

Strengthening WHO preparedness for and response to health emergencies

Proposal for amendments to the International Health Regulations (2005)

1. The Director-General has the honour to submit to the Health Assembly for its consideration, in accordance with paragraph 1 of Article 55 of the International Health Regulations (2005), the proposal for amendments to the Regulations received from the United States of America pursuant to the said provision (see Annex).
2. In accordance with paragraph 2 of Article 55 of the International Health Regulations (2005), the Director-General communicated the text of the proposal for amendments to all States Parties to the Regulations on 20 January 2022 via circular letter.
3. Pursuant to paragraph 3 of Article 55 of the International Health Regulations (2005), any amendments to the Regulations adopted by the Health Assembly would come into force for all States Parties on the same terms, and subject to the same rights and obligations, as provided for in Article 22 of the Constitution of WHO and Articles 59 to 64 of the International Health Regulations (2005).

ACTION BY THE HEALTH ASSEMBLY

4. The Health Assembly is invited to consider the proposed amendments to the International Health Regulations (2005).

ANNEX



**World Health
Organization**

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Proposal for amendments to the International Health Regulations (2005)

... The Director-General of the World Health Organization presents his compliments to States Parties to the International Health Regulations (2005) (IHR (2005)) and has the honour to transmit the text of the proposal for amendments of the IHR (2005) received from the United States of America pursuant to paragraph 1 of Article 55 of the IHR (2005).

In accordance with paragraph 2 of Article 55 of the IHR (2005), this letter constitutes a formal communication of the text of the amendments proposed by the United States of America.

The Director-General of the World Health Organization takes this opportunity to renew to States Parties to the IHR (2005) the assurance of his highest consideration.

GENEVA, 20 January 2022

... ENCLS.: (2)

منظمة الصحة العالمية • 世界卫生组织

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THE PERMANENT MISSION
OF THE
UNITED STATES OF AMERICA
TO THE
UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS
IN GENEVA

No. 4-22

The Permanent Mission of the United States of America to the United Nations Office and Other International Organizations in Geneva presents its compliments to the World Health Organization (WHO) and refers to the International Health Regulations (IHR) (2005). In accordance with Article 55(1) of the IHR (2005), the United States of America is proposing amendments to the IHR (2005). The Mission, by means of this note, and in accordance with Article 55(2) of the IHR (2005), respectfully requests the Director-General of the WHO to communicate the text of the attached proposed IHR amendments to all States Parties at least four months before the Seventy-fifth World Health Assembly. We are also transmitting via this note a letter to WHO Director-General Tedros Adhanom Ghebreyesus from the Assistant Secretary for Global Affairs of the United States Department of Health and Human Services, Loyce Pace, reiterating the critical importance of strengthening the IHR (2005) along with other efforts to strengthen the ability of the WHO and Member States to prevent, detect, and respond to future public health emergencies of international concern.

The Permanent Mission of the United States of America avails itself of this opportunity to renew to the WHO the assurances of its highest consideration.

Enclosed:

1. Letter from HHS Assistant Secretary Loyce Pace
2. Proposed IHR amendments

Geneva, 18 January 2022

World Health Organization



Submission of the United States of America
Proposed Amendments to the International Health Regulations (2005)
Articles 5, 6, 9, 10, 11, 12, 13, 15, 18, 48, 49, 53, 59

Explanation of changes: The proposed new text is shown in **bold underline**, and proposed deletions to existing text is shown in ~~strike through~~. All other text would remain unchanged.

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 detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1. **This capacity will be periodically reviewed through the Universal Health Periodic Review mechanism. Should such review identify resource constraints and other challenges in attaining these capacities, WHO and its Regional Offices shall, upon the request of a State Party, provide or facilitate technical support and assist in mobilization of financial resources to develop, strengthen and maintain such capacities.**

New 5. WHO shall develop early warning criteria for assessing and progressively updating the national, regional, or global risk posed by an event of unknown causes or sources and shall convey this risk assessment to States Parties in accordance with Articles 11 and 45 where appropriate. The risk assessment shall indicate, based on the best available knowledge, the level of risk of potential spread and risks of potential serious public health impacts, based on assessed infectiousness and severity of the illness.

Article 6: Notification

1. Each State Party shall assess events occurring within its territory by using the decision instrument in Annex 2 **within 48 hours of the National IHR Focal Point receiving the relevant information.** 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), **the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (OIE), the UN Environment Programme (UNEP) or other relevant entities,** WHO shall immediately notify the IAEA **relevant entities.**

2. Following a notification, a State Party shall continue to communicate to WHO, **by the most efficient means of communication available,** timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including **genetic sequence data,** 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 9: Other reports

1. WHO may take into account reports from sources other than notifications or consultations and shall assess these reports according to established epidemiological principles and then communicate information on the event to the State Party in whose territory the event is allegedly occurring. ~~Before taking any action based on such reports, WHO shall consult with and attempt to obtain verification from the State Party in whose territory the event is allegedly occurring in accordance with the procedure set forth in Article 10. To this end,~~ WHO shall make the information received available to the States Parties and only where it is duly justified may WHO maintain the confidentiality of the source. This information will be used in accordance with the procedure set forth in Article 11.

