

**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 (2005) (WGIHR) at its first meeting on 14-15 November 2022 decided that “the Secretariat shall publish the proposed amendments online, as submitted by Member States unless otherwise informed by the submitting Member States.”¹

In furtherance of the WGIHR’s decision above, this document includes proposals for amendments to the International Health Regulations (2005) (IHR), as submitted by Member States.

The proposals are listed in alphabetical order by Member State.

NOTE: This document was updated on 27 March 2024 to include the proposals for amendments as submitted by Japan on 22 September 2022.

¹ Document A/WGIHR/1/5.



**World Health
Organization**

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Armenia

Bangladesh

Brazil

Czech Republic

on behalf of the Member States of the European Union (EU)

Eswatini

on behalf of the Member States of the WHO African Region

India

Indonesia

Japan

Malaysia

Namibia

New Zealand

Republic of Korea

Russian Federation

on behalf of the Member States of the Eurasian Economic Union (EAEU)

Switzerland

United States of America

Uruguay

on behalf of the Member States of the Southern Common Market (MERCOSUR)

Armenia¹

¹ Note by the WHO Secretariat: On 30 September 2022, the Government of Armenia submitted its contribution in accordance with Decision WHA75(9). On 24 October 2022, the WHO Secretariat also received the above-mentioned contribution on headed paper. It is for this reason that the version included in this document is dated 24 October 2022.



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MINISTRY OF HEALTH OF THE REPUBLIC OF ARMENIA
FIRST DEPUTY MINISTER
МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ
АРМЕНИЯ
ПЕРВЫЙ ЗАМЕСТИТЕЛЬ МИНИСТРА

24.10.22 № 2/10.2/25096-22

Ձեր N _____

HEAD OF UNIT, INTERNATIONAL HEALTH REGULATIONS SECRETARIAT
WHO HEALTH EMERGENCIES PREPAREDNESS AND IHR
DR CARMEN DOLEA

Email: ihrcommittees@who.int

Dear Dr Carmen Dolea,

In response to the request of IHR secretariat, the Ministry of Health of the Republic of Armenia presents below the recommendations for the "Amendments to the International Health Regulations (2005) (IHR)":

I. Major problems

1. Global preparedness problem.
2. Significant personnel changes contributed to the fact that IHR did not work.
3. Insufficient cooperation between private and public institutions.
4. Pandemic tools (masks, tests, vaccines) shortage and reserve issues.
5. Improving the laboratory system (quality control mechanisms).

II. Sharing

6. Sharing of laboratory tests, vaccines/large quantity purchasing for region.



Առողջապահության
Նախարարություն
Ministry of Health of the Republic of Armenia

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- a. Equal distribution, consistent access, distribution based on need, flexibility with contracts with manufacturers/COVAX due to changing situations.
7. Information Sharing:
 - a. Each party should undertake exchange of information related to sequencing of data, cases, deaths, testing, new variants.
8. Technology sharing with regards to testing, vaccination, medications, etc.:
 - a. To allow for more countries to have access to technology needed to assess epidemiological situations, treat patients, and develop vaccines.
 - b. Equipment for treating pandemic situations.
9. Sharing of best practices when it comes to risk communication, public awareness campaigns, treatment of disease, vaccination etc. Training of pandemic tools, either face to face or E-learning (support from WHO, perhaps additional budget is needed).

III. Surveillance and response

10. Create electronic digital centralized system for a comprehensive data collection on case and its contacts, vaccination status, as well as using “One Health” approach to reduce the risks of developing zoonotic diseases.
11. Better breakdown of travel restriction criteria:
 - a. Creation of a board to advise on border closures.
 - b. Focusing more on security of people.
12. Country’s obligated to develop pandemic operational response plan (national human resource mobilization, public health management) with staff responsibility.
13. Establishment of national committee within countries on pandemic response which will be functioning during pandemic situations only (including different ministries and high-level government officials).
14. Sharing of best practices when it comes to public awareness campaigns, treatment of disease, etc.
15. Parties meeting (conference) on an annual basis to discuss budget and program.

- a. How budget will be collected and how the funds will be governed.
16. Need for the treaty to define the term “pandemic” and “pandemic tools”, “pathogens of concern” (currently absent in the IHR) and establish procedures for declaring pandemic and responsibilities and roles of parties and secretariat.
17. Pandemic treaty should be aligned with IHR.
18. Development of pandemic plan within each country with detailed budget included.
19. Timely response to questions raised by countries (while they are still relevant).
20. Establish mental health and psychosocial support platforms.
21. Regulations during a shortage of personnel (volunteers, medical students, but experienced).
22. Take into account health needs of special groups (prisons, testing of teachers, homeless people, persons with disability, factory workers, orphanage, nursing home).

IV. Research

23. Allocate resources for appropriate research pertaining to pandemic response (e.g. variants, effectiveness of vaccines, etc.):
 - a. Parties should support national/international efforts to strengthen national scientific and technical research capabilities particularly in developing countries.
24. A science-policy body under the prospective treaty linking to current bodies in place to ensure the parties are advised on science and technology advancements relevant to the development and implementation of international rules and guidelines under the treaty.
25. Create network to allow for research collaboration within the region.
26. Cost-effectiveness economic analysis, modelling.

V. Finances

27. Financial resources and mechanisms should be defined to ensure sustainable and predictable financing for global pandemic response.

VI. Compliance

- 28. Mechanisms for compliance and monitoring should be defined by the treaty, such as period peer reviews.
- 29. Submission of internal compliance reports on development of pandemic response plan.
- 30. Mechanism should be placed so that countries that do join the treaty have added benefits (e.g. sharing mechanisms, etc.).

SINCERELY,

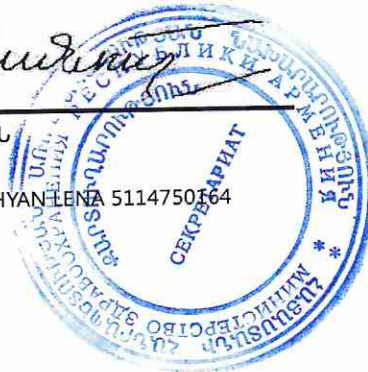
LENA NANUSHYAN

24.10.2022

X *L. Nanushyan*

ԼԵՆԱ ՆԱՆՈՒՇՅԱՆ

Signed by: NANUSHYAN LENA 5114750164



Executor: Lilit Aleksanyan
Department of International Relations
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Bangladesh



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Note Verbale

No.: BMG/WHO-525

The Permanent Mission of the People's Republic of Bangladesh to the United Nations and Other International Organisations in Geneva presents its compliments to the Secretariat of the World Health Organization in Geneva and in accordance with Article 55(1) of the International Health Regulations (IHR) (2005) and decision WHA75(9), the Government of Bangladesh is proposing amendments to the IHR(2005). The texts of the proposal of amendment along with a justification note is being sent herewith.

It would be highly appreciated if the esteemed Secretariat, as per Article 55(2) of the IHR(2005), could kindly communicate the texts of the amendment proposal by Bangladesh to all State Parties as well as take other measures as required.

The Permanent Mission of the People's Republic of Bangladesh to the United Nations and Other International Organisations in Geneva avails itself of this opportunity to renew to the Secretariat of the World Health Organization in Geneva the assurances of its highest consideration.

- Encl.: a. Texts of the proposed amendment to IHR(2005) (06 pages)**
b. A justification note for the proposed amendment (01 page)

Geneva, 30 September 2022



Secretariat of the World Health Organization
20, Avenue Appia-CH-1211
Geneva 27
Switzerland

Justification on the amendment being proposed by Bangladesh

Since the outbreak of the COVID-19 pandemic, all the countries have not been able to equally respond to the challenges owing to the differential resource and capacity constraints of their health systems. At the same time, the weaknesses of the global health governance and architecture have put up additional challenges on WHO limiting its scope to turn up as per the essential need across the globe. As a result, the unequal recovery from the pandemic is causing the inequalities within and among the societies; and this tends to widen further.

Under the above circumstances, it would be exigent to create enablers for strengthening WHO to secure health for everyone everywhere. In this pursuit, amendment of IHR (2005) would be a pragmatic approach while the discussion for concluding the pandemic instrument proceeds. Hence, Bangladesh is proposing amendment to the International Health Regulations (IHR) (2005) in the pursuit of achieving health equities for all the countries.

The amendment to the IHR(2005) which is being proposed by Bangladesh is aimed at enabling WHO to undertake reform initiatives to strengthen itself and help create level playing field among the vital players in effectively responding to future health emergencies. From the very beginning of the discussions in the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR) and Intergovernmental Negotiating Body (INB) on pandemic instrument, Bangladesh has been stressing upon strengthening the core capacities of the health systems of the Member States and enhancing their resilience as the key area in WHO's reform as well as in developing new instrument for pandemic prevention, preparedness and response.

COVID-19 pandemic has manifested that the fate of global community is intertwined as the health of the people of individual country cannot be secured in an isolated manner. Therefore, it would be seminal to forge effective international cooperation for financial, technical and technological support, assistance and cooperation among the Member States to develop health systems' building blocks in consistence with Universal Health Coverage principles. In that pursuit, amendment of IHR (2005) would be an effective approach.



**Proposal of amendment to the International Health Regulations(IHR) (2005)
by Bangladesh**

Legend in the texts:

- Deletion by strikethrough
- Addition of new texts in bold face letters

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Article 1: Definitions

“standing recommendation” means **non-binding** advice issued by WHO for specific ongoing public health risks pursuant to Article 16 regarding appropriate health measures for routine or periodic application needed to prevent or reduce the international spread of disease and minimize interference with international traffic;

...

“temporary recommendation” means **non-binding** advice issued by WHO pursuant to Article 15 for application on a time-limited, risk-specific basis, in response to a public health emergency of international concern, so as to prevent or reduce the international spread of disease and minimize interference with international traffic;

Article 2: Purpose and Scope

The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease **including through health systems readiness and resilience** in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic, and trade.

Article 3: Principles

2 bis. The States Parties shall develop and maintain capacities to implement the Regulations in accordance with their Common But Differentiated Responsibilities and Respective Capabilities (CBDR-RC), availability of international financial assistance and shared technological resources, and in this regard, primary preference shall be given to the establishment of functioning public health systems resilient to the public health emergencies.

Article 13: Public Health Response

New 7. Measures taken by States Parties shall not create barriers to or compromise the abilities of the other States Parties to effectively respond to public health emergency of international concern, unless exceptional circumstances warrant such measures. States Parties whose abilities to respond are affected by the measures taken by other States Parties shall have the right to enter into consultation with the States Party implementing such measures to find a solution at the earliest considering the country interest.

New Article 13A: WHO Led International Public Health Response

1. States Parties recognize WHO as the guidance and coordinating authority of international public health response during Public Health Emergency of International Concern and undertake to follow WHO’s recommendations in their international public health response.



2. WHO shall carry out an assessment of the availability and affordability of the health products such as diagnostics, therapeutics, vaccines, personal protective equipment and other tools required for responding to public health emergencies of international concern, including the potential increase in supply resulting from the surge and diversification of production and in cases of expected shortage of supply, WHO shall develop an allocation plan for health products so as to ensure equitable access to people of all states parties.

3. WHO shall, in its allocation plan for health products, inter alia identify and prioritize the recipients of health products, including health workers, frontline workers and vulnerable populations, and determine the required quantity of health care products for effective distribution to the recipients across States Parties.

4. Upon request of WHO, States Parties with the production capacities shall undertake measures to scale up production of health products, including through diversification of production, technology transfer and capacity building especially in the developing countries.

5. Upon request of WHO, States Parties shall ensure the manufacturers within their territory supply the requested quantity of the health products to WHO or other States Parties as directed by WHO in a timely manner in order to ensure effective implementation of allocation plan.

6. WHO shall develop and maintain a database containing the details of the ingredients, components, design, know-how, manufacturing process, or any other information required to facilitate manufacturing of health products required for responding to the potential public health emergencies of international concern. Within two years of the entry into the force of this provision, WHO shall develop this database for all PHEICS declared so far, including for the diseases identified in the IHR 1969.

7. WHO in accordance with the provisions of these Regulations and in particular Article 13A(1), shall collaborate with other international organizations, and other stakeholders consistent with provisions of FENSA, for responding to public health emergency of international concern. WHO shall report all its engagement with other stakeholders to the health assembly. The Director General shall provide documents and information relating to such engagements upon request of State Parties.

Article 44: collaboration and assistance

1. States Parties with assistance from WHO shall ~~undertake to~~ collaborate with ~~and assist each other~~, upon request, ~~to the extent possible~~, in:

(a) the detection and assessment of, and response to, events as provided under these Regulations;

(b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public



health capacities required under these Regulations **and in particular as provided in Annex 1;**

(c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations **and to establish an international financial mechanism for providing financial assistance to developing countries in the development, strengthening and maintenance of core capacities required under these Regulations and functioning health systems resilient to the public health emergencies.**

(d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations.

(e) **providing equitable access to health products such as diagnostics, therapeutics, vaccines, PPE equipment and other tools required for responding to public health emergencies of international concern to frontline workers, vulnerable populations and general population of all countries in order, as well as in prioritizing access to such health products for health workers of all countries in rolling out distribution plans.**

2. WHO shall collaborate with States Parties, upon request, with utmost effort **to the extent possible**, in:

(a) the evaluation and assessment of their public health capacities in order to facilitate the effective implementation of these Regulations;

(b) the provision or facilitation of technical cooperation and logistical support to States Parties; and

(c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1 **and to establish an international financial mechanism for providing financial assistance to developing country States Parties for the said purpose.**

(d) **in providing equitable access to health products such as diagnostics, therapeutics, vaccines, personal protective equipment and other tools required for responding to public health emergencies of international concern to frontline workers, vulnerable populations and general public of all countries in order, as well as in prioritizing access to such health products for health workers of all countries in rolling out distribution plans and production capacity.**

3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies **and if undertaken, shall be reported to health assembly through the report submitted under Article 54.**



New 4. WHO shall develop an evaluation matrix for assessing the contributions of States Parties to the international coordination of public health preparedness and response to health emergencies and shall make the results of such assessments publicly available within five years of entry into force of the provision, and thereafter every three years.

Annexure 1, Part A. Core Capacity Requirements for Surveillance and Response

1. States Parties shall utilize existing national structures and resources to meet their core capacity requirements under these Regulations **in accordance with principle 2 bis**, including with regard to:

(a) their surveillance, reporting, notification, verification, response and collaboration activities; and

(b) their activities concerning designated airports, ports and ground crossings.

New 1 bis. Developed Country States Parties shall provide financial and technological assistance to the Developing Country States Parties in order to ensure state-of-the-art facilities in developing country States Parties, including through international financial mechanism as envisaged in Article 44.

New 7. Health System Capacities: In accordance with principle 2 bis, States Parties need to build, develop and maintain health systems capacities resilient to public health emergency of international concern as stated below:

(i) **health-care infrastructure and service delivery: improved number and distribution of health care infrastructure and facilities at the local community level, primary, secondary, and tertiary health care levels to the resilience levels as defined by WHO, including inpatient beds and outpatient visiting slots, geographical accessibility of such facilities, providing general and specific services**

(ii) **upgradation of the health-care infrastructure and service: enhance the prompt and quality health care to the affected persons at the local community level and/or primary health care response level and to make available the state of art health care technologies, advanced tools and methods, acting in coordination with intermediate or national health response level.**

(iii) **health workforce: improved number and distribution of trained health workers at the local community level, primary, secondary, and tertiary health care levels to the resilience levels as defined by WHO, including an equitable Gender specific, cultural, regional and linguistic representation, availability of generalists and specialists, and adequate yearly replenishment or reinforcement ratio.**

(iv) **health information systems: establishment and maintenance of institutional mechanism in charge of health statistics, synthesis of data from different sources and validation of data from population-based and facility-based**



sources, periodic health systems performance assessment, health systems resource tracking, immunization coverage and periodic burden of disease studies and its dissemination, subject to national sovereignty of the States Parties and privacy of the personal data.

(v) access to health products: assessment and enhancement of availability and affordability of listed health products including improved agility of the health products listing by national authorities, ease of adoption of legal, administrative and technical measures to diversify and increase production, and improve distribution, and generic substitution.

(vi) financing: health care service delivery during health emergencies shall not result in catastrophic payments, i.e. that households shall not spend more than 10% of their total income on health.

(vi) leadership/governance: existence of national health strategy linked to national needs and priorities, including national medicines policy and health emergency preparedness and response plan, periodic updating of the same, and implementation – feedback – follow-up cycle, public confidence building measures and engagement of community participation in both agenda setting and implementation.



Brazil



*Permanent Mission of Brazil to the United Nations Office and other International Organizations in Geneva
15, Chemin Camille-Vidart
1202 Geneva – Switzerland*

Nº 343/2022

The Permanent Mission of Brazil to the United Nations Office and other International Organizations in Geneva presents its compliments to the World Health Organization and, with reference to decision WHA75(9) of 27 May 2022, has the honor to submit proposed amendments to the Annex 2 of the IHR (2005) on behalf of Brazil.

2. The Permanent Mission also has the honor to inform that Brazil is one of the proponents of the amendments submitted by Uruguay on behalf of the Mercosur countries (Argentina, Brazil, Paraguay and Uruguay), in accordance with the attached document.

3. The Permanent Mission respectfully requests the Director General of the WHO to communicate the proposed amendments to all State Parties in accordance with decision WHA75(9) and Article 55(2) of the IHR.

The Permanent Mission of Brazil avails itself of this opportunity to renew to the World Health Organization the assurances of its highest consideration.

Geneva, 30 September 2022.



To the
World Health Organization
Geneva

Brazil proposes a model for the evaluation and notification of events that may constitute PHEIC for countries to replace Annex 2:

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

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

MERCOSUR – Setiembre 2022
Propuestas de Enmiendas al RSI 2005

En el marco del proceso de enmiendas al RSI 2005 definido durante la celebración de la 75ª AMS, los Estados Parte del MERCOSUR acuerdan elevar las siguientes propuestas:

TÍTULO II - INFORMACIÓN Y RESPUESTA DE SALUD PÚBLICA

Artículo 5 Vigilancia

SUBITEM 4

4. (Nueva redacción) – “La OMS recopilará información sobre eventos a través de sus actividades de vigilancia y evaluará, a partir de criterios de evaluación de riesgos actualizados periódicamente y acordados con los Estados Miembros, su potencial de provocar una propagación internacional de enfermedades y su posible interferencia con el tráfico internacional. La información que la OMS reciba en virtud de este párrafo se manejará de conformidad con lo dispuesto en los artículos 11 y 45 cuando proceda”; (Estados miembros de la Unión Económica Euroasiática)”

AGREGAR UN APARTADO 5

5 - “Fortalecer el papel central de las autoridades sanitarias nacionales en el proceso de gestión y articulación con los niveles jerárquicos político, intersectorial, interministerial y multinivel para una vigilancia y respuesta oportuna y coordinada según el enfoque de riesgo internacional de salud pública establecido por el RSI, afianzando el rol central de las autoridades sanitarias nacionales en el proceso de conducción y articulación multinivel”.

Artículo 9 Otros informes

3. (Nueva redacción) En las recomendaciones que formule a los Estados Partes con respecto a la recolección, procesamiento y difusión de la información sanitaria, la OMS podrá aconsejar lo siguiente:

(a) seguir orientaciones de la OMS sobre criterios y modos análogos de procesamiento y tratamiento de la información sanitaria

Artículo 13 Respuesta de salud pública (VIGENTE)

3. (Nueva redacción). A petición de un Estado Parte, la OMS colaborará en la respuesta a los riesgos para la salud pública y otros eventos proporcionando orientación y asistencia técnica y evaluando la eficacia de las medidas de control adoptadas, incluida la movilización de equipos de expertos internacionales para que presten asistencia in situ, si procede, y si fuera necesario cooperará con dicho Estado Parte en la búsqueda de apoyo **y asistencia financiera internacional para facilitarle la contención del riesgo en la fuente.**

Título III – Recomendaciones

Artículo 18 Recomendaciones con respecto a las personas, equipajes, cargas, contenedores, medios de transporte, mercancías y paquetes postales

SUBITEM 2- Nueva redacción: - asegurar los mecanismos para el desarrollo y aplicación de una declaración de salud del viajero ante situaciones de emergencia de salud pública internacionales (ESPII) para proporcionar una mejor disponibilidad de información sobre el itinerario realizado, los síntomas que pudiera presentar o las medidas de prevención que hubiera cumplido así como para facilitar el rastreo de contactos, cuando proceda

Título VI - Documentos Sanitarios

Artículo 35 Disposición general

Se sugiere agregar: Los documentos de salud digitales deben tener una función para verificar su autenticidad recuperando el documento en un sitio web oficial, como un código QR

Propuesta al Título X – Disposiciones generales

Artículo 56 Solución de controversias

Agregar apartados **6, 7 y 8**

6. La OMS deberá comunicar todas las reclamaciones de los Estados Miembros sobre medidas adicionales no informadas por alguno de ellos o recomendadas por dicha Organización;

7. Los Estados Miembros que apliquen las medidas referidas en el apartado anterior deberán informar a la OMS la justificación científica de su implantación y sostenimiento en el tiempo y la OMS deberá difundir esa información;

8. La Asamblea Mundial de la Salud podrá analizar los informes del Comité de Examen sobre la pertinencia y duración de las medidas y demás datos aludidos en los puntos a) y b) comprendidos en este apartado 6 y efectuar recomendaciones respecto a la pertinencia de la continuidad de las medidas sanitarias adicionales.

ANEXO 3

MODELO DE CERTIFICADO DE EXENCIÓN DEL CONTROL DE SANIDAD A BORDO / CERTIFICADO DE CONTROL DE SANIDAD A BORDO

(...)

Para conferir la autenticidad, escanee en sitio oficial o como el código QR.

