 1 of Article 13 **and subparagraph (a) of Article 19**.
3. States Parties and WHO shall support assessments, planning and implementation processes under this Annex.
4. **Pursuant to Article 44, States Parties shall undertake to collaborate with each other, to the extent possible, in developing, strengthening and maintaining core capacities.**

A. CORE CAPACITIES REQUIREMENTS FOR PREVENTION, SURVEILLANCE, PREPAREDNESS AND RESPONSE

1. At the local community level and/or primary public health response level (**hereinafter the "Local level"**), **each State Party shall develop, strengthen and maintain the core capacities:**

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 the appropriate level of health-care response. At the community level, reporting shall be to local community health care institutions or the appropriate health personnel. At the primary public health response level, reporting shall be to the intermediate or national response level, depending on organizational structures. 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; ~~and~~
 - c) to **prepare for the implementation of, and** implement **immediately**, preliminary control measures immediately; ~~and~~
 - 5-**d) to prepare for the provision of, and facilitate access to health services necessary for responding to public health risks and events; and**
 - e) **to engage relevant stakeholders, including communities, in preparing for and responding to public health risks and events.**
2. At the intermediate public health response levels ~~The~~ (**hereinafter the "Intermediate level"**), **where applicable,¹ each State Party shall develop, strengthen and maintain the core** capacities:
 - a) to confirm the status of reported events and to support or implement additional control measures; ~~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-; **and**

¹ **In States Parties where, because of their administrative structure, an Intermediate level either absent or not clearly identifiable, the core capacities listed in subparagraphs (a) through (e) of this paragraph shall be understood to be developed, strengthened or maintained either at the Local level or at the National level, as appropriate, in accordance with national laws and context.**

- 6-c) to coordinate with and support the Local level in preventing, preparing for and responding to public health risks and events, including in relation to:**
- (i) surveillance;**
 - (ii) on-site investigations;**
 - (iii) laboratory diagnostics, including referral of samples;**
 - (iv) implementation of control measures;**
 - (v) access to health services and health products needed for the response;**
 - (vi) risk communication, including addressing misinformation and disinformation; and**
 - (vii) logistical assistance (e.g. equipment, medical and other relevant supplies and transport);**

3. At the national level

Assessment and notification. The **Each State Party shall develop, strengthen and maintain the core capacities:**

- a) to assess all reports of urgent events within 48 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 6 and Annex 2 and to inform WHO as required pursuant to Article 7 and paragraph 2 of Article 9.

*Public health **prevention, preparedness and response.*** The **Each State Party shall develop, strengthen and maintain the core capacities for:**

- a) ~~to determine rapidly the~~ **determining** control measures required to prevent domestic and international spread;
- b) ~~to provide support through~~ **surveillance;**
- c) **deploying** specialized staff,;
- d) laboratory analysis of samples (domestically or through collaborating centres) ~~and;~~
- e) logistical assistance (e.g. equipment, **medical and other relevant** supplies and transport);
- e) ~~to provide~~ **(f) providing** on-site assistance as required to supplement local investigations;
- d) ~~to provide~~ **(g) developing and/or disseminating guidance for clinical case management and infection prevention and control;**
- h) **access to health services and health products needed for the response;**
- i) **risk communication, including addressing misinformation and disinformation;**
- j) **providing** a direct operational link with senior health and other officials to approve rapidly and implement containment and control measures;
- e) ~~to provide~~ **(k) providing** direct liaison with other relevant government ministries;
- f) ~~to provide~~ **(l) providing**, 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~~ **(m) establishing, operating** and **maintaining** 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~~
- n) **coordinating activities nationally and supporting Local and Intermediate levels, where applicable, in preventing, preparing for and responding to public health risks and events; and**
- h) ~~to provide~~ **(o) providing** the foregoing on a 24-hour basis.

