

SECOND MEETING OF THE WORKING GROUP ON
AMENDMENTS TO THE INTERNATIONAL HEALTH
REGULATIONS (2005)
Provisional agenda item 6

A/WGIHR/2/7
6 February 2023

**Article-by-Article compilation of proposed amendments to the International Health
Regulations (2005) submitted in accordance with decision WHA75(9) (2022)**

The Working Group on Amendments to the International Health Regulations (WGIHR) at its first meeting on 14–15 November 2022 decided that “the Secretariat shall also publish online an article-by-article compilation of the proposed amendments, as authorized by the submitting Member States, in the six official languages, without attribution of the proposals to the Member States proposing them.”¹

In furtherance of the WGIHR’s decision above, this document provides an article-by-article compilation of the proposals for amendments to the International Health Regulations (IHR) (2005) submitted in accordance with decision WHA75(9) (2022).

Proposed amendments are presented as follows:

- ~~Strikethrough~~ = proposal to delete existing text (For on screen text editing purposes, strikethrough text in the proposed amendments is displayed as [xxx DEL])
- **Underlined and bold** = proposal to add text
- (...): existing text in the IHR (2005) in relation to which no proposals for amendments were submitted and which is therefore omitted from the compilation

The compilation is not intended to replace the proposed amendments to the IHR (2005) in the original submission.

¹ Document A/WGIHR/1/5.

**ARTICLE BY ARTICLE COMPILATION OF PROPOSED AMENDMENTS TO THE
INTERNATIONAL HEALTH REGULATIONS (2005) SUBMITTED BY STATES PARTIES
IN THE CONTEXT OF DECISION WHA75(9)²**

Legend

~~Strikethrough~~ = delete existing text

Underlined and bold = new text proposed

(...) = existing text in the IHR for which proposals for amendments were not submitted and thus omitted from this compilation

Article 4 Responsible authorities

1. Each State Party shall designate or establish a **[n entity with the role of RUS]** National IHR Focal Point and the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations. **[WHO shall provide technical assistance and collaborate with States Parties in capacity building of the National IHR focal points and authorities upon request of the States Parties. AF GROUP]**

[1bis. In addition, each State Party should inform WHO about the establishment of its National Competent Authority responsible for overall implementation of the IHR that will be recognized and held accountable for the NFP's functionality and the delivery of other IHR obligations. CHE]

[NEW (1bis) States Parties [shall DEL MYS / may MYS] enact or adapt legislation to provide National IHR Focal Points with the authority and resources to perform their functions, clearly defining the tasks and function of then entity with a role of National IHR Focal Point in implementing the obligations under these Regulations. RUS, MYS]

(...)

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

Article 6 Notification

1. Each State Party, **[within 48h after the Focal Point receives information about the event shall assess events occurring within its territory RUS, MYS]** by using the decision instrument in Annex 2, **[within 48 hours of the National IHR Focal Point receiving the relevant information IND, USA, NZL]**. 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

² This compilation is published following the agreements at the first meeting of the Working Group on amendments to the International Health Regulations (2005), as per document A/WGIHR/1/5.

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 UN entities,** IND USA, NZL, MYS] WHO shall immediately notify the [IAEA DEL IND, USA, NZL, MYS], **[relevant national and UN entities.** IND, USA, NZL, MYS]

2. Following a notification, a State Party shall continue to communicate to WHO **[by the most efficient means of communication available** USA, NZL] timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including **[genetic sequence data** USA, NZL], case definitions, laboratory results, **[epidemiological and clinical data, as well as microbial and genomic data in case of an event caused by an infectious agent,** EU] [**genome sequencing data if available,** RUS] source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures [employed DEL EU] **[implemented and other related information as per request of WHO** EU], **[genome sequence data** IDN]; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern[, **with regards to the sharing of genetic sequence data it will depend on Member States' capacity and prevailing national legislation.** MYS] **[With the aim of fostering event related research and assessment, the WHO shall make the information received available to all Parties in accordance with modalities to be adopted by the Health Assembly.** EU]

