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ANNEX

ANNEX

to the

Proposal for a Council Decision

authorising Member States to accept, in the interest of the European Union, the amendments to the International Health Regulations contained in the Annex to Resolution WHA 77.17 and adopted on 1 June 2024

Amendments to the International Health Regulations (2005) adopted by the Seventy-seventh World Health Assembly through resolution WHA77.17 (2024) are presented in underline and bold character (additions) and strike-through (deletions).

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"):

(…)

"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;

(…)

"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;

(…)

"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;

(…)

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 risk~~s,~~ 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**.

(…)

Article 4 Responsible authorities

1. Each State Party shall designate or establish**, in accordance with its national law and context, one or two entities to serve as National IHR Authority and** ~~a~~ 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 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.

(…)

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 **core** ~~capacity~~ **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.

(…)

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)**.

(…)

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

(…)

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

(…)

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

(…)

*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 **is occurring** ~~arises~~ 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 **is occurring** ~~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, **including, when appropriate, a pandemic emergency,** the Director-General shall consider:

(a) information provided by the State**(s)** Party**(ies)**;

(…)

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), (d) and (e) of paragraph 4 of this Article, and** following consultations with the State**(s)** Party**(ies)** within whose territory**(ies)** ~~the~~ **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 **core** ~~capacity~~ **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)**, 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.

(…)

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:

(…)

(d bis) availability of, and accessibility to relevant health products;

(…)

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

(…)

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;

(…)

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.

(…)

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:

(…)

2. States Parties sharing common borders should consider:

(…)

(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:

(…)

(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.

(…)

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

(…)

Article 27 Affected conveyances

1. (…)

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.

(…)

Article 28 Ships and aircraft at points of entry

(…)

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.

(…)

PART VI – HEALTH DOCUMENTS

Article 35 General rule

(…)

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 ~~Maritime~~ **Ship** Declaration of Health*

1. The master of a ship, before arrival at its first port of call in the territory of a State Party, shall ascertain the state of health on board, and, except when that State Party does not require it, the master shall, on arrival, or in advance of the vessel's arrival if the vessel is so equipped and the State Party requires such advance delivery, complete and deliver to the competent authority for that port a ~~Maritime~~ **Ship** Declaration of Health**,** which shall be countersigned by the ship's surgeon, if one is carried.

(…)

3. A ~~Maritime~~ **Ship** Declaration of Health shall conform to the model provided in Annex 8.

4. A State Party may decide:

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

(b) to require the submission of the ~~Maritime~~ **Ship** 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.

(…)

PART VIII – GENERAL PROVISIONS

(…)

Article 43 Additional health measures

(…)

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.**

(…)

*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**

(…)

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.

(…)

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

(…)

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:

(…)

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

(…)

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**.

(…)

Article 49 Procedure

(…)

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.

(…)

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 recommendation**s, 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:

(…)

(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.

(…)

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:

(…)

(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

(…)

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.

(…)

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.**

(…)

[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.~~**;**

(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**

(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

[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.**

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);

~~(c) 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 maintain**ing** 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:

(…)

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:~~

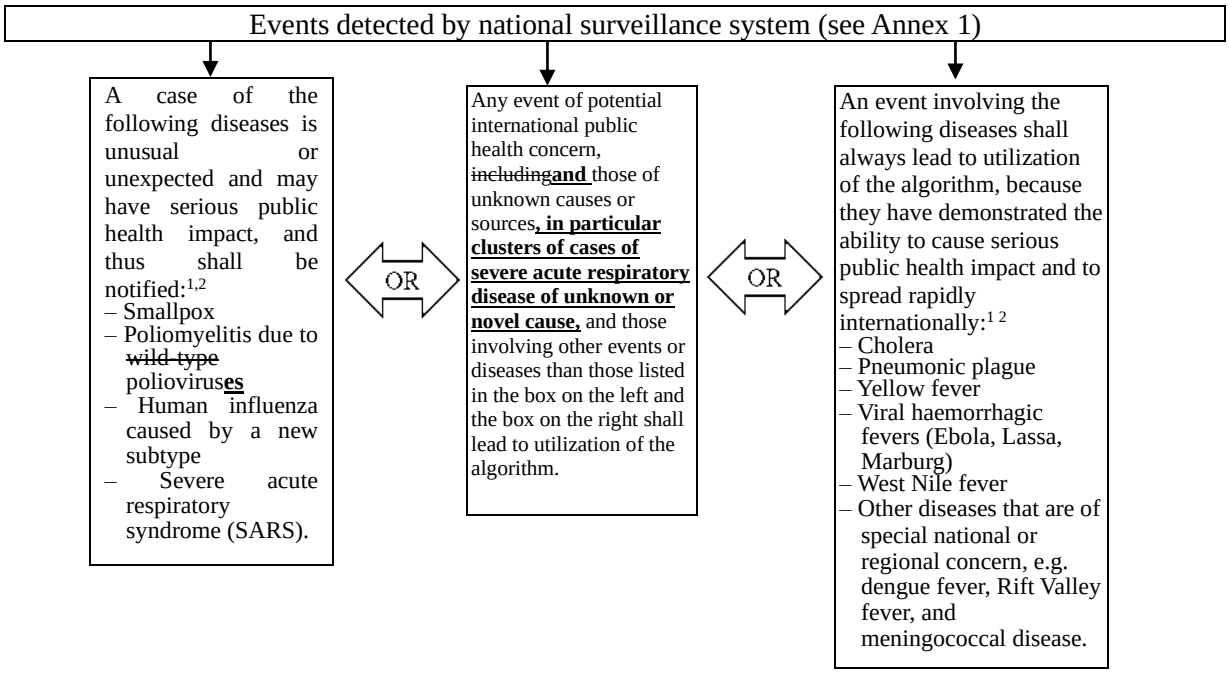
(…)

(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;

(…).

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 purposed of these Regulations.

ANNEX 3

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 s						
- 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. **Control measures indicated were applied on the date below.**

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

(…)

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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.

(…)

ANNEX 6

VACCINATION, PROPHYLAXIS AND RELATED CERTIFICATES

(…)

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** certificate**s** 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.**

(…)

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~~ indicate~~d~~ 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**.

(…)

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 follows[1] ……**, or, if applicable:**

name of the parent or guardian ……..

signature of the parent or guardian[1] ……..

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.**

(…)

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

ANNEX 8

MODEL OF ~~MARITIME~~SHIP DECLARATION OF HEALTH

(…)

ATTACHMENT TO MODEL OF ~~MARITIME~~SHIP DECLARATION OF HEALTH

(…)