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

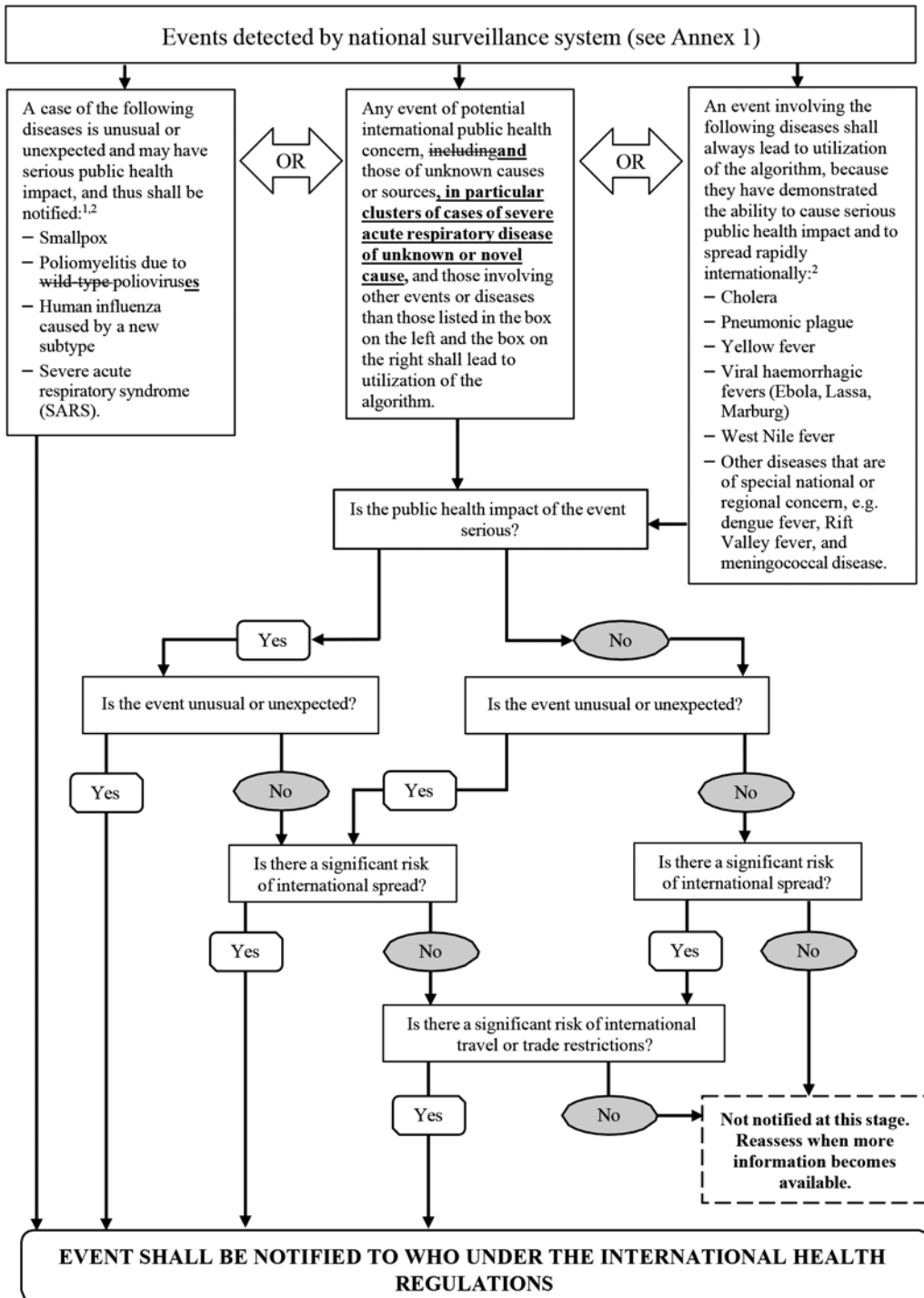
1. At all times ~~The~~, **each State Party shall develop, strengthen and maintain the core** capacities:
- a) to provide access to (i) an appropriate medical service, including diagnostic facilities located so as to allow the prompt assessment and care of ill travellers, and (ii) adequate staff, equipment and premises;
 - 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 as far as practicable 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, **each State Party shall develop, strengthen and maintain the core capacities:**

~~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 **and laboratories**, for their isolation, **and treatment, the analysis of their samples** and other support services that may be required;
 - c) to provide appropriate space, separate from other travellers, to interview suspect 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 disinsect, derat, disinfect, decontaminate or otherwise treat baggage, cargo, containers, conveyances, goods or postal parcels, 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 2

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



¹ As per WHO case definitions.

² The disease list shall be used only for the purposes of these Regulations.

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

The examples appearing in this Annex are not binding and are for indicative guidance purposes to assist in the interpretation of the decision instrument criteria.

DOES THE EVENT 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, time or population?</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 risk 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 public health response (natural catastrophes, armed conflicts, unfavourable weather conditions, multiple foci in the State Party). ✓ Event in an area with high population density. ✓ Spread of toxic, infectious or otherwise hazardous materials that may be occurring naturally or otherwise 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 in a timely manner.
IS THE PUBLIC HEALTH IMPACT OF THE EVENT SERIOUS? Answer “yes” if you have answered “yes” to questions 1, 2 or 3 above.	

Is the event unusual or unexpected?	II. Is the event unusual or unexpected?
	4. <i>Is the event unusual?</i> THE FOLLOWING ARE EXAMPLES OF UNUSUAL EVENTS: ✓ The event is caused by an unknown agent or the source, vehicle, route of transmission is unusual or unknown. ✓ Evolution of cases more severe than expected (including morbidity or case fatality) or with unusual symptoms. ✓ Occurrence of the event itself unusual for the area, season or population.
	5. <i>Is the event unexpected from a public health perspective?</i> THE FOLLOWING ARE EXAMPLES OF UNEXPECTED EVENTS: ✓ Event caused by a disease/agent that had already been eliminated or eradicated from the State Party or not previously reported.
	IS THE EVENT UNUSUAL OR UNEXPECTED? Answer “yes” if you have answered “yes” to questions 4 or 5 above.