[3. For better clarity, the provisions of Article 45 shall apply to notifications made pursuant to this Article. EU]

[New 3. No sharing of genetic sequence data or information shall be required under these Regulations. The sharing of genetic sequence data or information shall only be considered after an effective and transparent access and benefit sharing mechanism with standard material transfer agreements governing access to and use of biological material including genetic sequence data or information relating to such materials as well as fair and equitable sharing of benefits arising from their utilization is agreed to by WHO Member States, is operational and effective in delivering fair and equitable benefit sharing. AF GROUP]

[New 3: Upon receiving notification from a State Party, WHO shall not transfer the public health information received pursuant to paragraph 1 of this provision, and other information as defined in paragraph 2 of this provision to establishments, persons, non-state actors or any recipient whatsoever engaging directly or indirectly with conflict and violence elements. WHO shall also handle the information in a manner designed to avoid such actors accessing the information, directly or indirectly. MYS]

Article 7 Information-sharing during unexpected or unusual public health events

(...)

[2. Following a notification pursuant to Article 6 of an event caused by an infectious agent, a State Party shall make available to WHO the microbial and genetic material and samples related to the notified event, as appropriate, not later than (...) hours after such material and samples become available. EU] Note: The proposal for Article 7 is offered without prejudice to further discussion and reflection on where to allocate this issue between the IHR and the pandemic agreement).

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, DEL JPN] a State Party may nevertheless keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate health measures. **[However, where available information is insufficient to complete the decision instrument in Annex 2, a State Party shall keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate health measures within 72 hours of the National IHR Focal Point receiving the relevant information.** JPN] 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 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, DEL USA] 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.

(...)

[3. (New wording) In the recommendations made to the States Parties regarding the collection, processing and dissemination of health information, WHO could advise the following:

(a) To follow the WHO guidelines on criteria and analogous modes of processing and treating health information URY]

Article 10 Verification

1. **[Within 24 hours of receiving the information,** USA, NZL, MYS] WHO shall request, [in accordance with Article 9 DEL USA] **[as soon as possible or within a specific time** RUS] 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 DEL USA], 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** USA, NZL] that Article.

3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall [**as soon as possible or within a specific time** RUS] offer [**within 24 hours** USA, NZL, MYS] 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.

[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. USA]

4. If the State Party does not accept the offer of collaboration [**within 48 hours** USA], WHO [may DEL USA / **shall** USA], when justified by the magnitude of the public health risk, [**immediately** USA] 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. DEL USA]

Article 11[Provision of information by WHO DEL EU] [Exchange of information EU]

1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as appropriate, to relevant [**UN and** IND] [intergovernmental DEL EU] [**international and regional** EU] 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,** USA, NZL, MYS] / ALT **or which is otherwise available and whose validity is appropriately assessed by WHO** EU] and which is necessary to enable States Parties to respond to a public health risk. WHO [should DEL USA, NZL, MYS, EU] [**shall** USA, NZL, MYS, EU] communicate information to other States Parties that might help them in preventing the occurrence of similar incidents. [**For this purpose, WHO shall facilitate the exchange of information between States Parties and ensure that the Event Information Site For National IHR Focal Points offers a secure and reliable platform for information exchange among the WHO and States Parties and allows for interoperability with relevant data information systems.** EU]

2. WHO shall use information received under Articles 6, [and DEL USA, MYS] 8 and [paragraph 2 of Article DEL USA, MYS] 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 DEL USA, MYS] make this information generally available to other States Parties, [until such time as DEL USA, MYS] [**when:** USA, MYS]

(a) the event is determined to constitute a public health emergency of international concern, [**a public health emergency of regional concern, or warrants an intermediate public health alert,** USA, MYS] 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.

[(e) WHO determines it is necessary that such information be made available to other States Parties to make informed, timely risk assessments. USA, NZL, MYS]

3. WHO shall [consult with DEL USA, NZL] [**inform** USA, NZL] the State Party in whose territory the event is occurring as to its intent to make information available under this Article.