Imagen del código QR u otra aplicación de validación

Se sugiere incorporar "*embarcaciones fluviales internacionales*", en:

- I. El acápite de los certificados de sanidad a bordo y certificados de exención
- II. Los artículos y anexos y que hacen referencia a declaración marítima
- III. En todos los espacios que incorpora la palabra marítima

ANEXO 6

VACUNACIÓN, PROFILAXIS Y CERTIFICADOS CONEXOS

Propuesta de redacción¹:

Cuando fuera declarada una Emergencia de Salud Pública de Importancia Internacional, para el ingreso o egreso de los viajeros internacionales, en el caso de vacunaciones voluntarias con productos en fase de investigación o con muy limitada disponibilidad, a considerar las certificaciones de vacunas aprobadas según el marco normativo del país de origen, incluyendo lo referido al modelo/formato de certificación y el esquema de vacunación (tipo de vacuna y esquema).

¹ Fundamentación: Necesaria flexibilización del régimen de emergencia, requiere considerar la Certificación de vacunas aprobadas según marco normativo del país de origen en casos de vacunación voluntaria con productos en fase de investigación aprobados por OMS o de muy limitada disponibilidad mundial, en caso de una ESPII declarada por la misma, para la circulación de viajeros internacionales

Condiciones de los documentos digitales:

Los certificados analógicos deben ser asignados por el médico clínico que indica la administración de vacuna u otra profilaxis o por otro profesional de salud debidamente autorizado. Los certificados digitales deben poseer un recurso de verificación de autenticidad en sitios oficiales en redes, como el código QR.²

MODELO DE CERTIFICADO INTERNACIONAL DE VACUNACIÓN O PROFILAXIA

Se sugiere modificar redacción de apartado:

“Para conferir autenticidad cuando proceda escanee el en sitio oficial, como el código QR u otro método de verificación.

Imagen del código QR”

² Certificación de vacunación para el ingreso y egreso al territorio nacional:

Sobre los datos de los certificados se plantean dos escenarios:

Escenario de mínima:

Se aceptará la presentación de certificado/carné/constancia en formato papel.

Independientemente del diseño, se deberán consignar los siguientes datos:

1. Apellido y nombre
2. N° de DNI/Pasaporte
3. Tipo de vacuna: por ejemplo vacuna contra la fiebre amarilla / vacuna antipoliomielítica, vacuna contra el sarampión.
4. Lote de la vacuna (opcional, si se cuenta con la información)
5. Fecha de aplicación
6. Lugar de aplicación (efector)
7. Sello oficial (del profesional que intervino o de la institución)

Escenario de máxima:

Certificación del antecedente de vacunación mediante código QR

1. El antecedente de vacunación se acredita en formato digital o papel, mediante código QR
2. La lectura de código QR direcciona al sitio oficial del país de origen para levantar la información de su antecedente de vacunación.

Enfermedades en eliminación y/o erradicación:

Esto podría citarse para el INB: Respecto a la enfermedades en eliminación y en vías de erradicación, tales como la poliomielitis, el sarampión, rubéola y el síndrome de rubéola congénita, y entendiendo el esfuerzo que representa para la región de las Américas sostener los objetivos definidos en este sentido, y ante la persistencia de brotes de sarampión en diferentes regiones del mundo, la circulación de poliovirus salvaje tipo 1 en dos países y el incremento de casos de poliovirus circulantes derivados de la vacuna (cVDPV), consideramos que resulta necesario plantear una estrategia global respecto a los recomendación y/o requerimientos de vacunación de viajeros

ANEXO 8

MODELO DE DECLARACIÓN MARÍTIMA Y FLUVIAL INTERNACIONAL DE SANIDAD

Cuestionario de sanidad

Se sugiere incorporar:

10) ¿Hay un viajero sin la vacunación requerida en el Anexo 7? Sí..... No.....

En caso afirmativo, proporcione los detalles en el formulario adjunto.

“Para verificar la autenticidad al escanear el sitio oficial, como el código QR u otro método de verificación

Imagen del código QR

PLANILLA ADJUNTA AL MODELO DE DECLARACIÓN MARÍTIMA DE SANIDAD

Incluir la columna “Vacunación conforme al Anexo 7”

PROPUESTA PARA ENMIENDA DEL RSI 2005 EN RELACIÓN A PLANES DE CONTINGENCIA

Propuesta:

Artículo 19 - Obligaciones generales

- d) Nueva propuesta: La elaboración de planes de contingencia “binacionales” con contenidos mínimos a ser incluidos en los planes de acción en casos de fronteras compartidas para emergencias en salud pública de importancia internacional (ESP II).

Czech Republic

on behalf of the Member States of the European Union (EU)



MINISTRY OF HEALTH
OF THE CZECH REPUBLIC

Radek POLICAR
Deputy Minister for Legislation and Law

Prague 30 September 2022

Ref. no.: MZDR 28471/2022-1/MEZ



MZDRX01LSHR2

Dear Sir or Madame,

The Czech Republic, the current Presidency of the Council of the European Union, as a State Party to the International Health Regulations (IHR) (2005) hereby presents proposed amendments to the IHR (2005), in coordination with the European Union, and in accordance with decision WHA75(9), on its own behalf, as well as on behalf of the Member States of the European Union: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden as a State Party to the IHR (2005).

We respectfully request the Director-General of the WHO to communicate the text of the attached proposed amendments pursuant to the process established by the decision WHA 75(9).

Meanwhile, I assure you of my highest consideration and remain

Yours faithfully,

Enclosed: proposed amendments to the IHR (2005)

World Health Organisation
Av. Appia 20, 1211 Geneva
Switzerland



Ministry of Health, Palackého náměstí 4, 128 01 Prague 2, Czech Republic
tel./fax: +420 224 971 111, e-mail: mzcr@mzcr.cz, www.mzcr.cz

Submission of proposed amendments to the International Health Regulations (IHR) (2005), pursuant to decision WHA75(9) of the World Health Assembly, by the Czech Republic, the current Presidency of the Council of the European Union, as a State Party to the IHR and in coordination with the European Union, and on behalf of the Member States of the European Union:

Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden, as State Parties to the IHR (2005).

Proposed amendments

Articles 3, 6, 7, 11, 12, 15, 23, 35, 36, 43, 44, 48, 49, new 54 bis, Annex 1(4) and Annex 6

Explanation of changes: the proposed new text is shown in **bold underline**, and proposed deletions to the text of the International Health Regulations is shown in strikethrough. All other text would remain unchanged.

Article 3 – Principles

(...)

3. The implementation of these Regulations shall be guided by the goal of their universal application for the protection of all people of the world from the international spread of disease. **When implementing these Regulations, Parties and WHO should exercise precaution, in particular when dealing with unknown pathogens.**

(...)

Article 6 – Notification

(...)

2. Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, **epidemiological and clinical data, as well as microbial and genomic data in case of an event caused by an infectious agent**, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease, ~~and~~ the health measures **implemented and other related information as per request of WHO**; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern. **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.**

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

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

(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.)

(...)

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.

Art. 11 – ~~Provision of information by WHO~~ Exchange of information

1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as appropriate, to relevant ~~intergovernmental~~ **international and regional** 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 otherwise available and whose validity is appropriately assessed by WHO**, and which is necessary to enable States Parties to respond to a public health risk. WHO **shall** ~~should~~ 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.**

(...)

*Art. 12 – Determination of a public health emergency of international concern **and of a regional or intermediate public health emergency of international concern***

(...)

New paragraph 6:

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.

Article 15 – Temporary recommendations

(...)

2. **Temporary recommendations should be as evidence-based, concise and operational as possible, and refer to existing guidance and international technical standards, when appropriate.** Temporary recommendations may include health measures to be implemented

by the State Party experiencing the public health emergency of international concern, or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.

(...)

Article 23 - Health measures on arrival and departure

(...)

New paragraph 6:

6. Documents containing information concerning traveller's destination (hereinafter Passenger Locator Forms, PLFs) should preferably be produced in digital form, with paper form as a residual option. Such information should not duplicate the information the traveller already submitted in relation to the same journey, provided the competence authority can have access to it for the purpose of contact tracing.

The Health Assembly may adopt, in cooperation with the International Civil Aviation Organization (ICAO) and other relevant organisations, the requirements that documents in digital or paper form shall fulfil with regard to interoperability of information technology platforms, technical requirements of health documents, as well as safeguards to reduce the risk of abuse and falsification and to ensure the protection and security of personal data contained in such documents. Documents meeting such requirements shall be recognized and accepted by all Parties. Specifications and requirements for PLFs in digital or paper form shall take into account existing widely-used systems established at the regional or international level for the issuance and verification of documents. Parties which are low and lower middle income countries shall receive assistance in accordance with Article 44 for the implementation of this provision.

Article 35 - General rule

(...)

2. Health documents may be produced in digital or paper form, subject to the approval by the Health Assembly of the requirements that documents in digital form have to fulfil with regard to interoperability of information technology platforms, technical requirements of health documents, as well as safeguards to reduce the risk of abuse and falsification and to ensure the protection and security of personal data contained in the health documents. Health documents meeting the conditions approved by the Health Assembly shall be recognized and accepted by all Parties. Specifications and requirements for certificates in digital form shall take into account existing widely-used systems established at the international level for the issuance and verification of digital certificates. Parties which are low and lower middle income countries shall receive assistance in accordance with article 44 for the implementation of this provision.

Article 36 - Certificates of vaccination or other prophylaxis

(...)

3. Other types of proofs and certificates may be used by Parties to attest the holder's status as having a decreased risk of being the disease carrier, particularly where a vaccine or prophylaxis has not yet been made available for a disease in respect of which a public health emergency of international concern has been declared. Such proofs may include test certificates and recovery certificates. These certificates may be designed and approved by the Health Assembly according to the provisions set out for digital vaccination or prophylaxis certificates, and should be deemed as substitutes for, or be complementary to, the digital or paper certificates of vaccination or prophylaxis.

Article 43 – Additional health measures

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

- (a) achieve the same or greater level of health protection than WHO recommendations; or
- (b) are otherwise prohibited under Article 25, Article 26, paragraphs 1 and 2 of Article 28, Article 30, paragraph 1(c) of Article 31 and Article 33,

provided such measures are otherwise consistent with these Regulations.

Such measures **shall be based on regular risk assessments, provide a proportionate response to the specific public health risks, be reviewed on a regular basis and** shall not be more restrictive of international traffic and not more invasive or intrusive to persons than **reasonably available alternatives that would attain** the **highest achievable** level of health protection.

(...)

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. 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.

Parties taking measures pursuant to paragraphs 1 and 2 of this Article shall endeavour to ensure that such measures are compatible with measures taken by other Parties in order to avoid unnecessary interference with international traffic and trade while ensuring the highest achievable level of health protection.

To this end, at the request of the Director-General or of any Party impacted by a measure taken pursuant to paragraph 1 or 2 of this Article, Parties so requested shall undertake consultations either bilaterally, multilaterally or at the regional level as the case may be. The purpose of such consultations is to clarify the scientific information

and public health rationale underlying the measures and to find a mutually acceptable solution. The Director-General or WHO Regional Directors on his or her behalf shall:

- (a) facilitate those consultations and propose modalities for their conduct;**
- (b) review the evidence and information supplied by the Parties;**
- (c) provide his or her views on the necessity and proportionality of the measures in question and, as appropriate, make suggestions or proposals on a mutually acceptable solution;**
- (d) report to the Health Assembly on the conduct and outcome of consultations, with particular regard to general challenges and problems revealed by them.**

Article 44 – Collaboration and assistance

(...)

2. WHO shall collaborate with States Parties, upon request, to the extent possible, in:

(a) strengthening regional planning, preparedness and response, in close cooperation with WHO Regional Offices and relevant international and regional organizations;

~~(a)~~ **(b)** the evaluation and assessment of their public health capacities in order to facilitate the effective implementation of these Regulations;

~~(b)~~ **(c)** the provision or facilitation of technical cooperation and logistical support to States Parties; and

~~(c)~~ **(d)** the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1.

(...)

4. The WHO, in collaboration with other international organizations as appropriate, shall provide assistance in the organization of the collaboration provided for in this Article, with particular regard to the needs of the Parties which are low or lower-middle income countries. The Parties and WHO shall report on the results obtained to the Health Assembly at least every two years.

Article 48 – Terms of reference and composition

(...)

2. The Emergency Committee shall be composed of experts selected by the Director-General from the IHR Expert Roster and, when appropriate, other expert advisory panels of the Organization. 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 and **gender balance. The WHO, including through the WHO Academy, shall provide them with support as appropriate.** At least one member of the Emergency Committee should be an expert nominated by a State Party within whose territory the event arises.

Art. 49 – Procedure

(...)

2. The Director-General shall provide the Emergency Committee with ~~the~~ **a detailed** 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.**

(...)

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].

New Article 54 bis – Implementation

(Note: The proposal for Article 54 bis is without prejudice to the discussions on the governance structure of the Pandemic Agreement. Such institutional elements would need to be considered in a complementary fashion.)

1. The Health Assembly shall be responsible to oversee and promote the effective implementation of these Regulations. For that purpose, Parties shall meet every two years, in a dedicated segment during the regular annual session of the Health Assembly.

2. The Health Assembly shall take the decisions and recommendations necessary to promote the effective implementation of these Regulations. To this effect, it shall:

- (a) consider, at the request of any Party or the Director-General, any matter related to the effective implementation of these Regulations and adopt recommendations and decisions as appropriate on the strengthening of the implementation of these Regulations and improvement of compliance with their obligations;**
- (b) consider the reports submitted by Parties and the Director-General pursuant to Article 54 and adopt any recommendation of a general nature concerning the improvement of compliance with these Regulations;**
- (c) regularly assess the implementation of the Regulation by Parties and establish a strengthened review mechanism to that effect, with the aim of continuously improving the implementation of the Regulations by all Parties. In particular, the WHO and its Regional offices, upon request of a Party, which is a low or lower-middle income country, shall provide or facilitate technical support and assist in the mobilization of resources aimed to implement the recommendations of such a review mechanism to that Party;**

- (d) promote, as appropriate, the development, implementation and evaluation of strategies, plans, and programmes, as well as policies, legislation and other measures by Parties;
- (e) cooperate as appropriate with relevant WHO bodies, in particular those dealing with health emergency prevention, preparedness and response;
- (f) request, where appropriate, the services and cooperation of, and information provided by, competent and relevant organizations and bodies of the United Nations system and other international and regional intergovernmental organizations and nongovernmental organizations and bodies as referred to in Article 14, as a means of strengthening the implementation of these Regulations;
- (g) oversee the implementation by the Secretariat of its functions under these Regulations, without prejudice to the authority of the Director-General under Articles 12, 15 to 17 and 47 to 53;
- (h) consider other action, as appropriate, for the achievement of the objective of the Regulations in the light of experience gained in its implementation.

3. A Special Committee on the IHR is hereby established, as an expert committee. The Special Committee shall have (...) members, appointed in a manner to ensure equitable regional representation and gender balance. The Special Committee shall assist the Health Assembly in discharging the functions set out in this Article and report to the Assembly.

4. The Special Committee shall meet at least (once a year/ twice a year/ every two years/...).

Annex 1

A. CORE CAPACITY REQUIREMENTS FOR SURVEILLANCE AND RESPONSE

(Note: The proposed amendments to Annex 1(4) are to be read in conjunction with the amendments proposed to Article 6)

(...)

4. At the local community level and/or primary public health response level

The capacities:

- (a) to detect events involving disease or death above expected levels for the particular time and place in all areas within the territory of the State Party; and
- (b) to report all available essential information immediately to the appropriate level of healthcare 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, microbial, epidemiological, clinical and genomic data, 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 implement preliminary control measures immediately.

Annex 6 - Vaccination, prophylaxis and related certificates

(Note: The proposed amendments to Annex 6 are to be read in conjunction with the amendments proposed to Articles 35 and 36)

(...)

2. Persons undergoing vaccination or other prophylaxis under these Regulations shall be provided with an international certificate of vaccination or prophylaxis (hereinafter the “certificate”) in the digital or paper form as specified in this Annex.

International certificates may be issued in digital or paper form in accordance with Article 35 and with the specifications and requirements approved and reviewed periodically by the Health Assembly.

Such specifications and requirements should enable flexibility in terms of their validation and acceptance taking into account applicable national and regional rules and the need for rapid modifications due to changing epidemiological contexts. In order to enhance transparency specifications and requirements should be based on open standards and implemented as open source.

The paper certificates shall be issued in the form specified in this Annex. No departure shall be made in the paper certificates from the model of the certificate specified in this Annex.

(...)

4. Certificates must be signed in the hand of the clinician, who shall be a medical practitioner or other authorized health worker, supervising the administration of the vaccine or prophylaxis. The certificate must also bear the official stamp of the administering centre; however, this shall not be an accepted substitute for the signature. **Signatures and stamps may also be appended digitally by the clinician or the administering centre, or by the health authority on their behalf, in accordance with Article 35 and with the specifications and requirements approved and reviewed periodically by the Health Assembly.**

(...)

8. A parent or guardian shall sign the certificate when the child is unable to write. The signature of an illiterate shall be indicated in the usual manner by the person’s mark and the indication by another that this is the mark of the person concerned. **Such signatures shall not be required on a vaccination certificate in digital form.**

(...)

Appendix to the submission of proposed amendments to the International Health Regulations (IHR) (2005), pursuant to decision WHA75(9) of the World Health Assembly, by the Czech Republic, the current Presidency of the Council of the European Union, as a State Party to the IHR and in coordination with the European Union, and on behalf of the Member States of the European Union:

Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden, as State Parties to the IHR (2005).

Explanatory notes¹

Further to the submission of the proposed amendments on 30 September 2022, we are pleased to communicate short explanatory elements for each of the proposal submitted.

1. Article 3 - Principles

The objective of the proposed amendment is to introduce a precautionary approach in the International Health Regulations (IHR) by giving the possibility to WHO and States Parties to issue and implement precautionary measures when scientific evidence about an emerging and probable high risk pathogen is lacking or uncertain. Such precautionary measures must be applied in accordance with the other provisions of the IHR, in particular with Articles 2 and 43 of the IHR.

2. Article 6 - Notification, Article 7 - Information-sharing during unexpected or unusual public health events and Annex 1:

The COVID-19 pandemic has shown how crucial it is to ensure that epidemiological and clinical data, as well as microbial and genomic data, materials and samples, are shared as rapidly as possible at the global level after the detection of an event caused by an infectious agent.

The objectives of the proposed amendments to Article 6 and Annex 1 are:

- to extent the scope of the information that should be communicated to WHO, following the notification by a State Party of an event which may constitute a public health emergency of international concern, by including a requirement to notify in particular epidemiological and clinical data, as well as microbial and genomic data and while ensuring the protection and security of personal data;
- to ensure that the information received by WHO is made available to all State Parties, and can be widely used for related research and assessment;

¹ Note by the WHO Secretariat: This document, elaborated upon the rationale underpinning the proposed amendments to the IHR submitted by the Czech Republic on behalf of Member States of the European Union, was provided on 26 October 2022 in relation to the meeting of the IHR Review Committee regarding amendments to the International Health Regulations (2005) with WHO Member States / States Parties to the IHR, United Nations and its specialized agencies, and other relevant intergovernmental organizations or nongovernmental organizations in official relations with WHO, held on 27 October 2022, pursuant to Article 51.2 of the IHR.

- to ensure that State Parties have the required capacities to report such information at the appropriate level of healthcare response.

Likewise, the objective of the proposed amendments to Article 7 is to extend the scope of the information that needs to be provided to WHO, by including a requirement to share with WHO the microbial and genetic material and samples related to the notified event.

3. Article 11 - Exchange of information (new proposed title):

The proposed amendments aim at enabling information on health alerts to be shared more rapidly and more widely. In particular, the objectives of the proposed amendments are:

- to add a requirement that WHO shall inform all States Parties, and relevant international and regional organizations, of all event-related information and data, including any public health information not resulting from notifications or consultations, provided that its validity is appropriately assessed by WHO;
- to add a requirement that WHO shall provide a secure and reliable platform for the exchange of information among WHO and States Parties;
- to ensure that such a platform allows for interoperability with relevant data information systems.

4. Article 12 - Determination of a public health emergency of international concern and of a regional or intermediate public health emergency of international concern (new proposed title)

The current alert system, as established under the IHR, is sometime perceived as too restrictive, due the binary nature of the determination (an event either is, or is not, a public health emergency of international concern). The objective of the proposed amendment is to remedy this situation by introducing the possibility for the Director-General to determine that an event constitutes a regional public health emergency of international concern or an intermediate public health emergency of international concern (“yellow light”). The introduction of the categories of regional as well as intermediate PHEICs aims to take into account that there can be a regional component to a “yellow light” event, and that both the regional element as well as intensity need to be seen as interlinked. We would welcome the guidance of the IHR RC on how to further define such an intermediate alert.

This would raise awareness of the situation at national, regional and international level when an event of concern requires enhanced coordination at regional or international level to limit or slow down the spread of the disease, but does not fully meet the criteria for a public health emergency of international concern.

5. Article 15 - Temporary recommendations

The COVID-19 pandemic has shown that the governance of global response could benefit from stronger coordination underpinned by concise technical guidance and advice. The temporary recommendations issued by WHO following advice from the Emergency Committee are an internationally accepted and well-established mechanism to inform response interventions. The objective of the proposed amendment is to strengthen the role of the temporary

recommendations issued by WHO and to facilitate their implementation by promoting the adoption of more specific, concise and tailored recommendations.

6. Article 23 - Health measures on arrival and departure

There is currently no standardized and international recognized electronic system to allow for safe and secure data transfer between passengers and the competent health authorities of a State Party for contact tracing purpose, in case of a reported infectious disease.

The proposed amendments to Article 23 aim at:

- providing a clear legal basis in the IHR allowing for the use of Passenger Locator Forms in digital form, provided that the two proposed conditions of an agreement on the technical requirements and their endorsement/adoption by the Health Assembly are achieved;
- providing common technical standards, with appropriate safeguards against falsification and while ensuring data protection, and
- setting out the conditions for the recognition of the common technical standards, taking into account the legal provisions applicable across countries, as well as the need of low and lower middle income countries for capacity-building and technical cooperation, in line with Article 44 of the IHR.