Article 10: Verification

1. **Within 24 hours of receiving information,** 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 **paragraphs 1 and 2 of** that Article.

3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall offer **within 24 hours** 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.

3bis. Within 24 hours of receiving a WHO offer of collaboration, the State Party may request additional information supporting the offer. WHO shall provide such information within 24 hours. When 48 hours have elapsed since the initial WHO offer of collaboration, failure by the State Party to accept the offer of collaboration shall constitute rejection for the purposes of sharing available information with States Parties under Paragraph 4 of this section.

4. If the State Party does not accept the offer of collaboration **within 48 hours,** WHO ~~shall~~ **may,** when justified by the magnitude of the public health risk, **immediately** share with other States Parties the information 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, **or which is available in the public domain,** and which is necessary to enable States Parties to respond to a public health risk. WHO **shall** 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, **when until such time as:**

- (a) the event is determined to constitute a public health emergency of international concern 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; or
- (e) **WHO determines it is necessary that such information be made available to other States Parties to make informed, timely risk assessments.**

3. WHO shall **inform** ~~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 **shall** 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.

New 5. WHO shall annually report to the Health Assembly on all activities under this Article, including instances of sharing information that has not been verified by a State Party on whose territory an event that may constitute a public health emergency of international concern is or is allegedly occurring with States Parties through alert systems.

Article 12: Determination of a public health emergency of international concern, public health emergency of regional concern, or intermediate health alert

1. The Director-General shall determine, on the basis of information received, in particular from the State Party within whose territory an event is occurring, whether an event constitutes a public health emergency of international concern in accordance with the criteria and the procedure set out in these Regulations.
2. If the Director-General considers, based on an assessment under these Regulations, that a **potential or actual** public health emergency of international concern is occurring, the Director-General shall **notify all States Parties and seek to** consult with the State Party in whose territory the event arises regarding this preliminary determination **and may, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the “Emergency Committee”)**. If the Director-General determines ~~and the State Party are in agreement regarding this determination~~ **that the event constitutes a public health emergency of international concern**, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the ~~Committee established under Article 48 (hereinafter the “Emergency Committee”)~~ on appropriate temporary recommendations.
3. ~~If, following the consultation in paragraph 2 above, the Director-General and the State Party in whose territory the event arises do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern, a determination shall be made in accordance with the procedure set forth in Article 49.~~
4. In determining whether an event constitutes a public health emergency of international concern, the Director-General shall consider:
 - (a) Information provided by the State Party, **by other States Parties, available in the public domain, or otherwise available under Articles 5-10;**
 - (b) The decision instrument contained in Annex 2;
 - (c) The advice of the Emergency Committee;
 - (d) Scientific principles as well as 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.
5. If the Director-General, following consultations with the **Emergency Committee and relevant States Parties** ~~within whose territory the public health emergency of international concern has occurred~~, considers that a public health emergency of international concern has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49.

New 6. Where an event has not been determined to meet the criteria for a public health emergency of international concern but the Director-General has determined it requires heightened international awareness and a potential international public health response, the Director-General, on the basis of information received, may determine at any time to issue an intermediate

public health alert to States Parties and may consult the Emergency Committee in a manner consistent with the procedure set out in Article 49.

New 7. A Regional Director may determine that an event constitutes a public health emergency of regional concern and provide related guidance to States Parties in the region either before or after notification of an event that may constitute a public health emergency of international concern is made to the Director-General, who shall inform all States Parties.

Article 13: Public health response

3. ~~At the request of a State Party, WHO shall~~ offer assistance ~~collaborate to a State Party~~ 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. The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which WHO shall share with other States Parties.

4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern is occurring, it ~~shall~~ may offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State Party, 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. The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which WHO shall share with other States Parties. Regarding on-site assessments, in compliance with its national law, a State Party shall make reasonable efforts to facilitate short-term access to relevant sites; in the event of a denial, it shall provide its rationale for the denial of access.

Article 15: Temporary recommendations

2. Temporary recommendations may include the deployment of expert teams, as well as health measures to be implemented by the State Party experiencing the public health emergency of international concern, or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.

Article 18: Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels

New 3. In developing temporary recommendations, the Director-General shall consult with relevant international agencies such as ICAO, IMO and WTO in order to avoid unnecessary interference with international travel and trade, as appropriate. Additionally, temporary recommendations should allow for the appropriate exemption of essential health care workers and essential medical products and supplies from travel and trade restrictions.