[New 3 bis: State Parties receiving information from WHO pursuant to this provision shall not use it for conflict and violence purposes. State Parties shall also handle the information in a manner designed to avoid establishments, personals, non-state actors or any recipient whatsoever engaging directly or indirectly with conflict and violence elements, from accessing such information, directly or indirectly. MYS]

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 DEL USA, MYS] [**shall** USA, MYS] 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. USA]

[New para 5 – The Director-General shall report to the World Health Assembly on all activities under this article as part of their report pursuant to Article 54, including instances of information that has not been verified by a State Party in accordance with article 10. IND]

Article 12 Determination of a public health emergency of international concern [public health emergency of regional concern, or intermediate health alert** IND, USA, EU, KOR]**

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

2. If the Director-General considers, based on an assessment under these Regulations, that a [**potential or actual** IND, USA] public health emergency of international concern is occurring, the Director-General shall [**notify all States Parties and seek to** USA] 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”)** USA]. If the Director-General [**determines** USA] [and

the State Party are in agreement regarding this determination DEL USA], the Director-General shall **[notify all the States Parties** RUS, MYS], in accordance with the procedure set forth in Article 49, seek the views of [the Committee established under Article 48 (hereinafter the-DEL USA) “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. DEL USA]

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;** USA, MYS]

(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.

[4bis. The PHEIC declaration is not designed to mobilise funds in the case of an emergency event. The Director-General should use other mechanisms for this purpose. CHE]

5. If the Director-General, following consultations with the **[Emergency Committee and relevant States Parties** USA, CHE, MYS] [the State Party within whose territory the public health emergency of international concern has occurred, USA, CHE, MYS] 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. **[If there is still a need for recommendations, he should consider convening the Review Committee to advise on issuing standing recommendations in accordance with Articles 16 and 53.** CHE]

[New para 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. IND, USA, KOR, MYS]

[New para 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 preparedness activity, the Director-General, on the basis of information received, may determine at any time to issue a World Alert and Response Notice to States Parties and may seek advice from the Emergency Committee in a manner consistent with the procedure set out in Article 49. NZL]

[NEW (6) The Director-General, if the event is not designated as a public health emergency of international concern, based on the opinion/advice of the Emergency Committee, may designate the event as having the potential to develop into a public health emergency of international concern, communicate this and the recommended measures to States parties in accordance with procedures set out in Article 49 RUS, MYS]

[New para 6. The Director-General may determine that an event constitutes a regional public health emergency of international concern or an intermediate public health emergency of international concern and provide guidance to the Parties as appropriate. Such determination shall be in accordance with the process set out in this Article for the determination of a public health emergency of international concern. EU]

[New 6. Immediately after the determination of PHEIC, the activities of WHO in relation to such PHEIC shall be in accordance with the provisions of these Regulations. The Director General shall report all the activities carried out by WHO, including references to the corresponding provisions of these Regulations pursuant to Article 54. MYS]

[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. USA, MYS]

[New 6. Immediately after the determination of PHEIC, the activities of the WHO in relation to such PHEIC, including through partnerships or collaborations, shall be in accordance with the provisions of these Regulations. The Director General shall report all the activities carried out by WHO, including references to the corresponding provisions of these Regulations in pursuance to Article 54. AF GROUP]

[New 7. In case of any engagement with non-State actors in WHO's public health response to PHEIC situation, WHO shall follow the provisions of Framework for Engagement of Non-State Actors (FENSA). Any departure from FENSA provisions shall be consistent with paragraph 73 of FENSA. AF GROUP]

[New 7. A Regional Director may determine that an event constitutes a public health emergency of regional concern or issue an intermediate health alert and implement related measures to provide advice and support for capacity-building to States Parties in the region either before or after notification of the event. If the event meets the criteria for a public health emergency of international concern after the notification of the event that constitutes a public health emergency of regional concern, the Director-General shall inform all States Parties. KOR]

Article 15 Temporary recommendations

1. If it has been determined in accordance with Article 12 that a public health emergency of international concern is occurring, **[or the event has a potential to become PHEIC, IND]** the Director-General shall issue temporary recommendations in accordance with the procedure set out in Article 49. Such temporary recommendations may be modified or extended as appropriate, including after it has been determined that a public health emergency of international concern has ended, at which time other temporary recommendations may be issued as necessary for the purpose of preventing or promptly detecting its recurrence.