7. Article 35 - General rule, Article 36 - Certificates of vaccination or other prophylaxis and Annex 6 - Vaccination, prophylaxis and related certificates

A concern expressed during the COVID-19 pandemic has been the absence of clarity in the IHR on global standards for the use of digital vaccination certificates required for international travel.

The proposed amendments to Article 35 and Annex 6 aim at:

- providing a clear legal basis in the IHR for the use of digital certificates, thereby enabling travellers to use them in the same situations where paper-based certificates are accepted. This would provide certainty for the use of digital credentials in the future, provided that the two proposed conditions of an agreement on the technical requirements and their endorsement/adoption by the Health Assembly are achieved;
- providing common technical standards, with appropriate safeguards against falsification and while ensuring data protection, and
- setting out the conditions for the recognition of the common technical standards, taking into account the legal provisions applicable across countries, as well as the need of low and lower middle income countries for capacity-building and technical cooperation, in line with Article 44 of the IHR.

The proposed amendments to Article 36 aim at allowing States Parties the possibility to recognize test certificates and recovery certificates as an alternative or as a complementary tool to vaccination certificates.

8. Article 43 - Additional health measures

The COVID-19 pandemic has shown the need to improve and facilitate consultations and coordination among countries on the implementation of national health measures, such as border closures, visa suspensions or vaccination, testing and quarantine requirements.

The proposed amendments to Article 43 aim at:

- ensuring that additional health measures implemented by States Parties are based on strong and regular risk assessments, reviewed on a regular basis and that they are strictly proportionate to the specific public health risks;
- fostering consultations and discussions between States Parties on their respective risk management approaches, to avoid unnecessary disruptions to international traffic and trade;
- tasking WHO with a more active role in facilitating these discussions and in encouraging Parties to engage in such discussions, by providing a forum for consultations, reviewing the public health rationale of national measures and reporting to the Health Assembly on the conduct, outcomes and challenges of the consultations.

9. Article 44 - Collaboration and assistance

The objective of the proposed amendments to Article 44 are to strengthen the implementation of the IHR by improving the provision of technical assistance and capacity building.

The proposed amendments aim in particular at:

- strengthening the integration of regional coordination in the IHR;
- facilitating the provision of technical assistance by mandating the WHO Secretariat, in cooperation with other relevant international organizations, such as the quadripartite organizations, to provide support in the organisation of technical assistance and capacity building initiatives and actions, so as to allow for a better operationalization of the provisions of article 44.

The proposed reporting requirement aims at increasing the political importance and highlight given to collaboration and assistance activities and at facilitating the sharing of best practices.

10. Article 48 - Terms of reference and composition

The proposed amendments aim at:

- Ensuring a more diverse representation of the Emergency Committee;
- Ensuring that the experts of the Emergency Committee receive appropriate support and training, including through the WHO Academy.

11. Article 49 - Procedure

The objectives of the proposed amendments are:

- to strengthen the decision-making process for the determination of a public health emergency of international concern by improving the Emergency Committee meetings' output, through the standardisation of its agenda, leading to more specific and focused advice to the Director General;
- to strengthen the position of the Emergency Committee by ensuring that its recommendations are presented to relevant WHO bodies dealing with health emergency prevention, preparedness and response. The reference in brackets to the Standing Committee on Health Emergency Prevention, Preparedness and Response is not a reflection of disagreement within the EU. The brackets are put, pending the start of the work of the SCPPR and its review, as per decision EB 150(6)².

12. Article 54 bis - Implementation

An often-heard criticism of the IHR is that they suffer from low implementation and compliance and that States Parties are not sufficiently invested at a political level in their implementation.

The objectives of the new proposed article is:

- to promote the effective implementation of the IHR, by entrusting the Health Assembly with this task;
- defining the different functions of the Health Assembly in order to perform this new task;
- establishing, as an expert committee, a Special Committee to assist the Health Assembly in performing its functions.

² [https://apps.who.int/gb/ebwha/pdf_files/EB150/B150\(6\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/EB150/B150(6)-en.pdf)

Eswatini

on behalf of the Member States of the WHO African Region

IHR 2005 Targeted Amendments Proposals Submitted by Eswatini on behalf of the WHO Africa Region Member States¹

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¹Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cabo Verde, Cameroon, Central African Republic, Chad, Comoros, Congo, Cote d'Ivoire, Democratic Republic of Congo, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, South Africa, South Sudan, Togo, Uganda, United Republic of Tanzania, Zambia, Zimbabwe.

Note:

1. Text in bold represents “textual insertion/addition” proposed by Africa Group
2. Text in bold with strikethrough represents “textual deletions” proposed by Africa Group
3. Normal Text represents the already existing texts as available in IHR 2005.
4. Word “New” is added to the Paragraph/Article Number when an entirely new paragraph or provision is proposed.

PROPOSED AMENDMENTS BY THE AFRICA GROUP

I. Africa Group Proposal: *Article 1 Definition*

...

“health measure” means procedures applied to prevent the spread of disease or contamination; a health measure does not include law enforcement or security measures;

“health products” include therapeutics, vaccines, medical devices, personal protective equipment, diagnostics, assistive products, cell- and gene-based therapies, and their components, materials, or parts.

“health technologies and know-how” includes organized set or combination of knowledge, skills, health products, procedures, databases and systems developed to solve a health problem and improve quality of life, including those relating to development or manufacture of health products or their combination, its application or usage. “Health technologies” are interchangeably used as “health care technologies”.

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

...

Description:

Africa Group proposes to include the definition for “health products” and “health technologies and know-how” in Article 1 on Definitions, since the phrases will be repeatedly used in the provisions intending to improve equity in international public health response to Health Emergencies. The use of the above phrase “health products” is consistent with the use of language in various WHO Resolutions and UN Documents as well as public health approaches to health emergency response.

II. Africa Group Proposal: *Article 2 - Purpose and scope*

The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate

with and restricted to public health risks, and which avoid unnecessary interference with international traffic, ~~and~~ trade, **livelihoods, human rights, and equitable access to health products and health care technologies and know how.**

Description:

The proposal to change the text in Article 2 is to clarify the mandate to “avoid unnecessary interference with international traffic and trade” applies to those measures that affect equitable access to and supply of health products required for the response to the international spread of disease as well.

III. Africa Group Proposal: Article 4 - Responsible authorities

It is recommended to introduce a provision under this section on training and capacity building of National IHR Focal Points, since the COVID-19 pandemic has revealed several challenges in terms of preparedness and response particularly in many LMICs.

1. Each State Party shall designate or establish a 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.**

IV. Africa Group Proposal: Article 6 – Notification

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.

V. Africa Group Proposals: Article 12 – Determination of a Public Health Emergency of International Concern

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.

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.

Description:

The new paragraphs are proposed for bringing accountability and visibility of WHO Response to a PHEIC. These paragraphs are proposed within Article 12 to enhance the importance of the declaration of PHEIC and to keep WHO and Member States reminded that their activities and response measure to a public health event is very much linked to the determination of PHEIC by WHO under IHR 2005

VI. Africa Group Proposal: Article 13(5) Public health response – WHO Coordinated Response Activities

5. When requested by WHO, States Parties ~~should~~ **shall** provide, to the extent possible, support to WHO-coordinated response activities, **including supply of health products and technologies, especially diagnostics and other devices, personal protective equipment, therapeutics, and vaccines, for effective response to PHEIC occurring in another State Party's jurisdiction and/or territory, capacity building for the incident management systems as well as for rapid response teams. Any State Party unable to fulfil such requests shall inform the reasons for the same to WHO and the Director General shall include the same in the report submitted to WHA under Article 54 of these Regulations.**

Description:

Article 13(5) of IHR 2005 is one of the most potential provisions of IHR 2005 which can deliver against equity challenges. It provides for a better possibility of having a legally binding, and internationally coordinated public health response to PHEIC. Currently, the text of Article 13(5) is weak with usage of the verb “should” and the phrase “to the extent possible”. The proposed amendments bring address these weaknesses.

VII. Africa Group Proposal: New Article 13A: Access to Health Products, Technologies and Know-How for Public Health Response

- 1. Immediately after the determination of a public health emergency of international concern under Article 12, the Director General shall make an immediate assessment of availability and affordability of required health products and make recommendations, including an allocation mechanism, to avoid any potential shortages of health products and technologies pursuant to Article 15 or 16 as appropriate.**
- 2. States Parties shall co-operate with each other and WHO to comply with such recommendations pursuant to paragraph 1 and shall take measures to ensure timely availability and affordability of required health products such as diagnostics, therapeutics, vaccines, and other medical devices required for the effective response to a public health emergency of international concern.**
- 3. States Parties shall provide, in their intellectual property laws and related laws and regulations, exemptions and limitations to the exclusive rights of intellectual property holders to facilitate the manufacture, export and import of the required health products, including their materials and components.**
- 4. States Parties shall use or assign to potential manufacturers, especially from developing countries, on a non-exclusive basis, the rights over health product(s) or technology(ies), when the same is/are obtained in the course of research wholly or partially funded by public sources, and is/are identified as required health product(s) or technology(ies) to respond to a PHEIC, with a view to ensure equitable, timely availability and affordability through diversification of production.**
- 5. Upon request of a State Party, other States Parties or WHO shall rapidly cooperate and share relevant regulatory dossiers submitted by manufacturers concerning safety and efficacy, and manufacturing and quality control processes, within 30 days. The dossiers received by a requesting State Party shall be solely used by their regulatory authorities and manufacturers designated by the requesting State Party for the purposes of accelerating the manufacture and supply of product(s) or technology(ies) as well as expediting their regulatory approval. Requesting State Party shall take measures to prevent designated manufacturer(s) from disclosing such information to a third-party(ies) except for the purposes of producing and supplying any materials or components to the manufacturer(s) under a contract with non-disclosure provisions.**
- 6. WHO shall take measures to ensure availability and accessibility through the local production of required health products including:**
 - a) develop and publish a list of required health products,**
 - b) develop and publish specifications for the production of required health products,**

c) develop appropriate regulatory guidelines for the rapid approval of health products of quality including development of immunogenicity co-relative protection (ICP) for vaccines,

d) establish a database of raw materials and their potential suppliers,

e) establish a repository for cell-lines to accelerate the production and regulatory of similar biotherapeutics products and vaccines,

f) review and regularly update WHO Listed Authorities so as to facilitate appropriate regulatory approvals,

g) any other measures required for the purposes of this provision.

7. The States Parties shall take measures to ensure that the activities of non-state actors, especially the manufacturers and those claiming associated intellectual property rights, do not conflict with the right to the highest attainable standard of health and these Regulations and are in compliance with measures taken by the WHO and the States Parties under this provision, which includes:

a) to comply with WHO recommended measures including allocation mechanism made pursuant to paragraph 1.

b) to donate a certain percentage of their production at the request of WHO.

c) to publish the pricing policy transparently.

d) to share the technologies, know-how for the diversification of production.

e) to deposit cell-lines or share other details required by WHO repositories or database established pursuant to paragraph 5.

f) to submit regulatory dossiers concerning safety and efficacy, and manufacturing and quality control processes, when called for by the States Parties or WHO.

Description:

The new provision is proposed as an extension of Article 13 to address concerns relating to the equitable access to health products, by providing for technical assistance, technological transfer, providing for discipline for the behaviour of non-state actors, etc.

VIII. Africa Group Proposal: Article 43 - Additional health measures

....

New 3 bis. A State Party implementing additional health measures referred to in paragraph 1 of this Article shall ensure such measures generally do not result in obstruction or cause impediment to the WHO's allocation mechanism or any other State Party's access to health products, technologies and knowhow, required to effectively

respond to a public health emergency of international concern. States Parties adopting such exceptional measures shall provide reasons to WHO.

43.4. After assessing information **and public health rationale** provided pursuant to paragraphs 3, **3 bis** and 5 of this Article and other relevant information **within two weeks**, WHO ~~may request that shall make recommendations to~~ the State Party concerned to ~~reconsider, modify or rescind~~ the application of **the additional health measures in case of finding such measures as disproportionate or excessive. The Director General shall convene an Emergency Committee for the purposes of this paragraph.**

...

~~43.6. A State Party implementing a health measure pursuant to paragraph 1 or 2 of this Article shall within three months review such a measure taking into account the advice of WHO and the criteria in paragraph 2 of this Article. Recommendations made pursuant to paragraph 4 of this Article shall be implemented by the State Party concerned within two weeks from the date of recommendation. State Party concerned may approach WHO, within 7 days from the date of recommendations made under paragraph 4 of this Article, to reconsider such recommendations. Emergency Committee shall dispose the request for reconsideration within 7 days and the decision made on the request for reconsideration shall be final. The State Party concerned shall report to the implementation committee established under Article 53A on the implementation of the decision.~~

Description:

The proposal for amendments in Article 43 is made to make Article 43 operational. IHR Review committee has noted that Article 43 is not operational, and this has caused several excessive travel measures during Covid19 response and many of them were also discriminatory on a racial basis. The proposals in Article 43 made above provide a proper platform to review unilateral health measures made by States.

IX. Africa Group Proposal: Article 44 - Collaboration and assistance

1. States Parties shall ~~undertake to~~ collaborate with **and assist** each other, **in particular developing country States Parties**, upon request, ~~to the extent possible~~, in:

2. WHO shall collaborate with **and promptly assist** States Parties, in particular **developing countries** upon request, ~~to the extent possible~~, in:

.....

(c) **the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1 through the financial mechanism established under Article 44A;**

(d) the formulation of laws and other legal and administrative provisions for the implementation of these Regulations;

(e) training health and supportive workforce in the implementation of these Regulations;

(f) the facilitation of accessibility and affordability of health products, including sharing of technologies and know-how, establishment and maintenance of the local production and distribution facilities.

3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies **and if undertaken shall be reported to WHO. The Director General shall publish such information in pursuance of the Article 54, including the Director General's report to the World Health Assembly and the dedicated webpage.**

New 4. Collaboration and Assistance under this Article shall include activities mentioned under Annex 10 of the Regulations and shall be monitored by the implementation committee established under Article 53A.

Description:

The proposal is made to strengthen the duty to cooperate. It also makes certain obligations of duty to cooperate further explicit. A proper linkage to provision on reporting, financial mechanism, and implementation committee is also suggested to make the Article operational.

X. Africa Group Proposal: New Article 44A - Financial Mechanism for Equity in Health Emergency Preparedness and Response

1. A mechanism shall be established for providing the financial resources on a grant or concessional basis to developing countries. Such financial mechanism shall provide the financial assistance to achieve the following purposes:

(i) building, developing, strengthening, and maintaining of core capacities mentioned in Annex 1;

(ii) strengthening of Health Systems including its functioning capacities and resilience;

(iii) building, developing and maintaining research, development, adaptation, production and distribution capacities for health care products and technologies, in the local or regional levels as appropriate.

(iv) addressing the health inequities existing both within and between States Parties such that health emergency preparedness and response is not compromised;

2. The WHA shall make arrangements to implement the above-mentioned provisions, within 24 months of the adoption of this provision, reviewing and taking into existing availability of funds and WHO arrangements for health emergency preparedness and response and whether they shall be maintained. Every four years thereafter, the WHA shall review the financial mechanism and take appropriate measures to improve the functioning of the mechanism. WHA shall also ensure that the financial mechanism functions under the guidance of and be accountable to States Parties, which shall decide on its policies, programme priorities and eligibility criteria.

Description:

Lack of sufficient finance and funding both at the international and national level impedes the implementation of IHR obligations. Furthermore, when such a fund is created it should be accountable to WHO and its Member States, which shall decide on its policies, programme priorities and eligibility criteria for funds. In this regard a new Article 44 A is proposed. This also an extension of obligation to collaborate and assist in mobilizing financial resources under Article 44.

XI. Africa Group Proposal: Article 45 - Treatment of Personal Data

New Para 4: WHO receiving personal data, and States Parties receiving personal data from other States Parties, shall process the data in a manner such that the data is not duplicated or stored without the permission of the provider States Party.

Description:

The addition of a new Article 45 (4) brings in responsibility of recipient States Parties to handle personal data in the manner described therein, in accordance with the concept of national sovereignty over the data of its nationals.

XII. Africa Group Proposal: New Article 53A - Establishment of an Implementation Committee

The State Parties shall establish an Implementation Committee, comprising of all States Parties meeting annually, that shall be responsible for:

(a) Considering information submitted to it by WHO and States Parties relating to their respective obligations under these Regulations, including under Article 54 and through the IHR monitoring and Evaluation framework;

(b) Monitoring, advising on, and/or facilitating provision of technical assistance, logistical support and mobilization of financial resources for matters relating to implementation of the regulations with a view to assisting States Parties to comply with obligations under these Regulations, with regards to

(1) development and maintenance of IHR core capacities;

(2) cooperation with WHO and State Parties in responding to outbreaks or events.

(c) Promote international cooperation and assistance to address concerns raised by WHO and States Parties regarding implementation of, and compliance with, obligations under these Regulations in accordance with Article 44;

(d) Submit an annual report to each Health Assembly

Comment:

The proposal is a for a committee of all Member States to discuss implementation and functioning of IHR annually. The proposal is equivalent to an annual conference of parties, and it can monitor and review both the implementation of IHR (2005), as well as new international instrument ensuring better coherence and complementarity between the implementation of two instruments.

XIII. Africa Group Proposals: Annex 1

A. CORE CAPACITY REQUIREMENTS FOR DISEASE DETECTION, SURVEILLANCE AND HEALTH EMERGENCY RESPONSE

...

3. States Parties and WHO shall support assessments, planning and implementation processes in building, strengthening, developing and maintaining the core capacities requirements under this Annex in accordance with Article 44. The support of States Parties and WHO shall be in accordance with Annex 10.

4. At the local community level and/or primary public health response level

The capacities:

...

(d) to ensure infrastructure, personnel, technologies and access to health-care products especially PPE, diagnostics and other devices, therapeutics, and vaccines and the necessary logistics for their distribution;

(e) to engage and promote people's participation such as promotion of awareness and cooperation with control and response measures, social and welfare assistance to affected persons etc;

(f) to provide prompt and quality health care to affected persons, with the available resources.

(g) Implement prevention measures to reduce or contain the disease outbreaks with available resources.

5. At the intermediate public health response levels

The capacities:

...

(c) to detect and identify the responsible pathogen(s), investigate the cause, and assess the preliminary risk.

(d) to provide support to the local community level or primary health care response level, including

(i) laboratory support for detection, diagnosis and epidemiological investigation;

(ii) clinical guidance and treatment guidelines;

(iii) facilitation of field level public health interventions, if necessary.

(iv) assessment of the social and cultural context of populations at risk, gaps and rapid needs and schemes for enhancing capacities as mentioned in paragraph 4(e);

(v) information dissemination through socio-culturally appropriate messages and risk communication management;

(vi) supply of affordable health care products and technologies, including through effective management of emergency supply chains.

(e) to conduct research on cause and origin of disease, symptoms, transmission roots, progression of diseases, diagnosis methods, effective prevention and control of the risks etc.

(f) To coordinate, supervise and ensure the provision of prompt and quality health care to affected persons with available resource.

(g) to assist in self-sufficiency of emergency medical teams, provide logistics and field support to response teams including secure and comfortable accommodations, functional and secure working spaces and equipment, communications capabilities, safe staff transport and effective fleet management.

6. At the national level

Assessment and notification. The capacities:

..

(c) to isolate, identify, sequence and characterize pathogens, under appropriate biosafety conditions.

Public health response. The capacities:

...

(i) to make available affordable health products and any other response materials

(j) to access and absorb technologies and knowhow for the production of health care products including diagnostics, therapeutics and vaccines ensuring their timely availability and distribution to the local community level/primary health care response level and intermediate levels

(k) to develop clinical guidance, tools, methods and means to meet the specific logistical needs of medical facilities, cold chain management, and laboratories at local community level and/or primary health care response level and intermediary levels.

(l) to invest in development of infrastructure, and capacity building of local community level and/or primary health care response level, and intermediary levels to implement control and response measures, including health care services.

(m) to provide logistics and field support to response teams including secure and comfortable accommodations, functional and secure working spaces and equipment, communications capabilities, safe staff transport and effective fleet management.

(n) To coordinate, supervise and evaluate the provision of prompt and quality health care to affected persons with the available resource.

(o) ensure the implementation of available prevention measure(s) to prevent further transmission, prevent avoidable morbidity, mortality and disability.

New 7. Health System Capacities: States shall develop health systems capacities with a view to achieve resilience against health emergency outbreaks, including through

- (i) state-of-art health care infrastructure and service delivery including scene care and pre-hospital services,**
- (ii) upgradation of tools and methods, trained health workforce with equitable representation of gender, cultural and linguistic groups,**
- (iii) fair and decent working conditions for health workers,**
- (iv) adoption of legal, administrative and technical measures to diversify and increase production of health products,**
- (v) improved distribution, and generic substitution for therapeutics,**

- (vi) **information systems respectful of State Sovereignty over data and privacy of the personal data,**
- (vii) **financing solutions avoiding catastrophic burdens in the households,**
- (viii) **national planning and leadership.**
- (ix) **providing infrastructural facilities at points of entry including appropriate communication and transportation facilities.**

Description:

The proposals are made in consideration from the Member States discussions for strengthening Health Systems Capacities during the WGPR and INB. Also, few other amendments are proposed to Annex 1 in order to bring more clarity and details as to the response capacities required for effectively addressing the public health emergencies.

XIV. Africa Group Proposals: [New Annex 10](#)

OBLIGATIONS OF DUTY TO COOPERATE

1. States Parties may request collaboration or assistance from WHO or from other States Parties in any of the activities mentioned in paragraph 2 or any other activities in which collaboration or assistance with regard to health emergency preparedness and response become necessary. It shall be obligation of the WHO and States Parties, to whom such requests are addressed to respond to such request, promptly and to provide collaboration and assistance as requested. Any inability to provide such collaboration and assistance shall be communicated to the requesting States and WHO along with reasons.