Is there a significant risk of international	III. Is there a significant risk of international spread?
	6. <i>Is there evidence of an epidemiological link to similar events in other States?</i>
	7. <i>Is there any factor that should alert us to the potential for cross border movement of the agent, vehicle or host?</i> THE FOLLOWING ARE EXAMPLES OF CIRCUMSTANCES THAT MAY PREDISPOSE TO INTERNATIONAL SPREAD: ✓ Where there is evidence of local spread, an index case (or other linked cases) with a history within the previous month of: – international travel (or time equivalent to the incubation period if the pathogen is known); – participation in an international gathering (pilgrimage, sports event, conference, etc.); – close contact with an international traveller or a highly mobile population. ✓ Event caused by an environmental contamination that has the potential to spread across international borders. ✓ Event in an area of intense international traffic with limited capacity for sanitary control or environmental detection or decontamination.
	IS THERE A SIGNIFICANT RISK OF INTERNATIONAL SPREAD? Answer “yes” if you have answered “yes” to questions 6 or 7 above.

Risk of international	IV. Is there a significant risk of international travel or trade restrictions?
	8. <i>Have similar events in the past resulted in international restriction on trade and/or travel?</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 States?</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 6 of the International Health Regulations.

**MODEL SHIP SANITATION CONTROL EXEMPTION CERTIFICATE/SHIP
SANITATION CONTROL CERTIFICATE**

Port of Date:
 This Certificate records the inspection and 1) exemption from control or 2) control measures applied
 Name of ship or inland navigation vessel Flag Registration/IMO No.
 At the time of inspection the holds were unladen/laden with tonnes of cargo
 Name and address of inspecting officer

Ship Sanitation Control Exemption Certificate			Ship Sanitation Control Certificate			
Areas, [systems, and services] inspected	Evidence found ¹	Sample results ²	Documents reviewed	Control measures applied	Re-inspection date	Comments regarding conditions found
Galley			Medical log			
Pantry			Ship's log			
Stores			Other			
Hold(s)/cargo						
Quarters:						
- crew						
- officers						
- passengers						
- deck						
Potable water						
Sewage						
Ballast tanks						
Solid and medical waste						
Standing water						
Engine room						
Medical facilities						
Other areas specified - see attached						
Note areas not applicable, by marking N/A.						

No evidence found. Ship/vessel is exempted from control measures.
 Name and designation of issuing officer Signature and seal Date

¹ (a) Evidence of infection or contamination, including: vectors in all stages of growth; animal reservoirs for vectors; rodents or other species that could carry human disease, microbiological, chemical and other risks to human health; signs of inadequate sanitary measures. (b) Information concerning any human cases (to be included in the ~~Maritime~~Ship Declaration of Health).

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

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

ATTACHMENT TO MODEL SHIP SANITATION CONTROL EXEMPTION CERTIFICATE/SHIP SANITATION CONTROL CERTIFICATE

Areas/facilities/systems inspected¹	Evidence found	Sample results	Documents reviewed	Control measures applied	Re-inspection date	Comments regarding conditions found
Food						
Source						
Storage						
Preparation						
Service						
Water						
Source						
Storage						
Distribution						
Waste						
Holding						
Treatment						
Disposal						
Swimming pools/spas						
Equipment						
Operation						
Medical facilities						
Equipment and medical devices						
Operation						
Medicines						
Other areas inspected						

¹ Indicate when the areas listed are not applicable by marking N/A.

ANNEX 4

TECHNICAL REQUIREMENTS PERTAINING TO CONVEYANCES AND CONVEYANCE OPERATORS

Section A Conveyance operators

1. Conveyance operators shall **prepare for, as appropriate, and** facilitate:
 - a) inspections of the cargo, containers and conveyance;
 - b) medical examinations of persons on board;
 - c) application of other health measures under these Regulations, **including on board as well as during embarkation and disembarkation**; 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~~**Ship** Declaration of Health, or the Health Part of an Aircraft General Declaration, as required under these Regulations.

Section B Conveyances

1. Control measures applied to baggage, cargo, containers, conveyances and goods under these Regulations shall be carried out so as to avoid as far as possible injury or discomfort to persons or damage to the baggage, cargo, containers, conveyances and goods. Whenever possible and appropriate, control measures shall be applied when the conveyance and holds are empty.
2. States Parties shall indicate in writing the measures applied to cargo, containers or conveyances, 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 cargo, containers or conveyances, States Parties shall issue such information in writing to consignors, consignees, carriers, the person in charge of the conveyance or their respective agents.