2. **[Temporary recommendations should be as evidence-based, concise and operational as possible, and refer to existing guidance and international technical standards, when appropriate. EU] Temporary recommendations may include [the deployment of expert teams, as well as USA, MYS] 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 [and recommendations on the access and availability of health products, technologies, and know-how, including an allocation mechanism for their fair and equitable access. MYS]**

(...)

[New Para 2 bis: Temporary recommendations should be evidence based as per real time risk assessment of a potential or declared PHEIC, and the immediate critical gaps to be addressed for an optimal public health response, that shall be fair and equitable. The recommendations based on these assessments shall include:

(a) support by way of epidemic intelligence surveillance, laboratory support, rapid deployment of expert teams, medical countermeasures, finance as well as other requisite health measures to be implemented by the State Party experiencing the Public Health Emergency of International Concern, or

(b) prohibitive recommendations to avoid unnecessary interference with international traffic and trade. IND]

(...)

Article 16 Standing recommendations

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 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 **[and recommendations on the access and availability of health products, technologies, and know how, including an allocation mechanism for their fair and equitable access. MYS]** WHO may, in accordance with Article 53, modify or terminate such recommendations, as appropriate.

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;

(e) relevant international standards and instruments;

[New para (e1): Equitable access to and distribution of medical countermeasures i.e. vaccines, therapeutics and diagnostics for optimal public health response. IND]

(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.

[- ensure mechanisms to develop and apply a traveller's health declaration in international public health emergency of international concern (PHEIC) to provide better information about travel itinerary, possible symptoms that could be manifested or any prevention measures that have been complied with such as facilitation of contact tracing, if necessary URY]

[New para 3: In developing 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. IND]

[New 3. In Issuing such recommendation: The WHO should consult with other relevant international organization such as ICAO, IMO, WTO to avoid unnecessary interference with international travel and trade, such as the movement of essential health care workers and medical products and supplies. IDN]

[New 4. In implementing such recommendation: State Parties shall take into consideration their obligations under relevant international law when facilitating essential health care workers movement, ensuring protection of supply chains of essential medical products in PHEIC, and repatriating of travellers. IDN]

[NEW (3) Where States parties impose travel and/or goods and cargo restrictions, WHO may recommend that these measures not apply to movement of health personnel travelling to the State Party(ies) for a public health response and to the transport of medical immunobiological products needed for a public health response. RUS, MYS]

[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. USA, MYS]

[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 travelers is addressed in a timely manner, given evidence-based measures to prevent the spread of diseases. USA, MYS]

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;
- (b) the termination of a public health emergency of international concern; and
- (c) the proposed issuance, modification, extension or termination of temporary recommendations.

2. The Emergency Committee shall be composed of experts **[free from the conflict of interests selected MYS]** 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. USA, MYS]** 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 USA, MYS]** geographical representation **[and gender balance EU]** **[and require training in these Regulations before participation. USA, MYS]** **[The WHO, including through the WHO Academy, shall provide them with support as appropriate. EU]** [At least one member DEL USA, MYS] **[Members USA MYS]** of the Emergency Committee should [be an DEL USA, MYS] **[include at least one USA, MYS]** expert nominated by [a DEL USA, MYS] **[the USA, MYS]** 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 USA, MYS].**

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 [**free from the conflict of interests selected** MYS] to advise the Committee.

Article 49 Procedure

(...)

2. The Director-General shall provide the Emergency Committee with [the DEL EU] [**a detailed** EU] 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. [**The agenda should include a recurrent set of standard items for consideration of the Emergency Committee aimed at ensuring specificity, completeness and coherence of the advice provided.** EU]

(...)