2. WHO and States Parties collaborating and assisting with each other shall:

(a) with regard to surveillance capacities:

- i. identify, assess and update the listing of technologies for the surveillance on a periodic basis;**
- ii. identify, assess and update the listing of best practices related to organization structure and surveillance network;**
- iii. train human resources to detect, assess and report events under these Regulations, as according to the lists developed and maintained under the above paragraphs;**
- iv. facilitate sharing of technologies and know-how with States Parties in need, especially those technologies obtained in the course of research, wholly or partially funded by public sources;**
- v. facilitate adaptation of the best-practices to the national and cultural contexts of the States Parties.**

(b) With regard to response capacities:

- i. develop various guidelines and protocols for prevention, control and treatment of the diseases, including standard treatment guidelines, vector control measures;**
- ii. assist in the development of infrastructure and capacity building for the successful implementation of protocols and guidelines and provide the same to the States Parties in need;**
- iii. provide logistical support for the procurement and supply of health products;**
- iv. develop and publish product development protocols for the materials and health products required for the implementation of above paragraphs, including all relevant details to enhance production and access to such products;**
- v. develop and publish technical specifications of the health products, including details of technologies and knowhow with a view to facilitate local production of diagnostics, therapeutics and vaccines, including cell-lines, raw-materials, reagents, design of devices etc.;**
- vi. develop and maintain an agile database of health product required for various health emergencies taking into account the past experiences and the needs of the future;**
- vii. train health workers to respond with health emergencies, including in adaptation of best practices and using of required technologies and equipment;**
- viii. establish multidisciplinary and multisectoral rapid response teams to respond to alerts and PHEIC, swiftly acting upon request from states parties;**
- ix. carry out research and building capabilities for implementing of the regulations including the product development;**
- x. facilitate sharing of technologies and know-how with States Parties in need, especially those technologies obtained in the course of research wholly or partially funded by public sources.**
- xi. building and maintaining IHR facilities in points of entry and its operations.**

(c) With regard to legal assistance:

- i. take into consideration the socio-economic conditions of the States Parties concerned;**
- ii. adopt legal and administrative arrangements to support public health response;**
- iii. train implementation of such legal instruments.**

Description:

New Annex 10 is proposed to bring more consistency in the discharge of obligations under Article 44 and it provides a non-exhaustive list of activities in which WHO and States Parties may collaborate.

India

India's Proposal on targeted amendments to IHR (2005) to the IHR Review Committee

Article	Original Article	India's Comments	Rationale
Article 1 Definitions	Defines among others "disease, infection, Public Health Risk, PHEIC	<p>Many new terminologies need to be defined keeping in view the developments made since the last revision and the lessons learnt from Pandemic.</p> <p>In particular definitions of health products, disease outbreak, epidemic, Pandemic, endemic, Public Health Social Measures (PHSM), risk communication etc.</p> <p>Definition of surveillance also be further augmented for community based surveillance, syndromic surveillance, case based surveillance, laboratory surveillance, genomic surveillance, event based surveillance, etc.</p> <p>Further, terminologies in any additional article/amendment to any article, if accepted, need to be defined and included under Article 1.</p>	The scope of the amended IHR would be to manage epidemics and pandemics and there is need to include developments being made in the field of disease surveillance, laboratory capabilities, medical countermeasures etc.
Article 2 Purpose and scope	The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with	The purpose and scope of these Regulations are to prevent, protect against, prepare , control and provide a public health response to the international spread of diseases in ways that are commensurate with and restricted to all risks with a potential to impact public health , and which avoid unnecessary	Preparedness is a key intervention and is in line with IHR's stated objectives. The amended IHR would focus on human health, animal health and environmental risks including CBRN health

Article	Original Article	India's Comments	Rationale
	international traffic and trade.	interference with international traffic and trade.	emergencies impacting human health.
Article 3 Principles	1. The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons.	1. Para 1: The implementation of these Regulations shall be based on the principles of equity, inclusivity, coherence and in accordance with their common but differentiated responsibilities of the States Parties, taking into consideration their social and economic development.	Equity, inclusivity and coherence are principles central to the proposed Global Health Architecture.
Article 5: Surveillance	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	1. Para 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 refer the issue to World Health Assembly which will then take a decision on the same, taking into account the technical advice of the Committee established under Article 50 (hereinafter the "Review Committee"). After the period	As any timelines prescribed for implementation of revised IHR needs to take into account the capacities and capabilities of the State Parties, the decision on any extension of timeline needs to be reviewed by a body that includes representatives from all member countries.

Article	Original Article	India's Comments	Rationale
	<p>extension shall report annually to WHO on progress made towards the full implementation.</p> <p>4. WHO shall collect information regarding events through its surveillance activities and assess their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Articles 11 and 45 where appropriate.</p>	<p>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.</p> <p>2. Para 4: WHO shall collect information regarding events through its surveillance activities and assess on the basis of risk assessment criteria regularly updated and agreed with state parties their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Articles 11 and 45 where appropriate. (not with an outside party but member states)</p> <p>3. New para 5: WHO shall develop early warning criteria for assessing and progressively updating the national, regional, or global risk posed by an event of known or unknown causes or sources and shall convey this risk assessment to States Parties in accordance with Articles 11 and 45 where appropriate.</p>	<p></p> <p>Timely detection, reporting and response are core requirements under IHR for all State parties. Therefore, there is a need for developing early warning criteria by WHO for assessing and progressively updating the national, regional, or global risk posed by an event of known or</p>

Commented [h1]: As per Article 11, WHO shall not generally make the information it received (under Articles 6 and 8 and paragraph 2 of Article 9 for verification, assessment and assistance purposes under these Regulations), available to other States Parties, until such time as:

- (a) the event is determined to constitute a public health emergency of international concern in accordance with Article 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.

However, in these situations, Article 11 allows for this information to be shared with all State Parties and as appropriate to relevant intergovernmental organizations and may even make the same 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). However, WHO shall consult with the State Party in whose territory the event is occurring as to its intent to make information available under this Article.

Article	Original Article	India's Comments	Rationale
			unknown causes or sources
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), WHO shall immediately notify the IAEA.	1. Para 1: Each State Party shall assess events occurring within its territory by using the decision instrument in Annex 2 within 48 hours of the National IHR Focal Point receiving the relevant information. Each State Party shall notify WHO, by the most efficient means of communication available, by way of the National IHR Focal Point, and within 24 hours of assessment of public health information, of all events which may constitute a public health emergency of international concern within its territory in accordance with the decision instrument, as well as any health measure implemented in response to those events. If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA), the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (OIE), the UN Environment Programme (UNEP) or other relevant UN entities, WHO shall immediately notify the relevant national and UN entities.	The proposed time limit of 48 hours brings greater accountability on part of State parties to assess the situation in a time bound manner. This will also improve timeliness of requisite public health actions following an event with public health implications. The scope of information sharing has to be expanded beyond IAEA considering the expanded scope of risks that may have implications on public health. However, sharing of this information needs to be limited to relevant UN entities only.
Article 11: Provision of information by WHO	1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and,	1. Para 1: Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as	Makes WHO and State parties accountable for reporting any

Article	Original Article	India's Comments	Rationale
	<p>as appropriate, to relevant intergovernmental organizations, as soon as possible and by the most efficient means available, in confidence, such public health information which it has received under Articles 5 to 10 inclusive and which is necessary to enable States Parties to respond to a public health risk. WHO should communicate information to other States Parties that might help them in preventing the occurrence of similar incidents.</p>	<p>appropriate, to relevant UN and intergovernmental organizations, as soon as possible and by the most efficient means available, in confidence, such public health information which it has received under Articles 5 to 10 inclusive and which is necessary to enable States Parties to respond to a public health risk. WHO should communicate information to other States Parties that might help them in preventing the occurrence of similar incidents.</p> <p>2. 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.</p>	<p>event that has potential to constitute a public health emergency of international concern while minimizing the risk of misuse of such information.</p> <p>This will enable greater accountability on part of WHO as well as concerned State parties.</p>
<p>Article 12: Determination of a public health emergency of international concern, public health emergency of regional concern, or intermediate health alert</p>	<p>2. If the Director-General considers, based on an assessment under these Regulations, that a public health emergency of international concern is occurring, the Director-General shall consult with the State Party in whose territory the event arises regarding this preliminary</p>	<p>1. Para 2: If the Director-General considers, based on an assessment under these Regulations, that a potential or actual public health emergency of international concern is occurring, the Director-General shall consult with the State Party in whose territory the event arises regarding this preliminary determination. If the Director-General and the</p>	<p>Requisite clarity about the assessment of an event may not be available, especially in the initial period to take a call on declaration of PHEIC. However, inclusion of even potential PHEICs and intermediate levels of alerts</p>

Article	Original Article	India's Comments	Rationale
	determination. If the Director-General and the State Party are in agreement regarding this determination, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the "Emergency Committee") on appropriate temporary recommendations.	State Party are in agreement regarding this determination, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the "Emergency Committee") on appropriate temporary recommendations. 2. 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.	would alert the concerned stakeholders at National, Regional and Global levels. Provision for issuance of 'intermediate public health alert' would allow for concerned state parties to review existing public health preparedness and response capacities as well as take timely corrective measures. Regional Offices should have sufficient capacity to support DG, WHO in assessing the public health risk/event at regional level.
Article 13: Public health response	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	1. Para 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	As any timelines prescribed for implementation of revised IHR needs to take into account the capacities and capabilities of the State Parties, the decision on any

Article	Original Article	India's Comments	Rationale
	<p>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.</p> <p>3. At the request of a State Party, 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.</p>	<p>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, refer the issue to World Health Assembly which will then take a decision on the same, 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</p> <p>2. Para 3: At the request of a State Party, WHO shall collaborate articulated clearly defined assistance to a State Party in the response to public health risks and other events by providing technical guidance and assistance and by assessing the effectiveness of the control measures in place, including the mobilization of international teams of experts for on-site assistance, when necessary. The State Party shall accept or reject such an offer of assistance within 48</p>	<p>extension of timeline needs to be reviewed by a body that includes representatives from all member countries.</p> <p>There is a need for WHO to define the areas, domains of any assistance and also the quantum thereof.</p> <p>This will enable greater accountability on part of WHO as</p>

Article	Original Article	India's Comments	Rationale
		<p>hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which the WHO shall share with other States Parties. WHO will also share any request for assistance by the affected State party that could not be met by WHO.</p>	<p>well as concerned State parties.</p>
<p>Article 15: Temporary recommendations</p>	<p>1. If it has been determined in accordance with Article 12 that a public health emergency of international concern is occurring, the Director-General shall issue temporary recommendations in accordance with the procedure set out in Article 49. Such temporary recommendations may be modified or extended as appropriate, including after it has been determined that a public health emergency of international concern has ended, at which time other temporary recommendations may be issued as necessary for the purpose of preventing or promptly detecting its recurrence.</p>	<p>1. Para 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, 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.</p> <p>2. New Para 2 bis: Temporary recommendations should be evidence based as per real time risk assessment of a</p>	<p>Requisite clarity about the assessment of an event may not be available, especially in the initial period to take a call on declaration of PHEIC. However, inclusion of even potential PHEICs would alert the concerned stakeholders at National, Regional and Global levels.</p> <p>This is in line with the stated objective of IHR i.e. prevention of international spread of</p>

Article	Original Article	India's Comments	Rationale
		<p>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:</p> <p>(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</p> <p>(b) prohibitive recommendations to avoid unnecessary interference with international traffic and trade.</p>	<p>diseases while minimizing undue/unnecessary travel or trade restrictions.</p>
<p>Article 17 Criteria for recommendations</p>	<p>When issuing, modifying or terminating temporary or standing recommendations, the Director-General shall consider:</p> <p>(a) the views of the States Parties directly concerned;</p> <p>(b) the advice of the Emergency Committee or the Review Committee, as the case may be;</p>	<p>1. New para (e1): Equitable access to and distribution of medical countermeasures i.e. vaccines, therapeutics and diagnostics for optimal public health response.</p>	<p>Need to ensure equitable access to medical countermeasures is an important learning that emerged from COVID-19 pandemic.</p>

Article	Original Article	India's Comments	Rationale
	<p>(c) scientific principles as well as available scientific evidence and information;</p> <p>(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;</p> <p>(e) relevant international standards and instruments;</p> <p>(f) activities undertaken by other relevant intergovernmental organizations and international bodies; and</p> <p>(g) other appropriate and specific information relevant to the event</p> <p>With respect to temporary recommendations, the consideration by the Director-General of subparagraphs (e) and (f) of this Article may be subject to limitations</p>		

Article	Original Article	India's Comments	Rationale
	imposed by urgent circumstances.		
Article 18: Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels.		1. 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.	This is in line with the stated objective of IHR i.e. prevention of international spread of diseases while minimizing undue/unnecessary travel or trade restrictions.
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: (ii) information concerning the traveller's itinerary to ascertain if there was any travel in or near an affected area or other possible contacts with infection or contamination prior to arrival, as well as review of the traveller's health documents if they are required under these Regulations; and/or	1. Para 1 (a) (ii): information concerning the traveller's itinerary to ascertain if there was any travel in or near an affected area or other possible contacts with infection or contamination prior to arrival, as well as review of the traveller's health documents if they are required under these Regulations, including documents containing information for a lab test in digital or physical format; and/or	This reflects an important learning that emerged from COVID-19 pandemic.
Article 28 Ships and aircraft at points of entry	2. Subject to Article 43 or as provided in applicable international agreements, ships or aircraft shall not be refused free pratique by States Parties for public	1. Para 2: Subject to Article 43 or as provided in applicable international agreements, ships or aircraft shall not be refused free or a	During the Public health emergencies as per the prerogative of Member States the States Parties

Article	Original Article	India's Comments	Rationale
	health reasons; in particular they shall not be prevented from embarking or disembarking, discharging or loading cargo or stores, or taking on fuel, water, food and supplies. States Parties may subject the granting of free pratique to inspection and, if a source of infection or contamination is found on board, the carrying out of necessary disinfection, decontamination, disinsection or deratting, or other measures necessary to prevent the spread of the infection or contamination.	controlled pratique by States Parties for public health reasons; in particular, they shall not be prevented from embarking or disembarking, discharging or loading cargo or stores, or taking on fuel, water, food and supplies. States Parties may subject the granting of free or a controlled pratique to inspection and, if a source of infection or contamination is found on board, the carrying out of necessary disinfection, decontamination, disinsection or deratting, or other measures necessary to prevent the spread of the infection or contamination.	may change the granting of permission from free pratique to controlled pratique.
Article 49 Procedure	3. The Emergency Committee shall elect its Chairperson and prepare following each meeting a brief summary report of its proceedings and deliberations, including any advice on recommendations.	1. New para 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 Committee's report.	Similar provision already exists in Article 50 for Review Committee. It would be appropriate to have identical set of procedure for both Committees to the extent possible.
Annexure 1 part B		Annexure 1 is to be modified to include the below mentioned: 1. Use of latest digital technology by WHO to develop a global digital portal for mutual trust framework to verify digital credential . 2. Surveillance at PoE with the inclusion of	

Article	Original Article	India's Comments	Rationale
		One Health approach. 3. Information sharing with travelers.	

India's Proposal on targeted amendments to IHR (2005) to the IHR Review Committee

ANNEX 1

A. CORE CAPACITY REQUIREMENTS FOR SURVEILLANCE AND RESPONSE

1. States Parties shall utilize existing national structures and resources to meet their core capacity requirements under these Regulations **to identify public health risks**, including with regard to:
 - (a) their surveillance, reporting, notification, verification, response and collaboration activities; and
 - (b) their activities concerning designated airports, ports and ground crossings.
2. Each State Party shall assess, within two years following the entry into force of these Regulations 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.
3. States Parties, WHO shall support assessments, planning and implementation under this Annex.
4. **State (s) whose existing/ and or strengthened national structures and resources are not able to meet the core capacity requirements within time frame stipulated under para 2, shall be supported by WHO to fill gaps in critical capacities for surveillance, reporting, notification, verification, response.**
5. **Building capacities of the state parties (community level/ intermediate level) after consulting with concerned member state**
 - (a) **Collaborative surveillance networks to quickly detect public health events at human-animal-environmental interface including zoonotic spills and Anti-Microbial resistance within the territory of the State Party;**
 - (b) **Laboratory networks including that for Genomic sequencing and diagnostics to accurately identify the pathogen/ other hazards.**
 - (c) **Health emergency response systems to co-ordinate and implement public health response including surge capacity and state party response capacities.**
 - (d) **Health workforce development ~~at subnational level~~ to identify, track, test and treat to contain/ control the outbreak/ public health event**

(e) **Support for a Health information management system** 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;

(f) to assess **and verify** 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.

(g) **Leverage of communication channels to communicate the risk, countering misinformation and dis-information.**

6. At the national level

(i) *Assessment and notification.* The capacities:

(a) to assess all reports of urgent events within 48 hours; and

(b) to notify WHO immediately through the National IHR Focal Point when the assessment indicates the event is notifiable pursuant to paragraph 1 of Article 6 and Annex 2 and to inform WHO as required pursuant to Article 7 and paragraph 2 of Article 9.

(ii) *Public health **preparedness** and response.* The capacities:

(a) **Establish governance structure to manage a potential or declared Public Health Emergency of International concern.**

(b) **Establish co-ordinating mechanism to provide ~~direct liaison~~ collaboration with other relevant government ministries, sub-national level entities, Country office and Regional Office of WHO, other stakeholders including NGOs and civil society.**

(c) to establish, operate and maintain a national public health emergency response plan, including the creation of multidisciplinary/multisectoral teams to respond to events that may constitute a public health emergency of international concern;

(d) **Leverage digital technology for collaborative surveillance networks, forecasting, laboratory networks including that for genomic sequencing, health emergency response systems, supply chain management and risk communication.**

(e) to develop epidemiological intelligence to assess potential public health emergency of regional or international concern and determine rapidly the control measures required to prevent domestic and international spread;

(f) to support outbreak investigations, laboratory analysis, genomic sequencing of samples (domestically or through collaborating centres) and for quick and timely transportation of biological materials. logistical assistance (e.g. equipment, supplies and transport);

(g) to support timely exchange of biological materials and genetic sequence data to WHO, entities under WHO and other State Parties subject to equitable sharing of benefits derived therefrom.

(h) Work force development to provide emergency medical teams and specialized Rapid Response Teams including the creation of multidisciplinary/multisectoral teams to respond to events that may constitute a public health emergency of international concern; and ~~to provide on-site assistance as required to supplement local investigations; to provide a direct operational link with senior health and other officials to approve rapidly and implement containment and control measures; to provide direct liaison with other relevant government ministries;~~

~~to provide the foregoing on a 24-hour basis.~~

(i) to provide, by the most efficient means of communication available, links with hospitals, clinics, airports, ports, ground crossings, laboratories and other key operational areas for the dissemination of information and recommendations received from WHO regarding events in the State Party's own territory and in the territories of other States Parties;

(j) Capacity to research, manufacture and deploy quickly medical counter measures/ health products to respond to the health event

(k) For sustainable financing to develop core capacities and respond to health emergencies.

7. At the Global level, WHO shall strengthen capacities to

- a. Provide policy document, guidelines, operating procedures epidemic intelligence, forecasting tools for managing public health emergency of international concern
- b. Use evaluation framework in finding critical gaps and support such state parties in attaining the core capacities.
- c. Facilitate sharing of Biological materials and genetic sequencing data and transparent subject to equitable access to benefits derived therefrom.

- d. Facilitate research, technology transfer, development and timely distribution of health products to manage public health emergencies.
- e. Counter misinformation and disinformation
- f. Co-ordinate with UN agencies, academia, non-state actors and representatives of civil society.
- g. Ensure sustainable financing for managing health emergencies.

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

1. At all times

The capacities:

- (a) to provide access to (i) an appropriate medical service including diagnostic facilities located so as to allow the prompt assessment and care of ill travellers, and (ii) adequate staff, equipment and premises;
- (b) to provide access to equipment and personnel for the transport of ill travellers to an appropriate medical facility;
- (c) to provide trained personnel for the inspection of conveyances;
- (d) to ensure a safe environment for travellers using point of entry facilities, including potable water supplies, eating establishments, flight catering facilities, public washrooms, appropriate solid and liquid waste disposal services and other potential risk areas, by conducting inspection programmes, as appropriate; and
- (e) to provide as far as practicable a programme and trained personnel for the control of vectors and reservoirs in and near points of entry.

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

- (a) to provide appropriate public health emergency response by establishing and maintaining a public health emergency contingency plan, including the nomination of a coordinator and contact points for relevant point of entry, public health and other agencies and services;
- (b) to provide surveillance at point of entry and access to laboratory facilities for quick diagnosis of pathogens and other public health hazards.
- (c) to provide assessment of and care for affected travellers or animals by establishing arrangements with local medical and veterinary facilities for their isolation, treatment and other support services that may be required;

(d) to provide appropriate space, separate from other travellers, to interview suspect or affected persons;

(e) to provide for the assessment and, if required, quarantine of suspect travellers, preferably in facilities away from the point of entry;

(f) to apply recommended measures to disinsect, derat, disinfect, decontaminate or otherwise treat baggage, cargo, containers, conveyances, goods or postal parcels including, when appropriate, at locations specially designated and equipped for this purpose;

(g) to apply entry or exit controls for arriving and departing travellers; and

(h) to provide access to specially designated equipment, and to trained personnel with appropriate personal protection, for the transfer of travellers who may carry infection or contamination.

(i) to develop the POE work force for surveillance and POE response.

(j) Leverage digital technology for harmonising reporting capabilities and for uniform certification procedures / mutual trust framework / universal credential verification system.

(k) Standard SoPs for Infection prevention and control to be framed and implemented at all POEs

Indonesia



Permanent Mission
of the Republic of Indonesia to the UN, WTO,
and Other International Organizations
in Geneva

No: 117 /POL-II/IX/2022

The Permanent Mission of the Republic of Indonesia to the United Nations, WTO and other International Organization in Geneva presents its compliments to the World Health Organization (WHO) and refers to Article 55(1) of the the International Health Regulations (IHR) (2005) has the honor to submit the attached proposed amendments to the IHR (2005).