New 4: In implementing health measures pursuant to these Regulations, including Article 43, States Parties shall make reasonable efforts, taking into account relevant international law, to ensure that:

- (a) Contingency plans are in place to ensure that health care worker movement and supply chains are facilitated in a public health emergency of international concern;**
- (b) Travel restrictions do not unduly prevent the movement of health care workers necessary for public health responses;**
- (c) Trade restrictions make provision to protect supply chains for the manufacture and transport of essential medical products and supplies; and**
- (d) The repatriation of travellers is addressed in a timely manner, given evidence-based measures to prevent the spread of diseases.**

Article 48: Terms of reference and composition

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, **as well as Regional Directors from any impacted region.** 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 **age, gender, and** geographical representation, **and require training in these Regulations before participation.** ~~At least one member~~ **Members** of the Emergency Committee should **include be** ~~an~~ **at least one** expert nominated by ~~a~~ **the** State Party within whose territory the event arises, **as well as experts nominated by other affected States Parties.** **For the purposes of Articles 48 and 49, an “affected State Party” refers to a State Party either geographically proximate or otherwise impacted by the event in question.**

Article 49: Procedure

3 bis. If the Emergency Committee is not unanimous in its findings, any member shall be entitled to express his or her dissenting professional views in an individual or group report, which shall state the reasons why a divergent opinion is held and shall form part of the Emergency Committee’s report.

3 ter. The composition of the Emergency Committee and its complete reports shall be shared with Member States.

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

...

7. **Affected** States Parties ~~in whose territories the event has occurred~~ may propose to the Director-General the termination of a public health emergency of international concern and/or the temporary recommendations, and may make a presentation to that effect to the Emergency Committee.

New Chapter IV (Article 53 bis-quater): The Compliance Committee

53 bis Terms of reference and composition

1. The State Parties shall establish a Compliance Committee that shall be responsible for:

- (a) Considering information submitted to it by WHO and States Parties relating to compliance with obligations under these Regulations;
- (b) Monitoring, advising on, and/or facilitating assistance on matters relating to compliance with a view to assisting States Parties to comply with obligations under these Regulations;
- (c) Promoting compliance by addressing concerns raised by States Parties regarding implementation of, and compliance with, obligations under these Regulations; and
- (d) Submitting an annual report to each Health Assembly describing:
 - (i) The work of the Compliance Committee during the reporting period;
 - (ii) The concerns regarding non-compliance during the reporting period; and
 - (iii) Any conclusions and recommendations of the Committee.

2. The Compliance Committee shall be authorized to:

- (a) Request further information on matters under its consideration;
- (b) Undertake, with the consent of any State Party concerned, information gathering in the territory of that State Party;
- (c) Consider any relevant information submitted to it;
- (d) Seek the services of experts and advisers, including representatives of NGOs or members of the public, as appropriate; and
- (e) Make recommendations to a State Party concerned and/or WHO regarding how the State Party may improve compliance and any recommended technical assistance and financial support.

3. The Members of the Compliance Committee shall be appointed by States Parties from each Region, comprising six government experts from each Region. The Compliance Committee shall be appointed for four-year terms and meet three times per year.

53 ter. Conduct of business

1. The Compliance Committee shall strive to make its recommendations on the basis of consensus.

2. The Compliance Committee may request the Director-General to invite representatives of the United Nations and its specialized agencies and other relevant intergovernmental organizations or nongovernmental organizations in official relations with WHO to designate representatives to attend the Committee sessions, where appropriate to address a specific issue under consideration. Such representatives, with the consent of the Chairperson, make statements on the subjects under discussion.

53 quater Reports

1. For each session, the Compliance Committee shall prepare a report setting forth the Committee's views and advice. This report shall be approved by the Compliance Committee before the end of the session. Its views and advice shall not commit WHO, States Parties, or other entities and shall be formulated as advice to the relevant State Party.

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

3. The Compliance Committee's report shall be submitted to all States Parties and to the Director-General, who shall submit reports and advice of the Compliance Committee, to the Health Assembly or the Executive Board, as well as any relevant committees, for consideration, as appropriate.

Article 59: Entry into force; period for rejection or reservations

1. The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, these Regulations ~~or an amendment thereto~~, shall be 18 months from the date of the notification by the Director-General of the adoption of these Regulations ~~or of an amendment to these Regulations~~ by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.

1 bis. The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, an amendment to these Regulations shall be six months from the date of the notification by the Director-General of the adoption of an amendment to these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.

2. These Regulations shall enter into force 24 months after the date of notification referred to in paragraph 1 of this Article, **and amendments to these Regulations shall enter into force six months after the date of notification referred to in paragraph 1bis of this Article**, except for:

- (a) a State that has rejected these Regulations or an amendment thereto in accordance with Article 61;
- (b) a State that has made a reservation, for which these Regulations shall enter into force as provided in Article 62;
- (c) a State that becomes a Member of WHO after the date of the notification by the Director-General referred to in paragraph 1 of this Article, and which is not already a party to these Regulations, for which these Regulations shall enter into force as provided in Article 60; and

(d) a State not a Member of WHO that accepts these Regulations, for which they shall enter into force in accordance with paragraph 1 of Article 64.

3. If a State is not able to adjust its domestic legislative and administrative arrangements fully with these Regulations **or amendments thereto** within the periods set out in paragraph 2 of this Article, **as applicable**, that State shall submit within the period specified in paragraph 1 of this Article a declaration to the Director-General regarding the outstanding adjustments and achieve them no later than 12 months after the entry into force of these Regulations **or the amendments thereto** for that State Party.

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