[**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.** IND, USA, NZL]

[**3 ter The composition of the Emergency Committee and its complete reports shall be shared with Member States.** USA, NZL]

4. The Director-General shall invite [**affected States Parties, including** USA, MYS] the State Party in whose territory the event arises to present [its DEL USA, MYS] [**their** USA, MYS] views to the Emergency Committee. To that effect, the Director-General shall notify [to it DEL USA, MYS] [**States Parties of** USA, MYS] 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** USA, MYS] [concerned, however, DEL USA, MYS] may not seek a postponement of the meeting of the Emergency Committee for the purpose of presenting its views thereto.

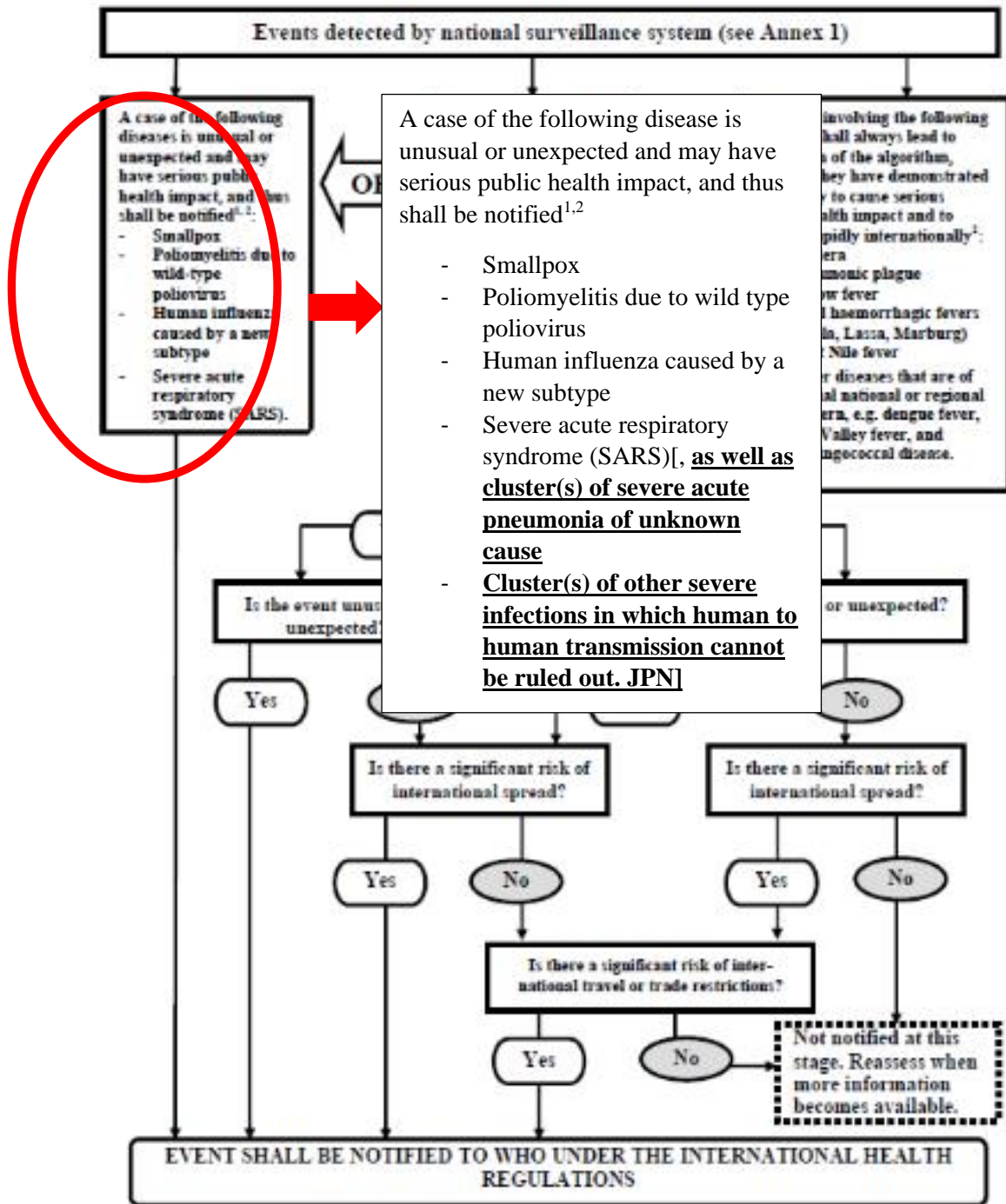
(...)