The Mission would also like to transmitt a letter from dr. Maxi Rein Rondonuwu, MARS the Director General for Disease Prevention and Control, Ministry of Health, reiterating the importance of strengthening the IHR (2005) through the inclusion of implementation of **digital health documents** for public health purposes and to guarantee respect for **equity** principle as well as that the IHR will secure safe travel during health emergency. The implementation of health documents in **digital format** will strengthen the ability of the WHO and Member states to perform **data interoperability** for better use cases such as safe travel.

The Permanent Mission respectfully request the Director General of the WHO to communicate the amendment to all State Parties, as appropriate, as well as in relation to the the upcoming discussion of a consolidated package of IHR amendment with all Member States.

The Permanent Mission of the Republic of Indonesia to the United Nations, WTO and other International Organization in Geneva avails itself of this opportunity to renew to the WHO the assurances of its highest consideration.

Geneva, 30 September 2022



Enclosed:

1. Proposed IHR Amendments
2. Letter from Director General for Disease Prevention and Control

The World Health Organization (WHO) Secretariat
Geneva



MINISTRY OF HEALTH REPUBLIC OF INDONESIA
DIRECTORATE GENERAL DISEASE PREVENTION AND CONTROL

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To:

Dr. Tedros Adhanom Ghebreyesus
Director-General of World Health Organization

I have the honour to convey the following Indonesia's proposed amendments to the IHR (2005) in accordance to Article 55(2) of the IHR (2005).

I have further the honour to request the Director-General of the WHO Tedros Adhanom Ghebreyesus to communicate these proposed IHR amendments to all States Parties

At this juncture, Indonesia reiterates the importance of strengthening the IHR (2005) through the inclusion of implementation of **digital health documents** for public health purposes and to guarantee respect for **equity** principle as well as that the IHR will **secure safe travel** during health emergency. The implementation of **health documents in digital format** will strengthen the ability of the WHO and Member states to perform data interoperability for better use cases such as safe travel.

G20 countries have raised these amendments through Indonesia's G20 presidency at the technical working groups, Health Working Group 1, and Health Ministers' Meeting. G20 countries have highlighted the importance of the implementation of **digital health** documents and have expressed support for the amendments to the IHR (2005).

The Ministry also proposes amendments to the IHR (2005) to take the issue of equity into account and promote the compliance to the IHR (2005).

I look forward to having further constructive consultation process to amend the IHR (2005) and providing further inputs during the discussion.

Enclosed:

1. Proposed IHR Amendments

Sincerely Yours,

Dr. dr. Maxi Rein Rondonuwu, DHSM., MARS.
Director General to Disease Prevention and Control
Ministry of Health of Indonesia



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Submission of the Indonesia
Proposed Amendments to the International Health Regulations (2005)
Articles 6, 18, 23, 31, 45 and Annex 6

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

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), WHO shall immediately notify the IAEA
2. Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed, **genome sequence data**; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern

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



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- implement exit screening and/or restrictions on persons from affected areas.
2. Recommendations issued by WHO to States Parties with respect to baggage, cargo, containers, conveyances, goods and postal parcels may include the following advice:
- no specific health measures are advised;
 - review manifest and routing;
 - implement inspections;
 - review proof of measures taken on departure or in transit to eliminate infection or contamination;
 - implement treatment of the baggage, cargo, containers, conveyances, goods, postal parcels or human remains to remove infection or contamination, including vectors and reservoirs;
 - the use of specific health measures to ensure the safe handling and transport of human remains;
 - implement isolation or quarantine;
 - seizure and destruction of infected or contaminated or suspect baggage, cargo, containers, conveyances, goods or postal parcels under controlled conditions if no available treatment or process will otherwise be successful; and
 - refuse departure or entry
3. **(New) 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.**
4. **(New) 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.**

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 **whether in paper based or digital format**, in arrival or departure:
- (a) with regard to travellers:



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- (i) information concerning the traveller's destination so that the traveller may be contacted;
 - (ii) information concerning the traveller's itinerary to ascertain if there was any travel in or near an affected area or other possible contacts with infection or contamination prior to arrival, as well as review of the traveller's health documents if they are required under these Regulations; and/or
 - (iii) a non-invasive medical examination which is the least intrusive examination that would achieve the public health objective;
 - (b) inspection of baggage, cargo, containers, conveyances, goods, postal parcels and human remains.
2. On the basis of evidence of a public health risk obtained through the measures provided in paragraph 1 of this Article, or through other means, States Parties may apply additional health measures, in accordance with these Regulations, in particular, with regard to a suspect or affected traveller, on a case-by-case basis, the least intrusive and invasive medical examination that would achieve the public health objective of preventing the international spread of disease.
 3. No medical examination, vaccination, prophylaxis or health measure under these Regulations shall be carried out on travellers without their prior express informed consent or that of their parents or guardians, except as provided in paragraph 2 of Article 31, and in accordance with the law and international obligations of the State Party.

Article 31 Health Measures relating to entry of travellers

1. Invasive medical examination, vaccination or other prophylaxis shall not be required as a condition of entry of any traveller to the territory of a State Party, except that, subject to Articles 32 42 and 45, these Regulations do not preclude States Parties from requiring medical examination, vaccination or other prophylaxis or proof of vaccination or other prophylaxis **whether in paper based or digital format**;
 - (a) when necessary to determine whether a public health risk exists;
 - (b) as a condition of entry for any travellers seeking temporary or permanent residence;
 - (c) as a condition of entry for any travellers pursuant to Article 43 or Annexes 6 and 7; or
 - (d) which may be carried out pursuant to Article 23.
2. If a traveller for whom a State Party may require a medical examination, vaccination or other prophylaxis under paragraph 1 of this Article fails to consent to any such



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measure, or refuses to provide the information or the documents referred to in paragraph 1(a) of Article 23, the State Party concerned may, subject to Articles 32, 42 and 45, deny entry to that traveller. If there is evidence of an imminent public health risk, the State Party may, in accordance with its national law and to the extent necessary to control such a risk, compel the traveller to undergo or advise the traveller, pursuant to paragraph 3 of Article 23, to undergo

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

Article 44 Collaboration and assistance

1. States Parties shall undertake to collaborate with each other, to the extent possible, in:
 - (a) the detection and assessment of, and response to, events as provided under these Regulations;
 - (b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health capacities required under these Regulations
 - (c) **(new) strengthening capacity to identify health threats including through surveillance, research and development cooperation, technological and information sharing.**
 - (d) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and
 - (e) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations
 - (f) **(new) facilitating the provision of equitable access to medical countermeasures**



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2. WHO shall collaborate with States Parties, upon request, to the extent possible, in:
 - (a) the evaluation and assessment of their public health capacities in order to facilitate the effective implementation of these Regulations
 - (b) the provision or facilitation of technical cooperation and logistical support to States Parties; and
 - (c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in **Annex 1 and Annex 6**
3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies.

Article 45 Treatment of personal data

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



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ANNEX 6

VACCINATION, PROPHYLAXIS AND RELATED CERTIFICATES

1. Vaccines or other prophylaxis specified in Annex 7 or recommended under these Regulations shall be of suitable quality; those vaccines and prophylaxis designated by WHO shall be subject to its approval. Upon request, the State Party shall provide to WHO appropriate evidence of the suitability of vaccines and prophylaxis administered within its territory under these Regulations.
2. Persons undergoing vaccination or other prophylaxis under these Regulations shall be provided with an international certificate of vaccination or prophylaxis (hereinafter the "certificate") in the form specified in this Annex **or in any digital format as being used in the country**. No departure shall be made from the model of the certificate specified in this Annex.
3. Certificates under this Annex **or any digital format** are valid only if the vaccine or prophylaxis used has been approved by WHO **or/and by State Parties**.
4. **For paper based format**, certificates must be signed in the hand of the clinician, who shall be a medical practitioner or other authorized health worker, supervising the administration of the vaccine or prophylaxis. The certificate must also bear the official stamp of the administering centre; however, this shall not be an accepted substitute for the signature.
5. **For digital format, certificates must be presented with QR code that contains the information mentioned on the Model International Certificate of Vaccinations or Prophylaxis and should be aligned with any current guidelines or/and agreed by state parties**
6. Certificates shall be fully completed in English or in French. They may also be completed in another language, in addition to either English or French.
7. Any amendment of this certificate, or erasure, or failure to complete any part of it, may render it invalid.
8. Certificates are individual and shall in no circumstances be used collectively. Separate certificates shall be issued for children.
9. A parent or guardian shall sign the certificate when the child **or a person with disability** is unable to write. The signature of an illiterate shall be indicated in the



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usual manner by the person's mark and the indication by another that this is the mark of the person concerned.

10. If the supervising clinician is of the opinion that the vaccination or prophylaxis is contraindicated on medical grounds, the supervising clinician shall provide the person with reasons, written in English or French, and where appropriate in another language in addition to English or French, underlying that opinion, which the competent authorities on arrival should take into account. The supervising clinician and competent authorities shall inform such persons of any risk associated with non-vaccination and with the non-use of prophylaxis in accordance with paragraph 4 of Article 23.
11. An equivalent document issued by the Armed Forces to an active member of those Forces shall be accepted in lieu of an international certificate in the form shown in this Annex if:
 - (a) it embodies medical information substantially the same as that required by such form; and
 - (b) it contains a statement in English or in French and where appropriate in another language in addition to English or French recording the nature and date of the vaccination or prophylaxis and to the effect that it is issued in accordance with this paragraph.



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**MODEL INTERNATIONAL CERTIFICATE OF VACCINATIONS
OR PROPHYLAXIS**

This is to certify that [name], date of birth, sex, nationality, national identification document, if applicable whose signature follows has on the date indicated been vaccinated or received prophylaxis against: (name of disease or condition) in accordance with the International Health Regulations.

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

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

This certificate must be signed in the hand of the clinician, who shall be a medical practitioner or other authorized health worker, supervising the administration of the vaccine or prophylaxis. The certificate must also bear the official stamp of the administering centre; however, this shall not be an accepted substitute for the signature.

Any amendment of this certificate, or erasure, or failure to complete any part of it, may render it invalid.

The validity of this certificate shall extend until the date indicated for the particular vaccination or prophylaxis. The certificate shall be fully completed in English or in French. The certificate may also be completed in another language on the same document, in addition to either English or French.

Sincerely Yours,

Dr. dr. Maxi Rein Rondonuwu, DHSM., MARS.
Director General to Disease Prevention and Control
Ministry of Health of Indonesia

Japan

MISSION PERMANENTE DU JAPON
AUPRÈS DES ORGANISATIONS INTERNATIONALES
GENÈVE-SUISSE

KS/WHO/382

The Permanent Mission of Japan to the International Organizations in Geneva presents its compliments to the World Health Organization and has the honour to transmit proposals for amendments to the International Health Regulation (2005).

The Permanent Mission of Japan to the International Organizations in Geneva avails itself of this opportunity to renew to the World Health Organization the assurances of its highest consideration.

Geneva, 22 September 2022



A handwritten signature in black ink, written over the bottom right portion of the red seal.

Japan: IHR Amendments

Article 8, 13, 24, 27, 28, 45, Annex 2

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 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.** 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 13 Public health response

1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern as set out in Annex 1. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response 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.

2bis. WHO shall provide to State Parties standardized forms for collaboration in the implementation of collaboration as provided in paragraph 1(a) of the Article 44 to facilitate State Parties' mutual collaboration essential for the effective implementation of public

health response.

3. At the request of a State Party, 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 concerned as provided in Article 12, determines that a public health emergency of international concern is occurring, it may offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State Party, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.

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

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

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;

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

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

(d) implement quarantine promptly on board as necessary.

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

ANNEX 4

**TECHNICAL REQUIREMENTS PERTAINING TO CONVEYANCES AND
CONVEYANCE OPERATORS**

Section A Conveyance operators

1. Conveyance operators shall 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; and
- (d) provision of relevant public health information requested by the State Party.

2. Conveyance operators shall provide to the competent authority a valid Ship Sanitation Control Exemption Certificate or a Ship Sanitation Control Certificate or a Maritime Declaration of Health, or the Health Part of an Aircraft General Declaration, as required under these Regulations.

3. Conveyance operators shall prepare in advance, where possible, a plan for taking appropriate measures required if evidence of a public health risk on board is found.

Section B Conveyances

1. Control measures applied to baggage, cargo, containers, conveyances and goods under these Regulations shall be carried out so as to avoid as far as possible injury or discomfort to persons or damage to the baggage, cargo, containers, conveyances and goods. Whenever possible and appropriate, control measures shall be applied when the conveyance and holds are empty.

2. States Parties shall indicate in writing the measures applied to cargo, containers or conveyances, the parts treated, the methods employed, and the reasons for their application. This information shall be provided in writing to the person in charge of an aircraft and, in case of a ship, on the Ship Sanitation Control Certificate. For other cargo, containers or conveyances, States Parties shall issue such information in writing to consignors, consignees, carriers, the person in charge of the conveyance or their respective agents.

Article 27 Affected conveyances

1. If clinical signs or symptoms and information based on fact or evidence of a public health risk, including sources of infection and contamination, are found on board a conveyance, the competent authority shall consider the conveyance as affected and may:

- (a) disinfect, decontaminate, disinsect or derat the conveyance, as appropriate, or cause these measures to be carried out under its supervision; and
- (b) decide in each case the technique employed to secure an adequate level of control of the public health risk as provided in these Regulations. Where there are methods or materials advised by WHO for these procedures, these should be employed, unless the competent authority

determines that other methods are as safe and reliable.

The competent authority may implement additional health measures, including isolation of the conveyances, **and demand the conveyance operators, the pilot in command of the aircraft or the officer in command of the ship to take practicable measures on the conveyances** as necessary, to prevent the spread of disease. Such additional measures should be reported to the National IHR Focal Point.

2. If the competent authority for the point of entry is not able to carry out the control measures required under this Article, the affected conveyance may nevertheless be allowed to depart, subject to the following conditions:

(a) the competent authority shall, at the time of departure, inform the competent authority for the next known point of entry of the type of information referred to under subparagraph (b); and

(b) in the case of a ship, the evidence found and the control measures required shall be noted in the Ship Sanitation Control Certificate. Any such conveyance shall be permitted to take on, under the supervision of the competent authority, fuel, water, food and supplies.

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

(a) the measures provided in paragraph 1 of this Article have been effectively carried out; and

(b) there are no conditions on board that could constitute a public health risk.

Article 28 Ships and aircraft at points of entry

1. Subject to Article 43 or as provided in applicable international agreements, a ship or an aircraft shall not be prevented for public health reasons from calling at any point of entry. However, if the point of entry is not equipped for applying health measures under these Regulations, the ship or aircraft may be ordered to proceed at its own risk to the nearest suitable point of entry available to it, unless the ship or aircraft has an operational problem which would make this diversion unsafe.

2. Subject to Article 43 or as provided in applicable international agreements, ships or aircraft shall not be refused free pratique by States Parties for public health reasons; in particular they shall not be prevented from embarking or disembarking, discharging or loading cargo or stores, or taking on fuel, water, food and supplies. States Parties may subject the granting of free pratique to inspection and, if a source of infection or contamination is found on board, the carrying out of necessary disinfection, decontamination, disinsection or deratting, or other measures necessary to prevent the spread of the infection or contamination.

3. Whenever practicable and subject to the previous paragraph, a State Party shall authorize the granting of free pratique by radio or other communication means to a ship or an aircraft when, on

the basis of information received from it prior to its arrival, the State Party is of the opinion that the arrival of the ship or aircraft will not result in the introduction or spread of disease.

4. Officers in command of ships or pilots in command of aircraft, or their agents, shall make known to the port or airport control as early as possible before arrival at the port or airport of destination any cases of illness indicative of a disease of an infectious nature or evidence of a public health risk on board as soon as such illnesses or public health risks are made known to the officer or pilot. This information must be immediately relayed to the competent authority for the port or airport. In urgent circumstances, such information should be communicated directly by the officers or pilots to the relevant port or airport authority. **The competent authority for the port or airport which received information pursuant to this paragraph may notify the health measures applicable to a ship or an aircraft as necessary.**

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

(a) the pilot in command of the aircraft or the officer in command of the ship or other person in charge shall make every effort to communicate without delay with the nearest competent authority;

(b) as soon as the competent authority has been informed of the landing it may apply health measures recommended by WHO or other health measures provided in these Regulations;

(c) unless required for emergency purposes or for communication with the competent authority, no traveller on board the aircraft or ship shall leave its vicinity and no cargo shall be removed from that vicinity, unless authorized by the competent authority; and

(d) when all health measures required by the competent authority have been completed, the aircraft or ship may, so far as such health measures are concerned, proceed either to the airport or port at which it was due to land or berth, or, if for technical reasons it cannot do so, to a conveniently situated airport or port.

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

Article 45 Treatment of personal data

1. Health information collected or received by a State Party pursuant to these Regulations from another State Party or from WHO which refers to an identified or identifiable person shall be kept

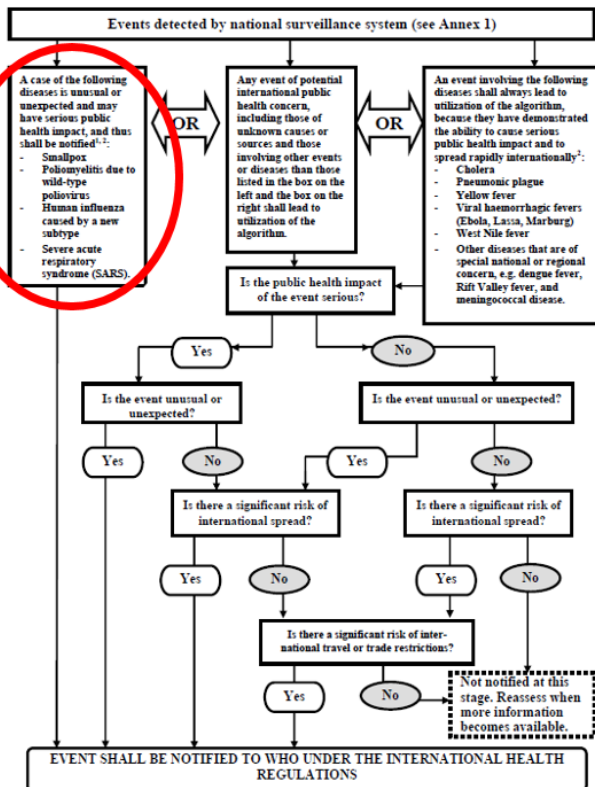
confidential and processed anonymously as required by national law.

2. Notwithstanding paragraph 1, States Parties may ~~disclose and~~ process **and disclose** personal data where essential for the purposes of assessing and managing a public health risk. **In the case where disclosure of personal data is essential for such purposes, State Parties should obtain consent from the State Party which provided the information. When processing and/or disclosing personal data,** State Parties, in accordance with national law, and WHO must ensure that the personal data are:

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

ANNEX 2

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



A case of the following diseases is unusual or unexpected and may have serious public health impact, and thus shall be notified^{1,2}:

- Smallpox
- Poliomyelitis due to wild-type poliovirus
- Human influenza caused by a new subtype
- Severe acute respiratory syndrome (SARS) as well as cluster(s) of severe acute pneumonia of unknown cause
- Cluster(s) of other severe infections in which human to human transmission cannot be ruled out.