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 **under this Annex issued in non-digital format** must be signed ~~in the hand of~~ **by** the clinician, who shall be a medical practitioner or other authorized health worker, supervising the administration of the vaccine or prophylaxis. ~~The~~ **Such** certificates must also bear the official stamp of the administering centre; however, this shall not be an accepted substitute for the signature. **Regardless of the format in which they have been issued, certificates must bear the name of the clinician supervising the administration of the vaccine or prophylaxis, or of the relevant authority responsible for issuing the certificate or overseeing the administering centre.**
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~~ **For certificates under this Annex issued in non-digital format, a** parent or guardian shall sign the certificate when the child is unable to write. ~~The signature of an illiterate~~ **A person who is unable to sign** 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, **which shall be considered their signature. With respect to persons with a guardian, the guardian shall sign the certificate on their behalf.**
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 4 of Article 23.
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 **a** 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~~ **indicating** 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, national identification document, if applicable
 whose signature follows¹, **or, if applicable:**

name of the parent or guardian

signature of the parent or guardian¹

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	Name of supervising clinician, or relevant authority responsible for issuing this certificate, or for overseeing the administering centre	Signature and professional status of supervising clinician ¹	Manufacturer and batch No. of vaccine or prophylaxis	Certificate valid from until	Official stamp of administering centre ¹
1.						
2.						

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

This certificate **in non-digital format** must be signed ~~in the hand of~~ **by** 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. **Regardless of the format in which this certificate has been issued, it must bear the name of the clinician supervising the administration of the vaccine or prophylaxis, or of the relevant authority responsible for issuing the certificate or overseeing the administering centre.**

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.

¹ Only applies to certificates issued in non-digital format.

ANNEX 7

REQUIREMENTS CONCERNING VACCINATION OR PROPHYLAXIS FOR SPECIFIC DISEASES¹

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 Party:

Vaccination against yellow fever.

2. Recommendations and 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 10 days following the administration of the vaccine;
 - (iii) this protection continues for the life of the person vaccinated; and
 - (iv) the validity of a certificate of vaccination against yellow fever shall extend for the life of the person vaccinated, beginning 10 days after the date of vaccination.
- b) Vaccination against yellow fever may be required of any traveller leaving an area where the Organization has determined that a risk of yellow fever transmission is present.
- 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 suspect, even if coming from an area where the Organization has determined that 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 shall designate specific yellow fever vaccination centres within their territories in order to ensure the quality and safety of the procedures and materials employed.
- g) Every person employed at a point of entry in an area where the Organization has determined that a risk of yellow fever transmission is present, and every member of the crew of a conveyance using any such point of entry, shall be in possession of a valid certificate of vaccination against yellow fever.
- 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 that 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 an authorized medical officer or an authorized health worker, 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 or other symptoms to the competent authority and be placed under surveillance.

¹ The **Amended by the** Sixty-seventh World Health Assembly, through resolution WHA67.13 (2014), adopted amendments **as** to Annex 7, paras. 2 (a) **subparagraphs** (iii) and (iv). These amendments **of Section 2(a) in resolution WHA67.13, 24 May 2014. This amendment** entered into force for all **IHR (2005)** States Parties to the International Health Regulations (2005) as of 11 July 2016.

ANNEX 8

ATTACHMENT TO MODEL OF MARITIMESHIP 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 ¹	Drugs, medicines or other treatment given to patient	Comments

¹ 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.

MODEL OF MARITIMESHIP 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 from sailing to (Nationality)(Flag of vessel) 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 the World Health Organization? Yes No Port and date of visit

List ports of call from commencement of voyage with dates of departure, or within past thirty days, 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 thirty days, 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) Namejoined 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)?

9. Is there a sick animal or pet on board? Yes No

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) landular 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

G. INWERKINGTREDING

De wijzigingen van 1 juni 2024 van de artikelen van en bijlagen bij de Internationale Gezondheidsregeling (2005) zullen ingevolge artikel 22 van het Statuut junctis de artikelen 55, derde lid, en 59, eerste en tweede lid, van de Internationale Gezondheidsregeling (2005), voor de Partijen bij het Statuut die de wijzigingen van 28 mei 2022 van de Internationale Gezondheidsregeling (2005) (Trb. 2022, 135) hebben verworpen, waaronder het Koninkrijk der Nederlanden, op 19 september 2026 in werking treden, behalve voor de Partijen die uiterlijk op 19 maart 2026 de Directeur-Generaal van de Wereldgezondheidsorganisatie kennisgeven dat zij de wijzigingen verwerpen of ten aanzien ervan voorbehouden maken.

Uitgegeven de *vierde* november 2024.

De Minister van Buitenlandse Zaken,

C.C.J. VELDKAMP