6. The Director-General shall communicate to States Parties the determination and the termination of a public health emergency of international concern, any health measure taken by the State Party concerned, any temporary recommendation, and the modification, extension and termination of such recommendations, together with the views of the Emergency Committee. The Director-General shall inform conveyance operators through States Parties and the relevant international agencies of such temporary recommendations, including their modification, extension or termination. The Director-General shall subsequently make such information and recommendations available to the general public [**including the reasons behind such recommendations.** MYS]

7. [**Affected** USA, MYS] States Parties [in whose territories the event has occurred DEL USA] 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.

[8. After the declaration of a public health emergency of international concern, the Emergency Committee should present its recommendations to relevant WHO bodies dealing with health emergency prevention, preparedness and response [, such as the Standing Committee on Health Emergency Prevention, Preparedness and Response]. EU]

ANNEX 2
 DECISION INSTRUMENT FOR THE ASSESSMENT AND NOTIFICATION
 OF EVENTS THAT MAY CONSTITUTE A PUBLIC HEALTH EMERGENCY
 OF INTERNATIONAL CONCERN



ANNEX 2

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

[BRA proposes the following model for the evaluation and notification of events that may constitute PHEIC for countries to replace Annex 2]

Events detected by national surveillance system:

Questions in four areas should be considered for the decision, evaluation and notification of events that may constitute a potential PHEIC:

1. Geographical scope/ risk of territorial spread

1.1 Has the event already been notified in more than one country?

1.2 Has the event already been flagged by more than one unit within the national health system?

1.3. Has the event been the subject of national alert or international alert (disease contained in a priority list of the IHR)?

1.4 Is there a risk of national or international spread?

2. Characteristics of the event- whether it is rare, reemerging, presents changes in its epidemiological profile and/or has serious health impact

2.1. Is the event unexpected or unusual?

2.2. Is the event the reemergence of a previously eradicated disease?

2.3. Were there changes in the epidemiological clinical profile (levels of incidence, mortality, lethality) or in the alert zone ("Corresponds to the area delimited by the endemic curve itself and by the upper limit in each time unit of the calendar year")?

2.4. Does the event present high pathogenicity, virulence and transmissibility?

2.5. Is the public health impact of the event serious?

3. Healthcare relevance - whether the event risks compromising the delivery of healthcare and/or poses a risk to health professionals

3.1. Does the event impair the delivery of healthcare services, for instance, because there is no treatment available or treatment requires the use of controlled medications?

3.2. Is there a significant increase in treatment provision or in hospitalizations?

3.3. Does the event affect healthcare professionals?

4. Social and Economic Relevance - whether the event affects vulnerable populations, has high social impact and/or poses a risk to international travel or trade

4.1. Does the event affect vulnerable populations?

4.2. Is it a disease or public health event with high social impact (which generates fear, stigmatization or social grievance)?

4.3. Does the event affect social interaction?

4.4. Does the event affect local tourism or has a high economic impact?

4.5. Is there a significant risk for international travelling or trade?

The risk must be evaluated in accordance to the aforementioned questions, with a value of 1 for Yes and 0 for No. The sum of the value of all responses will guide the Member State regarding the decision to notify the WHO, according to Art. 6 of the RSI.

For the risk level, the following scores were assigned:

LOW: Equal to or < 5 - Keep monitoring it internally

AVERAGE: 5 to 11 - Potential for spread between countries - Notify WHO according to Art. 6 of the RSI

HIGH: > 11 -Potential PHEIC - Notify the WHO according to Art. 6 of the RSI

= = =