EVENT SHALL BE NOTIFIED TO WHO UNDER THE INTERNATIONAL HEALTH REGULATIONS

end

Malaysia

Malaysia's Proposal for Targeted Amendment of the International Health Regulations (2005)

Present Status/ Text From IHR 2005	Amendment Suggestion (proposed changes in bold, underline/ strikethrough)	Rationale by MALAYSIA
<p><i>Article 1 Definitions</i></p> <p>1. For the purposes of the International Health Regulations (hereinafter “the IHR” or “Regulations”):</p> <p>.....</p> <p>“health measure” means procedures applied to prevent the spread of disease or contamination; a health measure does not include law enforcement or security measures;</p> <p>“ill person” means an individual suffering from or affected with a physical ailment that may pose a public health risk;</p>	<p>1. For the purposes of the International Health Regulations (hereinafter “the IHR” or “Regulations”):</p> <p>.....</p> <p>“health measure” means procedures applied to prevent the spread of disease or contamination; a health measure does not include law enforcement or security measures;</p> <p><u>“health products” include medicines, vaccines, medical devices, diagnostics, assistive products, cell- and gene-based therapies, and other health technologies, but not limited to this course</u></p> <p>“ill person” means an individual suffering from or affected with a physical ailment that may pose a public health risk;</p>	<p>1. IHR 2005 currently does not have a definition on health products. Besides, the issue of equitable access to health products, technologies and know-how required to respond effectively to a PHEIC is not addressed explicitly within IHR 2005. The COVID-19 response has exposed the gap related to this. Hence, a definition for the phrase “health products” has become imperative and Malaysia strongly feels that it should be included in “<i>Article 1 Definitions</i>”.</p> <p>2. The proposed definition for “health products” is adapted from the Resolution WHA 72.8 titled “Improving The Transparency Of Markets For Medicines, Vaccines, And Other Health Products”¹.</p> <p>3. In view of the alphabetical order contained within Article 1, the placement of the definitions for “health products” is suggested to be position between “health measure” and “ill person”.</p> <p>¹https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf</p>

Malaysia's Proposal for Targeted Amendment of the International Health Regulations (2005)

<p><i>Article 3 Principles</i></p> <p>.....</p> <p>4. States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to legislate and to implement legislation in pursuance of their health policies. In doing so they should uphold the purpose of these Regulations.</p>	<p>.....</p> <p>4. States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to legislate and to implement legislation in pursuance of their health policies. In doing so they should uphold the purpose of these Regulations.</p> <p><u>New 5. The State Parties shall implement these Regulations on the basis of equity, solidarity as well as and in accordance with their common but differentiated responsibilities and respective level of development of the State Parties.</u></p> <p><u>New 6: Exchange of information between State Parties or between State Parties and WHO pursuant to the implementation of these Regulations shall be exclusively for peaceful purposes.</u></p>	<p><u>New Paragraph 5</u></p> <ol style="list-style-type: none"> 1. The new paragraph 5 is proposed as at present IHR 2005 treats all State Parties at an equal footing without recognizing their different capacities and capabilities, as well as ignoring their developmental inequities. 2. The concept of common but differentiated responsibilities and respective capabilities (CBDR) is not a new concept in international law, as it has been used within the United Nations Framework Convention on Climate Change (UNFCC). 3. State Parties are differentiated because not every State has the same capacities to deal with the problem of international spread of disease in the same manner. The needs of the States also differ according to their level of development.
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Malaysia's Proposal for Targeted Amendment of the International Health Regulations (2005)

		<p><u>New Paragraph 6</u></p> <ol style="list-style-type: none"> 1. The new paragraph 6 is proposed to address security concerns, to guard against the misuse of the information shared. This is also consistent with WHO's theme for the recent 75th World Health Assembly, "Health for peace, peace for Health". 2. Prompt and timely sharing of information is vital for PHEIC management, however it must not compromise the national security.
<p><i>Article 5 Surveillance</i></p> <ol style="list-style-type: none"> 1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1, but no later than five years from the entry into force of these Regulations. 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 	<ol style="list-style-type: none"> 1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1. <u>Developed State Parties and WHO shall offer assistance to developing State Parties depending on the availability of finance, technology and know-how for the full implementation of this article, in pursuance of the Article 44.</u> 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 	<p><u>New Insertion in Paragraph 1</u></p> <ol style="list-style-type: none"> 1. The new insertion of texts in paragraph 1 is proposed as at present IHR 2005 treats all State Parties at an equal footing without recognizing their different capacities and capabilities, as well as ignoring their developmental inequities. With this pandemic we saw the magnitude of help that developed states can offer to developing states in times of a crisis. 2. The concept of common but differentiated responsibilities and respective capabilities (CBDR) is not a new concept in international law, as it has been used within the United Nations

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<p>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.</p> <p>3. WHO shall assist States Parties, upon request, to develop, strengthen and maintain the capacities referred to in paragraph 1 of this Article.</p>	<p>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.</p> <p>3. Developed State Parties and WHO₂ shall assist any State Parties, upon request, to develop, strengthen and maintain the capacities referred to in paragraph 1 of this Article.</p>	<p>Framework Convention on Climate Change (UNFCCC).</p> <p>3. State Parties are differentiated because not every States has the same capacities to deal with the problem of international spread of disease in the same manner. The needs of the States also differ according to their level of development. Therefore, Malaysia strongly feels that the developed states parties can play a substantial role in assisting the developing states parties.</p> <p>4. The sharing of resources pursuant to Article 44, will help the developing countries in establishing and maintaining their core capacities, as well as managing PHEIC optimally.</p> <p>5. Similar provision can be seen in UNFCC agreement Article 4(7) which reads : <i>"The extent to which developing country Parties will effectively implement their commitments under the Convention will depend on the effective implementation by developed country Parties of their commitments under the Convention related to financial resources and transfer of technology and will take fully into account that economic and social development and poverty eradication are the first and overriding priorities of the developing country Parties."</i></p>
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Malaysia’s Proposal for Targeted Amendment of the International Health Regulations (2005)

		<p><u>New Insertion in Paragraph 3</u> 1. The new insertion of texts in paragraph 3 is proposed to create shared obligation between WHO and developed States Parties. Due to financial constraint, this cannot be fulfilled solely by WHO.</p>
<p><i>Article 6 Notification</i></p> <p>.....</p> <p>2. Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern.</p>	<p>.....</p> <p>2. Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern.</p> <p><u>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, personals, non-state actors or any recipient whatsoever engaging directly or indirectly with conflict and violence elements. WHO shall also</u></p>	<p>The proposed new paragraph is consistent with the new principle on “peaceful purposes” introduced in the Article 3. This will help protect the national security interests of the state as well as to bring a discipline in the manner in which WHO is handling highly sensitive health and biological information. This is also consistent with WHO’s theme for the recent 75th World Health Assembly, “Health for peace, peace for Health”.</p>

Malaysia's Proposal for Targeted Amendment of the International Health Regulations (2005)

	<u>handle the information in a manner designed to avoid such actors accessing the information, directly or indirectly.</u>	
<p><i>Article 11 Provision of information by WHO</i></p> <p>.....</p> <p>3. WHO shall consult with the State Party in whose territory the event is occurring as to its intent to make information available under this Article.</p>	<p>.....</p> <p>3. WHO shall consult with the State Party in whose territory the event is occurring as to its intent to make information available under this Article.</p> <p><u>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.</u></p>	<p>The proposed new paragraph is consistent with the new principle on “peaceful purposes” introduced in the Article 3. This will help protect the national security interests of the state as well as to bring a discipline in the manner in which State Parties are handling highly sensitive health and biological information. This is also consistent with WHO’s theme for the recent 75th World Health Assembly, “Health for peace, peace for Health”.</p>
<p><i>Article 12 Determination of the Public Health Emergency of International Concern</i></p> <p>.....</p> <p>5. If the Director-General, following consultations with the State Party within</p>	<p>.....</p> <p>5. If the Director-General, following consultations with the State Party within</p>	

Malaysia's Proposal for Targeted Amendment of the International Health Regulations (2005)

<p>whose territory the public health emergency of international concern has occurred, considers that a public health emergency of international concern has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49.</p>	<p>whose territory the public health emergency of international concern has occurred, considers that a public health emergency of international concern has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49.</p> <p><u>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.</u></p>	<p>The new paragraph 6 is proposed to instil the importance of transparency in managing PHEIC by WHO. This will ensure that State Parties are well informed regarding all the activities that have been undertaken by WHO under this provision. This would enhance the trust that people have in WHO when activities carried out are all clearly outlined immediately, in real time.</p>
<p><i>Article 13 Public Health Response</i></p> <p>1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern as set out in Annex 1. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response capacities.</p>	<p>1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern as set out in Annex 1. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response capacities.</p> <p><u>Developed State Parties and WHO shall offer assistance to developing State Parties depending on the availability of</u></p>	<p><u>New Insertion in Paragraph 1</u></p> <p>1. The new insertion of texts in paragraph 1 is proposed as at present IHR 2005 treats all State Parties at an equal footing without recognizing their different capacities and capabilities, as well as ignoring their developmental inequities.</p> <p>2. The concept of common but differentiated responsibilities and respective capabilities (CBDR) is not a new concept in international law, as it has been used within the United Nations Framework Convention on Climate</p>

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<p>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.</p> <p>3. At the request of a State Party, 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.</p>	<p><u>finance, technology and know-how for the full implementation of this article, in pursuance of the Article 44.</u></p> <p>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.</p> <p>3. At the request of a State Party, WHO shall collaborate in the response to public health risks and other events by providing technical guidance, <u>health products, technologies, know-how, deployment of civil medical personals,</u> and any other 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.</p>	<p>Change (UNFCCC). Therefore, Malaysia strongly feels that the developed states parties can play a substantial role in assisting the developing states parties.</p> <p>3. State Parties are differentiated because not every States has the same capacities to deal with the problem of international spread of disease in the same manner. The needs of the States also differ according to their socio-economic status.</p> <p>4. The sharing of resources pursuant to Article 44, will help the developing countries in establishing and maintaining their core capacities, as well as to manage PHEIC optimally.</p> <p><u>New Insertion in Paragraph 3</u> The amendments to paragraph 3 have been proposed to improve clarity on the required resources by State Parties from WHO.</p>
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<p>4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern is occurring, it may offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State Party, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.</p> <p>5. When requested by WHO, States Parties should provide, to the extent possible, support to WHO-coordinated response activities.</p> <p>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.</p>	<p>4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern is occurring, it may offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State Party, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.</p> <p>5. When requested by WHO, States Parties should provide, to the extent possible, support to WHO-coordinated response activities, <u>including supply of health products and technologies especially diagnostics and other devices, therapeutics, and vaccines for effective response to PHEIC.</u></p> <p>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.</p> <p><u>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</u></p>	<p><u>New Insertion in Paragraph 5</u> The amendments to paragraph 5 have been proposed to improve clarity on the required resources.</p> <p><u>New Paragraph 7</u> 1. The new paragraph 7 is proposed to reflect the requirement outlined in paragraph 73 of FENSA:</p>
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	<p><u>(FENSA). Any departure from FENSA provisions shall be consistent with paragraph 73 of FENSA.</u></p>	<p><i>“The Director-General, in the application of this framework, when responding to acute public health events described in the International Health Regulations (2005) or other emergencies with health consequences, will act according to the WHO Constitution and the principles identified in this framework. In doing so, the Director-General may exercise flexibility as might be needed in the application of the procedures of this framework in those responses, when he/she deems necessary, in accordance with WHO’s responsibilities as health cluster lead, and the need to engage quickly and broadly with non-State actors for coordination, scale up and service delivery. The Director-General will inform Member States through appropriate means, including in particular written communication, without undue delay when such a response requires exercise of flexibility, and include summary information with justification on the use of such flexibility in the annual report on engagement with non-State actors.”</i></p> <p>2. This new paragraph 7 is introduced to bring more visibility to FENSA within the IHR and thereby reiterates that the Director-General ought to be cautious in engagement with Non-State Actors.</p>
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<p><i>Proposal for New Article 13 bis Access to Health Products, Technologies and Know-How for Public Health Response</i></p>		<ol style="list-style-type: none"> 1. Malaysia would like to propose a new article related to access to health products, technologies and know-how for public health response. 2. One of the concerns, which affects the public health response to disease outbreaks and its international spread is the lack of availability and affordability of the required health products. This is mainly because of the limited manufacturing, statutory monopolies, and surge in the demand. Therefore, it is important to address the root causes of the lack of availability and affordability. 3. The best way to scale up the production and distribution of the required health products in the shortest possible time is through the diversification of the production and transfer of technology. 4. It is obligatory for the State Parties to cooperate with each other and WHO to ensure timely availability and affordability of required health products, for the effective response to PHEIC.
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<p><i>Article 15 Temporary Recommendations</i></p> <p>2. Temporary recommendations may include health measures to be implemented by the State Party experiencing the public health emergency of international concern, or by other States Parties, regarding persons, 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.</p>	<p>2. Temporary recommendations may include health measures to be implemented by the State Party experiencing the public health emergency of international concern, or by other States Parties, regarding persons, 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 <u>and recommendations on the access and availability of health products, technologies, and know-how, including an allocation mechanism for their fair and equitable access.</u></p>	<p>The amendments to paragraph 2 have been proposed to improve clarity on temporary recommendations. In addition, there is explicit mention that these are related to access to health products and technologies, that can be adopted by WHO.</p>
<p><i>Article 16 Standing Recommendations</i></p> <p>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. WHO may, in accordance with Article 53, modify or terminate such recommendations, as appropriate.</p>	<p>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 <u>and recommendations on the access and availability of health products, technologies, and know how, including an allocation mechanism</u></p>	<p>The new insertion of texts in this Article have been proposed to improve clarity on standing recommendations. In addition, there is explicit mention that these are related to access to health products and technologies, that can be adopted by WHO.</p>

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	<p>for their fair and equitable access. WHO may, in accordance with Article 53, modify or terminate such recommendations, as appropriate.</p>	
<p><i>Article 42 Implementation of health measures</i></p> <p>Health measures taken pursuant to these Regulations shall be initiated and completed without delay, and applied in a transparent and non-discriminatory manner.</p>	<p>Health measures taken pursuant to these Regulations, <u>including the recommendations made under Article 15 and 16,</u> shall be initiated and completed without delay <u>by all State Parties,</u> and applied in a transparent, <u>equitable</u> and non-discriminatory manner. <u>State Parties shall also take measures to ensure Non-State Actors operating in their respective territories comply with such measures.</u></p>	<ol style="list-style-type: none"> 1. The existing text of Article 42 does not clarify the actors who need to carry out the health measures taken pursuant to IHR. It also lacks focus on equity. The proposed changes address this issue. 2. The new proposed changes will ensure that the State Parties are clear on their responsibilities. In addition to that, the mention of Non-State Actors is to emphasize that measures ought to be taken by State Parties to ensure adherence of NSAs to existing framework such as the FENSA.
<p><i>Article 43 Additional Health Measures</i></p> <p>.....</p> <p>3. A State Party implementing additional health measures referred to in paragraph 1 of this Article which significantly interfere with international traffic shall provide to WHO the public health rationale and relevant scientific information for it. WHO shall share this information with other States Parties and shall share information regarding the health</p>		<p>Malaysia would like to propose new paragraphs or insertion of new texts in this Article to tackle the concern pertaining to the implementation of additional health measures by any State Parties, which shall not cause obstruction to the allocation mechanism or access to the required resources.</p>

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<p>measures implemented. For the purpose of this Article, significant interference generally means refusal of entry or departure of international travellers, baggage, cargo, containers, conveyances, goods, and the like, or their delay, for more than 24 hours.</p> <p>.....</p>		
<p><i>Article 44 Collaboration and Assistance</i></p> <p>1. States Parties shall undertake to collaborate with each other, to the extent possible, in:</p> <p style="padding-left: 40px;">(a) the detection and assessment of, and response to, events as provided under these Regulations;</p> <p style="padding-left: 40px;">(b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health capacities required under these Regulations;</p> <p style="padding-left: 40px;">(c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and</p> <p style="padding-left: 40px;">(d) the formulation of proposed laws and other legal and administrative provisions for the implementation of</p>		<p>Malaysia would like to propose new paragraphs or insertion of new texts in this Article to tackle the following concerns:</p> <ol style="list-style-type: none"> 1. Collaboration and assistance between State Parties should recognize the concept of common but differentiated responsibilities and respective capabilities (CBDR) among State Parties. 2. To establish a mechanism for monitoring and ensuring implementation of such obligations pursuant to this Article. <p>Therefore, the amendments proposed aimed at bringing more clarity, transparency, predictability and measurability to the obligations under Article 44. Besides, collaboration and assistance under this Article should be governed by a new annexure.</p>

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<p>these Regulations.</p>		
<p><i>Proposal for New Article 44 bis: Financial Mechanism for Equity in Health Emergency Preparedness and Response</i></p>		<ol style="list-style-type: none"> 1. Malaysia would like to propose a new article related to financial mechanism for equity in health emergency preparedness and response. 2. One of the key findings of the IHR Review Committee is that lack of sufficient finance and funding both at international and national level hinders the implementation of IHR obligations. To ensure such financing and its equitable nature, a legal basis for this concern should be created in IHR 2005.
<p><i>Article 48 Terms of reference and composition</i></p> <p>...</p> <p>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</p>	<p>...</p> <p>2. The Emergency Committee shall be composed of experts <u>free from the conflict of interests</u> 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</p>	<p>The new insertion of texts in this Article have been proposed to ensure that the appointed experts should be free from conflict of interests.</p>

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<p>expertise and experience required for any particular session and with due regard to the principles of equitable geographical representation. At least one member of the Emergency Committee should be an expert nominated by a State Party within whose territory the event arises.</p> <p>3. The Director-General may, on his or her own initiative or at the request of the Emergency Committee, appoint one or more technical experts to advise the Committee.</p>	<p>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 of the Emergency Committee should be an expert nominated by a State Party within whose territory the event arises.</p> <p>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 <u>free from the conflict of interests</u> to advise the Committee.</p>	
<p><i>Article 49 Procedure</i></p> <p>...</p> <p>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</p>	<p>...</p> <p>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</p>	<p>The new insertion of texts in this Article have been proposed to make the information and recommendation conveyed by the Director-General more acceptable and transparent, in support of the function of the Emergency Committee.</p>

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<p>such information and recommendations available to the general public.</p>	<p>such information and recommendations available to the general public <u>including the reasons behind such recommendations.</u></p>	
<p><i>Article 54 Reporting and Review</i></p> <p>.....</p> <p>3. WHO shall periodically conduct studies to review and evaluate the functioning of Annex 2. The first such review shall commence no later than one year after the entry into force of these Regulations. The results of such reviews shall be submitted to the Health Assembly for its consideration, as appropriate.</p>	<p>.....</p> <p>3. WHO shall periodically conduct studies to review and evaluate the functioning of Annex 2. The first such review shall commence no later than one year after the entry into force of these Regulations. The results of such reviews shall be submitted to the Health Assembly for its consideration, as appropriate.</p> <p><u>New 4. Apart from providing information to the State Parties and reporting to the Health Assembly in this Article, WHO shall maintain a webpage/ dashboard to provide the details of the activities carried out under the various provisions of these Regulations including Articles 5(3), 12, 13(5), 14, 15, 16, 18, 43, 44, 46, and 49.</u></p>	<p><u>New Paragraph 4</u> The new paragraph 4 is proposed to improve clarity on reporting methodology that can be adopted by WHO.</p>

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<p><i>Proposal for New Annexure 10: Obligations of Duty to Collaborate and Assist</i></p>		<ol style="list-style-type: none"> 1. Malaysia would like to propose a new annexure related to the obligations of duty to collaborate and assist as this will bring more clarity and explanation to Article 44. 2. Taking into consideration the guiding principles when delivering collaboration and assistance, which includes: <ul style="list-style-type: none"> • “Right to health” centric • Needs based and upon request • Non-interference with Sovereign Rights of State Parties • Strengthening of public health systems and resilience • Transparency, accountability and free from conflict of interest • Sustainability • Access and benefit sharing
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Proposal For Targeted Amendments To The International Health Regulations (2005) From USA
(Source: Seventy-Fifth World Health Assembly, Document A75/18, 12 April 2022)

Present Status/ Text From IHR 2005	Proposed Amendments By USA	(Agree/ disagree/ reservation) with rationale
<p><i>Article 5: Surveillance</i></p> <p>1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1.</p>	<p>1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1. <u>This capacity will be periodically reviewed through the Universal Health Periodic Review mechanism. Should such review identify resource constraints and other challenges in attaining these capacities, WHO and its Regional Offices shall, upon the request of a State Party, provide or facilitate technical support and assist in mobilization of financial resources to develop, strengthen and maintain such capacities.</u></p> <p>.....</p> <p><u>New 5. WHO shall develop early warning criteria for assessing and progressively updating the national, regional, or global risk posed by an event of unknown causes or sources and shall convey this risk assessment to States Parties in accordance with Articles 11 and 45 where appropriate. The risk assessment shall indicate, based on the best available knowledge, the level of risk of potential spread and risks of potential serious public health impacts, based on assessed infectiousness and severity of the illness.</u></p>	<p>Malaysia seeks clarification on the UHPR mechanism and requests for the report of the pilot study.</p> <p>Malaysia agrees to the proposed text in New 5 of Article 5.</p>

**Proposal For Targeted Amendments To The International Health Regulations (2005) From USA
(Source: Seventy-Fifth World Health Assembly, Document A75/18, 12 April 2022)**

<p><i>Article 6 : Notification</i></p> <p>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), WHO shall immediately notify the IAEA.</p> <p>2. Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern.</p>	<p>1. Each State Party shall assess events occurring within its territory by using the decision instrument in Annex 2 <u>within 48 hours of the National IHR Focal Point receiving the relevant information.</u> 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), <u>the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (OIE), the UN Environment Programme (UNEP) or other relevant entities,</u> WHO shall immediately notify the IAEA <u>relevant entities.</u></p> <p>2. Following a notification, a State Party shall continue to communicate to WHO, <u>by the most efficient means of communication available,</u> timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including <u>genetic sequence data,</u> case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the</p>	<p>Malaysia is agreeable to the proposed text in Para 1, Article 6.</p> <p>Malaysia wishes to delete “genetic sequence data”. Instead, Malaysia wishes to add at the end of Para 2 Article 6 “with regards to the sharing of genetic sequence data it will depend on Member States’ capacity and prevailing national legislation.”</p>
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**Proposal For Targeted Amendments To The International Health Regulations (2005) From USA
(Source: Seventy-Fifth World Health Assembly, Document A75/18, 12 April 2022)**

	potential public health emergency of international concern.	
<p><i>Article 9: Other reports</i></p> <p>1. WHO may take into account reports from sources other than notifications or consultations and shall assess these reports according to established epidemiological principles and then communicate information on the event to the State Party in whose territory the event is allegedly occurring. Before taking any action based on such reports, WHO shall consult with and attempt to obtain verification from the State Party in whose territory the event is allegedly occurring in accordance with the procedure set forth in Article 10. To this end, WHO shall make the information received available to the States Parties and only where it is duly justified may WHO maintain the confidentiality of the source. This information will be used in accordance with the procedure set forth in Article 11.</p>	<p>1. WHO may take into account reports from sources other than notifications or consultations and shall assess these reports according to established epidemiological principles and then communicate information on the event to the State Party in whose territory the event is allegedly occurring. Before taking any action based on such reports, WHO shall consult with and attempt to obtain verification from the State Party in whose territory the event is allegedly occurring in accordance with the procedure set forth in Article 10. To this end, WHO shall make the information received available to the States Parties and only where it is duly justified may WHO maintain the confidentiality of the source. This information will be used in accordance with the procedure set forth in Article 11.</p>	<p>Malaysia objects to the deletion of the text in Para 1, Article 9 and would like to retain the original text. Malaysia is in view that consultation and attempt to obtain verification from the State Party concerned is critical and imperative. This would provide an opportunity to the State Party to provide clarifications and verification.</p>
<p><i>Article 10: Verification</i></p> <p>1. WHO shall request, in accordance with Article 9, verification from a State Party of reports from sources other than notifications or consultations of events which may constitute a public health emergency of international concern allegedly occurring in the State's territory. In such cases, WHO shall inform the State Party concerned regarding the reports it is seeking to verify</p>	<p>1. <u>Within 24 hours of receiving information</u>, WHO shall request, in accordance with Article 9, verification from a State Party of reports from sources other than notifications or consultations of events which may constitute a public health emergency of international concern allegedly occurring in the State's territory. In such cases, WHO shall inform the State Party concerned regarding the reports it is seeking to verify.</p>	<p>Malaysia agrees to the insertion of "Within 24 hours of receiving" in Para 1, Article 10.</p>

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(Source: Seventy-Fifth World Health Assembly, Document A75/18, 12 April 2022)**

<p>2. Pursuant to the foregoing paragraph and to Article 9, each State Party, when requested by WHO, shall verify and provide:</p> <p>(a) within 24 hours, an initial reply to, or acknowledgement of, the request from WHO;</p> <p>(b) within 24 hours, available public health information on the status of events referred to in WHO's request; and</p> <p>(c) information to WHO in the context of an assessment under Article 6, including relevant information as described in that Article.</p> <p>3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall offer to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures. Such 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.</p>	<p>2. Pursuant to the foregoing paragraph and to Article 9, each State Party, when requested by WHO, shall verify and provide:</p> <p>(a) within 24 hours, an initial reply to, or acknowledgement of, the request from WHO;</p> <p>(b) within 24 hours, available public health information on the status of events referred to in WHO's request; and</p> <p>(c) information to WHO in the context of an assessment under Article 6, including relevant information as described in <u>paragraphs 1 and 2 of</u> that Article.</p> <p>3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall offer <u>within 24 hours</u> 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.</p> <p><u>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</u></p>	<p>Malaysia requests to retain the original text in Para 2 (c), Article 10.</p> <p>Malaysia agrees to Para 3, Article 10 for the insertion of "within 24 hours". However, Malaysia disagrees to Para 3bis as the timeframe stipulated is too restrictive and a delay from State Party to respond does not necessarily imply that State Party rejects WHO's offer to collaborate considering that State Party is in crisis mode during an event that may constitute a public health emergency of international concern.</p>
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**Proposal For Targeted Amendments To The International Health Regulations (2005) From USA
(Source: Seventy-Fifth World Health Assembly, Document A75/18, 12 April 2022)**

<p>4. If the State Party does not accept the offer of collaboration, WHO may, when justified by the magnitude of the public health risk, 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.</p>	<p><u>information with States Parties under Paragraph 4 of this section.</u></p> <p>4. If the State Party does not accept the offer of collaboration <u>within 48 hours</u>, WHO <u>shall</u> may, when justified by the magnitude of the public health risk, <u>immediately</u> 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.</p>	<p>Malaysia requests to retain the original text in Para 4, Article 10 as it respect the decision and view of the State Party concerned and a delay from State Party to respond does not necessarily imply that member state rejects WHO's offer to collaborate considering that State Party is in crisis mode during an event that may constitute a public health emergency of international concern.</p>
<p><i>Article 11: Provision of information by WHO</i></p> <p>1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as appropriate, to relevant intergovernmental organizations, as soon as possible and by the most efficient means available, in confidence, such public health information which it has received under Articles 5 to 10 inclusive and which is necessary to enable States Parties to respond to a public health risk. WHO should communicate information to other States Parties that might help them in preventing the occurrence of similar incidents.</p>	<p>1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as appropriate, to relevant intergovernmental organizations, as soon as possible and by the most efficient means available, in confidence, such public health information which it has received under Articles 5 to 10 inclusive, <u>or which is available in the public domain</u>, and which is necessary to enable States Parties to respond to a public health risk. WHO should <u>shall</u> communicate information to other States Parties that might help them in preventing the occurrence of similar incidents.</p>	<p>Malaysia agrees to the insertion of new text in Para 1, Article 11.</p>

**Proposal For Targeted Amendments To The International Health Regulations (2005) From USA
(Source: Seventy-Fifth World Health Assembly, Document A75/18, 12 April 2022)**

<p>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:</p> <ul style="list-style-type: none"> (a) the event is determined to constitute a public health emergency of international concern in accordance with Article 12; or (b) information evidencing the international spread of the infection or contamination has been confirmed by WHO in accordance with established epidemiological principles; or (c) there is evidence that: <ul style="list-style-type: none"> (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. 	<p>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, <u>when</u> until such time as:</p> <ul style="list-style-type: none"> (a) the event is determined to constitute a public health emergency of international concern in accordance with Article 12; or (b) information evidencing the international spread of the infection or contamination has been confirmed by WHO in accordance with established epidemiological principles; or (c) there is evidence that: <ul style="list-style-type: none"> (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) <u>WHO determines it is necessary that such information be made available to other States Parties to make informed, timely risk assessments.</u> 	<p>Malaysia agrees to the deletion and insertion of new texts in Para 2, Article 11.</p>
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**Proposal For Targeted Amendments To The International Health Regulations (2005) From USA
(Source: Seventy-Fifth World Health Assembly, Document A75/18, 12 April 2022)**

<p>3. WHO shall consult with the State Party in whose territory the event is occurring as to its intent to make information available under this Article.</p> <p>4. When information received by WHO under paragraph 2 of this Article is made available to States Parties in accordance with these Regulations, WHO may also make it available to the public if other information about the same event has already become publicly available and there is a need for the dissemination of authoritative and independent information.</p>	<p>3. WHO shall inform consult with the State Party in whose territory the event is occurring as to its intent to make information available under this Article</p> <p>4. When information received by WHO under paragraph 2 of this Article is made available to States Parties in accordance with these Regulations, WHO shall may 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.</p> <p><u>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.</u></p>	<p>Malaysia proposes to retain the original text in Para 3, Article 11 as it respect the decision and view of the State Party concerned.</p> <p>Malaysia agrees to the proposed amendments in Para 4, Article 11.</p> <p>New 5: Malaysia disagrees to the proposed text as it may lead to mistreatment of the State Party concerned and disclosure of such information is unnecessary.</p>
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**Proposal For Targeted Amendments To The International Health Regulations (2005) From USA
(Source: Seventy-Fifth World Health Assembly, Document A75/18, 12 April 2022)**

<p><i>Article 12: Determination of a public health emergency of international concern</i></p> <p>2. If the Director-General considers, based on an assessment under these Regulations, that a public health emergency of international concern is occurring, the Director-General shall consult with the State Party in whose territory the event arises regarding this preliminary determination. If the Director-General and the State Party are in agreement regarding this determination, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the "Emergency Committee") on appropriate temporary recommendations.</p> <p>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</p>	<p><i>Article 12: Determination of a public health emergency of international concern, <u>public health emergency of regional concern, or intermediate health alert</u></i></p> <p>2. If the Director-General considers, based on an assessment under these Regulations, that a <u>potential or actual</u> public health emergency of international concern is occurring, the Director-General shall <u>notify all States Parties and seek to consult with the State Party in whose territory the event arises regarding this preliminary determination and may, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the "Emergency Committee")</u>. If the Director-General determines and the State Party are in agreement regarding this determination <u>that the event constitutes a public health emergency of international concern</u>, 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.</p> <p>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.</p>	<p>Malaysia seeks clarification on the determination criteria of public health emergency of regional concern and intermediate health alert, as proposed.</p> <p>Malaysia wishes to retain original text of Para 2 and Para 3, Article 12 as it takes into consideration the decision and view of the State Party concerned.</p>
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**Proposal For Targeted Amendments To The International Health Regulations (2005) From USA
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<p>in accordance with the procedure set forth in Article 49.</p> <p>4. In determining whether an event constitutes a public health emergency of international concern, the Director-General shall consider:</p> <ul style="list-style-type: none"> (a) information provided by the State Party; (b) the decision instrument contained in Annex 2; (c) the advice of the Emergency Committee; (d) scientific principles as well as the available scientific evidence and other relevant information; and (e) an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic. <p>5. If the Director-General, following consultations with the State Party within whose territory the public health emergency of international concern has occurred, considers that a public health emergency of international concern has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49.</p>	<p>4. In determining whether an event constitutes a public health emergency of international concern, the Director-General shall consider:</p> <ul style="list-style-type: none"> (a) Information provided by the State Party, <u>by other States Parties, available in the public domain, or otherwise available under Articles 5-10;</u> (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. <p>5. If the Director-General, following consultations with the <u>Emergency Committee and relevant States Parties</u> within whose territory the public health emergency of international concern has occurred, considers that a public health emergency of international concern has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49.</p> <p><u>New 6. Where an event has not been determined to meet the criteria for a public health emergency of international concern but the Director-General has determined it requires heightened international awareness and a potential international public health response, the Director-</u></p>	<p>Malaysia agrees to the insertion of new text in Para 4, Article 12.</p> <p>Malaysia agrees to the proposed amendments in Para 5, Article 12.</p> <p>Malaysia is agreeable to the proposed New 6 and New 7, Article 12. However, Malaysia seeks clarification on the determination criteria of public health emergency of regional</p>
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	<p><u>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.</u></p> <p><u>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.</u></p>	<p>concern and intermediate health alert, as proposed.</p>
<p><i>Article 13: Public health response</i></p> <p>3. At the request of a State Party, 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.</p>	<p>3. At the request of a State Party, WHO shall <u>offer assistance collaborate to a State Party</u> 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. <u>The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which WHO shall share with other States Parties.</u></p>	<p>Malaysia agrees with the new text proposed in the first part of Para 3, Article 13. However, Malaysia disagrees with subsequent insertion in Para 3, Article 13. "i.e. The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which WHO shall share with other States Parties."</p> <p>Malaysia is in view that WHO should facilitate the coordination</p>

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<p>4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern is occurring, it may offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State Party, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.</p>	<p>4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern is occurring, it <u>shall</u> may offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State Party, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer. <u>The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which WHO shall share with other States Parties. Regarding on-site assessments, in compliance with its national law, a State Party shall make reasonable efforts to facilitate short-term access to relevant sites; in the event of a denial, it shall provide its rationale for the denial of access.</u></p>	<p>and collaboration between States Parties and not act as an enforcement authority over States Parties.</p> <p>Malaysia agrees with the new text proposed in the first part of Para 4, Article 13. However, Malaysia disagrees with subsequent insertion in Para 4, Article 13. “i.e. The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which WHO shall share with other States Parties. Regarding on-site assessments, in compliance with its national law, a State Party shall make reasonable efforts to facilitate short-term access to relevant sites; in the event of a denial, it shall provide its rationale for the denial of access.” Malaysia is in view that WHO should facilitate the coordination and collaboration between States Parties and not act as an enforcement authority over States Parties.</p>
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**Proposal For Targeted Amendments To The International Health Regulations (2005) From USA
(Source: Seventy-Fifth World Health Assembly, Document A75/18, 12 April 2022)**

<p><i>Article 15: Temporary recommendations</i></p> <p>2. Temporary recommendations may include health measures to be implemented by the State Party experiencing the public health emergency of international concern, or by other States Parties, regarding persons, 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.</p>	<p>2. Temporary recommendations may include <u>the deployment of expert teams, as well as</u> 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.</p>	<p>Malaysia is agreeable to the proposed amendments in Para 2, Article 15.</p>
<p><i>Article 18: Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels</i></p> <p>.....</p>	<p><u>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.</u></p> <p><u>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:</u></p>	<p>Malaysia is agreeable to the proposed Para New 3 and New 4, Article 18.</p>

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	<p><u>(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;</u></p> <p><u>(b) Travel restrictions do not unduly prevent the movement of health care workers necessary for public health responses;</u></p> <p><u>(c) Trade restrictions make provision to protect supply chains for the manufacture and transport of essential medical products and supplies; and</u></p> <p><u>(d) The repatriation of travellers is addressed in a timely manner, given evidence-based measures to prevent the spread of diseases.</u></p>	
<p><i>Article 48: Terms of reference and composition</i></p> <p>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</p>	<p>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, <u>as well as Regional Directors from any impacted region.</u> 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</p>	<p>Malaysia is agreeable to the proposed amendments in Para 2, Article 48.</p>

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<p>principles of equitable geographical representation. At least one member of the Emergency Committee should be an expert nominated by a State Party within whose territory the event arises.</p>	<p>particular session and with due regard to the principles of equitable <u>age, gender, and</u> geographical representation, <u>and require training in these Regulations before participation.</u> At least one member <u>Members</u> of the Emergency Committee should <u>include</u> be an <u>at least one</u> expert nominated by a <u>the</u> State Party within whose territory the event arises, <u>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.</u></p>	
<p><i>Article 49: Procedure</i></p> <p>3. The Emergency Committee shall elect its Chairperson and prepare following each meeting a brief summary report of its proceedings and deliberations, including any advice on recommendations.</p> <p>4. The Director-General shall invite the State Party in whose territory the event arises to present its views to the Emergency Committee. To that effect, the Director-General shall notify to it the dates and the agenda of the meeting of the Emergency Committee with as much advance notice as</p>	<p><u>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.</u></p> <p><u>3 ter. The composition of the Emergency Committee and its complete reports shall be shared with Member States.</u></p> <p>4. The Director-General shall invite <u>affected States Parties, including</u> the State Party in whose territory the event arises, <u>to present its</u> their views to the Emergency Committee. To that effect, the Director-General shall notify <u>States Parties of</u> to it the dates and the agenda of the meeting of the Emergency</p>	<p>Malaysia wishes to retain original text of Para 3, Article 49. The proposed text may lead to mistreatment of the expert concerned and disclosure of such information is unnecessary.</p> <p>Malaysia is agreeable to the proposed amendments in Para 4, Article 49.</p>

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<p>necessary. The State Party concerned, however, may not seek a postponement of the meeting of the Emergency Committee for the purpose of presenting its views thereto.</p> <p>.....</p> <p>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 and/or the temporary recommendations, and may make a presentation to that effect to the Emergency Committee.</p>	<p>Committee with as much advance notice as necessary. The State Party <u>in whose territory the event arises</u> concerned, however, may not seek a postponement of the meeting of the Emergency Committee for the purpose of presenting its views thereto.</p> <p>.....</p> <p>7. <u>Affected</u> States Parties in whose territories the event has occurred may propose to the Director-General the termination of a public health emergency of international concern and/or the temporary recommendations, and may make a presentation to that effect to the Emergency Committee.</p>	<p>Malaysia is agreeable to the proposed amendments in Para 7, Article 49.</p>
<p>-</p>	<p><u>New Chapter IV (Article 53 bis-quater): The Compliance Committee</u> <i>53 bis Terms of reference and composition</i></p> <p><u>1. The State Parties shall establish a Compliance Committee that shall be responsible for:</u></p> <p><u>(a) Considering information submitted to it by WHO and States Parties relating to compliance with obligations under these Regulations;</u></p> <p><u>(b) Monitoring, advising on, and/or facilitating assistance on matters relating to compliance with a view to assisting States Parties to comply with obligations under these Regulations;</u></p> <p><u>(c) Promoting compliance by addressing concerns raised by States Parties</u></p>	<p>Malaysia wishes to seek clarification on “New Chapter IV (Article 53 bis-quater): The Compliance Committee”. Nevertheless, there is no mechanism currently to oversee or monitor the implementation or obligations under IHR. Therefore, it is imperative to establish a dedicated platform (i.e. via the proposed committee) consisting of State Parties that can follow through the implementation of IHR provisions - in view of the limited time for deliberation offered by the World Health Assembly.</p>

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	<p><u>regarding implementation of, and compliance with, obligations under these Regulations; and</u></p> <p><u>(d) Submitting an annual report to each Health Assembly describing:</u></p> <p><u>(i) The work of the Compliance Committee during the reporting period;</u></p> <p><u>(ii) The concerns regarding non-compliance during the reporting period; and</u></p> <p><u>(iii) Any conclusions and recommendations of the Committee.</u></p> <p><u>2. The Compliance Committee shall be authorized to:</u></p> <p><u>(a) Request further information on matters under its consideration;</u></p> <p><u>(b) Undertake, with the consent of any State Party concerned, information gathering in the territory of that State Party;</u></p> <p><u>(c) Consider any relevant information submitted to it;</u></p> <p><u>(d) Seek the services of experts and advisers, including representatives of NGOs or members of the public, as appropriate; and</u></p>	
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	<p align="center"><u>(e) Make recommendations to a State Party concerned and/or WHO regarding how the State Party may improve compliance and any recommended technical assistance and financial support.</u></p> <p><u>3. The Members of the Compliance Committee shall be appointed by States Parties from each Region, comprising six government experts from each Region. The Compliance Committee shall be appointed for four-year terms and meet three times per year.</u></p> <p><i>53 ter. Conduct of business</i></p> <p><u>1. The Compliance Committee shall strive to make its recommendations on the basis of consensus.</u></p> <p><u>2. The Compliance Committee may request the Director-General to invite representatives of the United Nations and its specialized agencies and other relevant intergovernmental organizations or nongovernmental organizations in official relations with WHO to designate representatives to attend the Committee sessions, where appropriate to address a specific issue under consideration. Such representatives, with the consent of the Chairperson, make statements on the subjects under discussion.</u></p> <p><i>53 quater Reports</i></p> <p><u>1. For each session, the Compliance Committee shall prepare a report setting forth the Committee's views and advice. This report shall be approved by the Compliance Committee before the end of the session. Its views and advice shall</u></p>	
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	<p><u>not commit WHO, States Parties, or other entities and shall be formulated as advice to the relevant State Party.</u></p> <p><u>2. If the Compliance Committee is not unanimous in its findings, any member shall be entitled to express his or her dissenting professional views in an individual or group report, which shall state the reasons why a divergent opinion is held and shall form part of the Committee's report.</u></p> <p><u>3. The Compliance Committee's report shall be submitted to all States Parties and to the Director-General, who shall submit reports and advice of the Compliance Committee, to the Health Assembly or the Executive Board, as well as any relevant committees, for consideration, as appropriate.</u></p>	
<p><i>Article 59: Entry into force; period for rejection or reservations</i></p> <p>1. The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, these Regulations or an amendment thereto, shall be 18 months from the date of the notification by the Director-General of the adoption of these Regulations or of an amendment to these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.</p>	<p>1. The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, these Regulations or an amendment thereto, shall be 18 months from the date of the notification by the Director-General of the adoption of these Regulations or of an amendment to these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.</p>	<p>Malaysia has no intention to reject or to make reservation to the proposed amendment of Article 59 and the consequent necessary update to Article 55, 61, 62 and 63 of the IHR (2005) set out in documents WHA 75.12 (dated 28 May 2022). Therefore, kindly refer to the abovesaid document.</p>

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(Source: Seventy-Fifth World Health Assembly, Document A75/18, 12 April 2022)**

<p>2. These Regulations shall enter into force 24 months after the date of notification referred to in paragraph 1 of this Article, except for:</p> <ul style="list-style-type: none"> (a) a State that has rejected these Regulations or an amendment thereto in accordance with Article 61; (b) a State that has made a reservation, for which these Regulations shall enter into force as provided in Article 62; (c) a State that becomes a Member of WHO after the date of the notification by the Director- General referred to in paragraph 1 of this Article, and which is not already a party to these Regulations, for which these Regulations shall enter into force as provided in Article 60; and (d) a State not a Member of WHO that accepts these Regulations, for which they shall enter into force in accordance with paragraph 1 of Article 64. 	<p><u>1 bis. The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, an amendment to these Regulations shall be six months from the date of the notification by the Director-General of the adoption of an amendment to these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.</u></p> <p>2. These Regulations shall enter into force 24 months after the date of notification referred to in paragraph 1 of this Article, <u>and amendments to these Regulations shall enter into force six months after the date of notification referred to in paragraph 1bis of this Article,</u> except for:</p> <ul style="list-style-type: none"> (a) a State that has rejected these Regulations or an amendment thereto in accordance with Article 61; (b) a State that has made a reservation, for which these Regulations shall enter into force as provided in Article 62; (c) a State that becomes a Member of WHO after the date of the notification by the Director-General referred to in paragraph 1 of this Article, and which is not already a party to these Regulations, for which these Regulations shall enter into force as provided in Article 60; and (d) a State not a Member of WHO that accepts these Regulations, for which they shall enter into force in accordance with paragraph 1 of Article 64. 	
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(Source: Seventy-Fifth World Health Assembly, Document A75/18, 12 April 2022)**

<p>3. If a State is not able to adjust its domestic legislative and administrative arrangements fully with these Regulations within the period set out in paragraph 2 of this Article, that State shall submit within the period specified in paragraph 1 of this Article a declaration to the Director-General regarding the outstanding adjustments and achieve them no later than 12 months after the entry into force of these Regulations for that State Party.</p>	<p>3. If a State is not able to adjust its domestic legislative and administrative arrangements fully with these Regulations <u>or amendments thereto</u> within the periods set out in paragraph 2 of this Article, <u>as applicable</u>, that State shall submit within the period specified in paragraph 1 of this Article a declaration to the Director-General regarding the outstanding adjustments and achieve them no later than 12 months after the entry into force of these Regulations <u>or the amendments thereto</u> for that State Party.</p>	
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**Proposal For Targeted Amendments To The International Health Regulations (2005)
From Russian Federation
(Source: Ref.:C.L.20.2022, 22 April 2022)**

Present Status/ Text From IHR 2005	Proposed by Member States of the Eurasian Economic Union (Russian Federation)	(Agree/ disagree/ reservation) with rationale
<p><i>Article 4 Responsible authorities</i></p> <p>1. Each State Party shall designate or establish a National IHR Focal Point and the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations.</p> <p>2. National IHR Focal Points shall be accessible at all times for communications with the WHO IHR Contact Points provided for in paragraph 3 of this article. The functions of National IHR Focal Points shall include:</p> <p>(a) Sending to WHO IHR Contact Points, on behalf of the State Party concerned, urgent communications concerning the implementation of these Regulations, in particular under Articles 6 10 12; and</p> <p>(b) disseminating information to, and consolidating input from, relevant sectors of the administration of the State Party concerned, including those responsible for surveillance and reporting, points of entry,</p>	<p>1. Each State Party shall designate or establish <u>an entity with a role of</u> National IHR Focal Point, and the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations.</p> <p><u>NEW (1bis), States Parties shall enact or adapt their legislation to provide National IHR Focal Points with the authority and resources to perform their functions, clearly defining the tasks and functions of the entity with a role of National IHR Focal Point in implementing the obligations under these Regulations.</u></p> <p>2. National IHR Focal Points shall be accessible at all times for communications with the WHO IHR Contact Points provided for in paragraph 3 of this Article. The functions of National IHR Focal Points shall include:</p> <p>(a) Sending to WHO IHR Contact Points, on behalf of the State Party concerned, urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12; and</p> <p>(b) disseminating information to, and consolidating input from, relevant sectors of the administration of the State Party concerned, including those responsible for surveillance and reporting, points of entry,</p>	<p>Malaysia would like to retain the original text in Para 1, Article 4.</p> <p>Besides, Malaysia is agreeable to the proposed paragraph New (1bis), as follows - "States Parties shall may enact or adapt their legislation to provide National IHR Focal Points with the authority and resources to perform their functions, clearly defining the tasks and functions of the entity with a role of National IHR Focal Point in implementing the obligations under these Regulations."</p>

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(Source: Ref.:C.L.20.2022, 22 April 2022)**

<p>public health services, clinics and hospitals and other government departments.</p> <p>3. WHO shall designate IHR Contact Points, which shall be accessible at all times for communications with National IHR Focal Points. WHO IHR Contact Points shall send urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12, to the National IHR Focal Point of the States Parties concerned. WHO IHR Contact Points may be designated by WHO at the headquarters or at the regional level of the Organization.</p> <p>4. States Parties shall provide WHO with contact details of their National IHR Focal Point and WHO shall provide States Parties with contact details of WHO IHR Contact Points. These contact details shall be continuously updated and annually confirmed. WHO shall make available to all States Parties the contact details of National IHR Focal Points it receives pursuant to this Article.</p>	<p>public health services, clinics and hospitals and other government departments.</p> <p>3. WHO shall designate IHR Contact Points, which shall be accessible at all times for communications with National IHR Focal Points. WHO IHR Contact Points shall send urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12, to the National IHR Focal Point of the States Parties concerned. WHO IHR Contact Points may be designated by WHO at the headquarters or at the regional level of the Organization.</p> <p>4. States Parties shall provide WHO with contact details of their National IHR Focal Point and WHO shall provide States Parties with contact details of WHO IHR Contact Points. These contact details shall be continuously updated and annually confirmed. WHO shall make available to all States Parties the contact details of National IHR Focal Points it receives pursuant to this Article.</p>	
<p><i>Article 5: Surveillance</i></p> <p>1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1.</p>	<p>1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1.</p>	

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<p>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.</p> <p>3. WHO shall assist States Parties, upon request, to develop, strengthen and maintain the capacities referred to in paragraph 1 of this Article.</p> <p>4. WHO shall collect information regarding events through its surveillance activities and assess their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Articles 11 and 45 where appropriate.</p>	<p>2. Following the assessment referred to in paragraph 2, Part A of Annex I, 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 fulfill the obligation in paragraph I 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 I of this Article, the State Party that has obtained an extension shall report annually to WHO on progress made towards the full implementation.</p> <p>3. WHO shall assist States Parties, upon request, to develop, strengthen and maintain the capacities referred to in paragraph I of this Article.</p> <p>4. WHO shall collect information regarding events through its surveillance activities and assess, <u>on the basis of risk assessment criteria regularly updated and agreed with States Parties</u>, their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Articles 11 and 45 where appropriate.</p>	<p>Malaysia is agreeable to the proposed text in Para 4, Article 5 – limited to “on the basis of risk assessment criteria regularly updated.”</p>
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<p><i>Article 6 Notification</i></p> <p>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), WHO shall immediately notify the IAEA.</p> <p>2. Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern.</p>	<p>1. Each State Party, <u>within 48 hours after the Focal Point receives information about the event,</u> 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), WHO shall immediately notify the IAEA.</p> <p>2. Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, <u>genome sequencing data, if available.</u> Source and type of risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern.</p>	<p>Malaysia is agreeable to the proposed text in Para 1, Article 6.</p> <p>Malaysia wishes to delete “genome sequencing data”, instead Malaysia wishes to add at the end of Para 2 Article 6 “with regards to the sharing of genetic sequence data it will depend on Member States’ capacity and prevailing national legislation.”</p>
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<p><i>Article 10 Verification</i></p> <p>1. WHO shall request, in accordance with Article 9, verification from a State Party of reports from sources other than notifications or consultations of events which may constitute a public health emergency of international concern allegedly occurring in the State's territory. In such cases, WHO shall inform the State Party concerned regarding the reports it is seeking to verify.</p> <p>2. Pursuant to the foregoing paragraph and to Article 9, each State Party, when requested by WHO, shall verify and provide:</p> <ul style="list-style-type: none"> (a) within 24 hours, an initial reply to, or acknowledgement of, the request from WHO; (b) within 24 hours, available public health information on the status of events referred to in WHO's request; and (c) information to WHO in the context of an assessment under Article 6, including relevant information as described in that Article. <p>3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall offer to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures. Such activities may include collaboration with other standard-setting</p>	<p>1. WHO shall request, in accordance with Article 9, <u>as soon as possible or within a specific time,</u> 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.</p> <p>2. Pursuant to the foregoing paragraph and to Article 9, each State Party, when requested by WHO, shall verify and provide:</p> <ul style="list-style-type: none"> (a) within 24 hours, an initial reply to, or acknowledgement of, the request from WHO; (b) within 24 hours, available public health information on the status of events referred to in WHO's request; and (c) information to WHO in the context of an assessment under Article 6, including relevant information as described in that Article. <p>3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall, <u>as soon as possible or within a specific time,</u> 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.</p>	<p>Malaysia disagrees to the proposed texts of Para 1 and Para 3, Article 10 and would like to propose "within 24 hours of receiving information" instead of "as soon as possible or within a specific time". This is to provide definitive time frame, thus ensuring timely management of PHEIC.</p>
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<p>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.</p> <p>4. If the State Party does not accept the offer of collaboration, WHO may, when justified by the magnitude of the public health risk, 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.</p>	<p>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.</p> <p>4. If the State Party does not accept the offer of collaboration, WHO may, when justified by the magnitude of the public health risk, 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.</p>	
<p><i>Article 12 Determination of a public health emergency of international concern</i></p> <p>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.</p> <p>2. If the Director-General considers, based on an assessment under these Regulations, that a public health emergency of international concern is occurring, the Director-General shall consult with the State Party in whose territory the event arises regarding this preliminary determination. If the Director-General and the State Party are in</p>	<p>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.</p> <p>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 and consult with the State Party in whose territory the event arises regarding this preliminary determination. If the Director-General and the State Party are in</p>	<p>Malaysia is agreeable to the proposed text in Para 2, Article 12.</p>

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<p>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.</p> <p>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.</p> <p>4. In determining whether an event constitutes a public health emergency of international concern, the Director-General shall consider:</p> <ul style="list-style-type: none"> (a) information provided by the State Party; (b) the decision instrument contained in Annex 2; (c) the advice of the Emergency Committee; (d) scientific principles as well as the available scientific evidence and other relevant information; and (e) an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic. <p>5. If the Director-General, following consultations with the State Party within whose territory the public health emergency of international concern has</p>	<p>agreement regarding this determination, the Director-General shall <u>notify all the States Parties</u>, 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.</p> <p>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.</p> <p>4. In determining whether an event constitutes a public health emergency of international concern, the Director-General shall consider:</p> <ul style="list-style-type: none"> (a) information provided by the State Party; (b) the decision instrument contained in Annex 2; (c) the advice of the Emergency Committee; (d) scientific principles as well as the available scientific evidence and other relevant information; and (e) an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic. <p>5. If the Director-General, following consultations with the State Party within whose territory the public health emergency of international concern has</p>	
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<p>occurred, considers that a public health emergency of international concern has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49.</p>	<p>occurred, considers that a public health emergency of international concern has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49.</p> <p><u>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 the States Parties in accordance with the procedure set out in Article 49.</u></p>	<p>Malaysia agrees to para New (6.), Article 12. Malaysia feels that there is a need to determine the criteria of potential PHEIC.</p>
<p><i>Article 18 Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels</i></p> <p>1. Recommendations issued by WHO to States Parties with respect to persons may include the following advice:</p> <ul style="list-style-type: none"> - 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; 	<p>1. Recommendations issued by WHO to States Parties with respect to persons may include the following advice:</p> <ul style="list-style-type: none"> - 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; 	

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<ul style="list-style-type: none"> - 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. <p>2. Recommendations issued by WHO to States Parties with respect to baggage, cargo, containers, conveyances, goods and postal parcels may include the following advice:</p> <ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - 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. <p>2. Recommendations issued by WHO to States Parties with respect to baggage, cargo, containers, conveyances, goods and postal parcels may include the following advice:</p> <ul style="list-style-type: none"> - 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 	
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<p>parcels under controlled conditions if no available treatment or process will otherwise be successful; and</p> <ul style="list-style-type: none"> - refuse departure or entry. 	<p>parcels under controlled conditions if no available treatment or process will otherwise be successful; and</p> <ul style="list-style-type: none"> - refuse departure or entry. <p><u>New(3.) States Parties impose travel and/or goods and cargo restrictions, WHO may recommend that these measures not apply to the movement of health personnel travelling to the State Party(ies) for a public health response and to the transport of medical devices, medical immunobiological products needed for a public health response;</u></p>	<p>Malaysia is agreeable to the addition of Para New (3), Article 18.</p>
<p><i>Article 23 Health measures on arrival and departure</i></p> <p>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:</p> <p>(a) with regard to travellers:</p> <ul style="list-style-type: none"> (i) information concerning the traveller's destination so that the traveller may be contacted; (ii) information concerning the traveller's itinerary to ascertain if there was any travel in or near an affected area or other possible contacts with infection or contamination prior to arrival, as well as review of the traveller's health documents if they are required under these Regulations; and/or 	<p>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:</p> <p>(a) with regard to travellers:</p> <ul style="list-style-type: none"> (i) information concerning the traveller's destination so that the traveller may be contacted; (ii) information concerning the traveller's itinerary to ascertain if there was any travel in or near an affected area or other possible contacts with infection or contamination prior to arrival, as well as review of the traveller's health documents if they are required under these Regulations, including documents 	<p>Malaysia disagrees to the proposed text in Para 1a(ii), Article 23 and wishes to retain original text because the insertion of new text would require amendment to Annexure</p>

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<p>(iii) a non-invasive medical examination which is the least intrusive examination that would achieve the public health objective;</p>	<p><u>containing information on a laboratory test for a pathogen and/or information on vaccination against a disease, including those provided at the request of the State Party in digital/ electronic form; and/or)</u></p> <p>(iii) a non-invasive medical examination which is the least intrusive examination that would achieve the public health objective;</p>	<p>6 and 7 which has not been provided.</p>
<p><i>Article 44 Collaboration and assistance</i></p> <p>1. States Parties shall undertake to collaborate with each other, to the extent possible, in:</p> <p>(a) the detection and assessment of, and response to, events as provided under these Regulations;</p> <p>(b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health capacities required under these Regulations;</p> <p>(c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and</p> <p>(d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations.</p>	<p>1. States Parties shall undertake to collaborate with each other, to the extent possible, in:</p> <p>(a) the detection and assessment of, and response to, events as provided under these Regulations;</p> <p>(b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health capacities required under these Regulations;</p> <p><u>(c) (New) building capacity to identify emerging public health threats, including through laboratory methods and genome sequencing;</u></p> <p>(d) (c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and</p>	<p>Malaysia is agreeable to Para 1(c) New, Article 44.</p>

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	<p><u>(e) (New) collaborating with each other, with WHO, the medical and scientific community, laboratory and surveillance networks, to facilitate the timely, safe, transparent and rapid exchange of specimens and genetic sequence data for pathogens with the potential to cause pandemics and epidemics or other high risk situations, given the relevant national and international laws, regulations, commitments and principles, including, as appropriate, the Convention on Biological Diversity, the Pandemic Influenza Preparedness Framework, and the importance of rapidly securing access to human pathogens for public health preparedness and taking response measures;</u></p> <p><u>(f) (New) strengthening cooperation and establishing mechanisms for upgrading, coordinating and explaining in contiguous territories programs on health issues that are recognized as being of common interest in terms of an appropriate response to health risks and emergencies of international concern;</u></p> <p><u>(g)(New) developing recommendations and guidance on the use of digital technologies to improve and modernize communication for preparedness and response to health emergencies, including to better meet the obligations of these Rules;</u></p> <p><u>(h) (New) in countering the dissemination of false and unreliable information about public health events, preventive and anti-epidemic</u></p>	<p>Malaysia wishes to retain the original text in Para 1 (a,b,c,d) as the area of collaboration is general and States Parties can have the flexibility to implement based on national and regional capacities.</p>
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<p>2. WHO shall collaborate with States Parties, upon request, to the extent possible, in:</p> <p>(a) the evaluation and assessment of their public health capacities in order to facilitate the effective implementation of these Regulations;</p> <p>(b) the provision or facilitation of technical cooperation and logistical support to States Parties; and</p> <p>(c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1.</p>	<p><u>measures and activities in the media, social networks and other ways of disseminating such information</u></p> <p>(i) (d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations.</p> <p>2. WHO shall collaborate with States Parties, upon request, to the extent possible, in:</p> <p>(a) the evaluation and assessment of their public health capacities in order to facilitate the effective implementation of these Regulations;</p> <p>(b) the provision or facilitation of technical cooperation and logistical support to States Parties; and;</p> <p><u>(c)(New) Implementation of the timely, secure and transparent exchange of samples and genetic sequence data of pathogens capable of causing pandemics and epidemics or other high-risk situations, taking into account relevant national and international legal provisions, rules, obligations and principles, including, these Regulations, as appropriate, the Convention on Biological Diversity, and the importance of rapid access to information on human pathogens for public health preparedness and response;</u></p> <p><u>(d) (New) application of digital technologies to improve and upgrading communications for health emergency preparedness and</u></p>	<p>Malaysia wishes to retain the original text in Para 2 (a,b,c,) as the area of collaboration is general and States Parties can have the flexibility to implement based on national and regional capacities.</p>
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	<p><u>response, including through the development of an interoperability mechanism for secure global digital exchange of health information,</u></p> <p><u>(e) (New) countering the dissemination of false and unreliable information about public health events, preventive and anti-epidemic measures and activities in the media, social networks and other ways of disseminating such information;</u></p> <p>(f) (c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex I;</p> <p><u>(g) (New) support to States Parties in enhancing reporting capabilities in accordance with the requirements of these Regulations, including the simplification and harmonization of reporting processes by States Parties;</u></p> <p><u>(h) (New) facilitation of the development of national public health emergency response plans by developing, disseminating and updating policy documents and technical guidance, training materials, data and science to enable response;</u></p> <p><u>(i) (New) strengthening the capacity of Focal Points, including through regular and targeted training events and workshops, consultations;</u></p>	<p>Malaysia agrees with Para 2(i) New, Article 44.</p>
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<p>3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies.</p>	<p><u>(j) (New) ensuring that differences in contexts and priorities among different States Parties, respect for their sovereignty, including health system strengthening, are taken into account when developing recommendations and supporting their implementation by WHO in order to improve pandemic preparedness and effective response for public health emergencies.</u></p> <p>3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies</p>	
<p>ANNEX 1 A. CORE CAPACITY REQUIREMENTS FOR SURVEILLANCE AND RESPONSE</p> <p>6. At the national level <i>Public health response.</i> The capacities:</p> <p>(a) to determine rapidly the control measures required to prevent domestic and international spread;</p> <p>(b) to provide support through specialized staff, laboratory analysis of samples (domestically or through collaborating centres) and logistical assistance (e.g. equipment, supplies and transport);</p>	<p>6. At the national level <i>Public health response.</i> The capacities:</p> <p>(a) to determine rapidly the control measures required to prevent domestic and international spread;</p> <p>(b) to provide support through specialized staff, laboratory analysis of samples, genome sequencing domestically or through collaborating centres) and logistical assistance (e.g. equipment, supplies and transport);</p>	<p>Malaysia agrees to the proposed text in Annex 1, Para 6 Public health response (b).</p>

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Namibia



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Ref: 4/5

The Permanent Mission of the Republic of Namibia to the United Nations Office at Geneva and other International Organisations in Switzerland presents its compliments to the World Health Organization (WHO) and has the honour to submit the following in its national capacity with regards to the IHR (2005) amendment proposals process:

1. The Republic of Namibia places on record its concerns regarding how access and benefit sharing (ABS) measures, including how they would apply to the use of genetic sequence data or digital sequence information (GSD/DSI), will eventually be resolved in these IHR (2005) amendment negotiations, under the Working Group on Strengthening the International Health Regulations 2005 (WGIHR), and in WHO more generally.
2. In this regard, Namibia notes the on-going discussions under the Convention on Biological Diversity (CBD) that are highly relevant to this matter, with a decision expected at CBD COP 15 in December 2022.
3. Namibia, therefore, reserves its right to introduce additional proposals on ABS and GSD/DSI at a later stage, if needed. Namibia is of the view that nothing is agreed until everything is agreed.

The Permanent Mission of the Republic of Namibia to the United Nations Office at Geneva and other International Organisations in Switzerland avails itself of this opportunity to renew to the World Health Organization (WHO), the assurance of its highest consideration.

World Health Organization (WHO)
GENEVA

All official correspondence must be addressed to the Head of Mission.



New Zealand

New Zealand Submission to the World Health Organization Working Group on Amendments to the International Health Regulations (2005)

In response to the decision WHA75(9) on Strengthening WHO preparedness for and response to health emergencies, New Zealand welcomes the opportunity to submit our views on proposed amendments to the International Health Regulations (2005) (IHR) for the consideration of WHO Director-General Dr Tedros Ghebreyesus.

New Zealand views the establishment of a dedicated Member State-led process to consider amendments to the IHR (Working Group on Amendments to the International Health Regulations – WGIHR) as a critical development in our collective efforts to strengthen the global health architecture for pandemic prevention, preparedness and response (PPPR). We note, in particular, the importance of the WGIHR's work progressing in parallel with the negotiations of the Intergovernmental Negotiating Body (INB) towards a treaty or instrument on PPPR, to ensure Member States deliver a coherent and complementary global health system for future generations.

Strengthening the International Health Regulations (2005)

The IHR is a cornerstone of the international system for PPPR, providing a framework for shared surveillance, risk assessment, priority setting and coordinated responses to health emergencies. When considering amendments to the IHR, New Zealand will prioritise those that further enhance the early detection, assessment and reporting of potentially significant events, building on the lessons learned of the COVID-19 pandemic.

Draft amendments to the IHR proposed by the United States – January 2022

New Zealand recalls C.L.2.2022 (20 January 2022) in which Director-General Tedros Ghebreyesus transmitted proposed amendments to the IHR received from the United States of America (US). WHA75 saw Member States reach agreement on the US-proposed amendment to Article 59; New Zealand believes that a number of the other amendments proposed by the United States are now suitable for the IHR Expert Review Committee and Member States' consideration.

These include amendments relating to **notification, risk assessment and communication mechanisms** between Member States and the Secretariat. As a package, amendments in these areas represent credible improvements to support all Member States and the WHO in its implementation of the IHRs. In New Zealand's view, these amendments would strengthen the effectiveness of the legal framework as well as the Organization's ability to respond to risks.

We attach C.L.2.2022, in which the following amendments are detailed fully, and provide a high-level outline for the Secretariat's reference below.

Article(s)	New Zealand Commentary
NEW Article 5.5 – Explicit requirement for risk assessment and alerting for events of unknown origins	New Zealand considers that the inclusion of a new Article 5.5 will serve to improve risk assessment and alert processes.
Article 6.1 – (i) State party responsibility to assess events happening in its territory within 48 hours of an IHR National Focal Point notification, and (ii) promoting relevant interagency coordination in the context of such a notification.	These amendments to Articles 6.1 and 6.2 promote sensible interagency coordination and seek to strengthen communication between WHO Member States and the Secretariat in the event of a PHEIC.
Article 6.2 – (i) State party responsibility to communicate with WHO by most efficient means possible, and (ii) adding “genetic sequence data” to the list of information provided as part of a notification of an event that may constitute a PHEIC.	New Zealand agrees that genetic sequence data is sufficiently important to be specified in its own right as crucial information sharing within the notification phase (though we suggest it should be listed after “laboratory results”, rather than being the first item itemised after “including...”). We also maintain that specific timeframes for verification requests of State Parties and WHO offers of collaboration will effectively streamline the WHO’s process for assessing the extent of the event in question.
Article 10.1 – inclusion of a timeframe for the WHO request for verification from a State Party.	These three amendments to Article 10 will clarify timeframes for WHO to request verification and make offers of collaboration.
Article 10.2(c) – Inclusion of reference to Article 6 paras 1-2.	
Article 10.3 – WHO offer of collaboration to be made within 24 hours of notification.	
Article 11.1 – Inclusion of information ‘available in public domain’ and the use of ‘shall’.	New Zealand considers that these amendments to Article 11 will strengthen the WHO’s role in the issuance of information critical to Member States’ decision making at the national and regional levels in the event of a PHEIC.
NEW Article 11.2 (e) – WHO issuance of information to other Member States for risk assessment purposes.	
Article 11.3 – Replacing ‘consult’ with ‘inform’.	

<p>Article 12.6 – For events that fall short of a PHEIC, WHO Director-General can issue ‘global alerts’.</p>	<p>New Zealand agrees that the ability of the Director-General to issue early alerts to Member States for events which fall short of a PHEIC may be a useful addition. We would propose minor adjustments to this amendment, including in line with recommendations from the 2020 IHR Review Committee:</p> <ul style="list-style-type: none"> • Line 3 - we would delete "a potential international public health response" and replace it with "preparedness activity". • Line 4 - we would delete "a intermediate public health alert" and replace it with "a World Alert and Response Notice" (as recommended by the IHR RC). • Line 5 - we would delete "consult" and replace with "seek advice from".
<p>NEW Article 49.3 bis – Expression and reporting of divergent views of IHR Emergency Committee Members.</p>	<p>These new additions to Article 49 will enable further transparency around the IHR Emergency Committee’s processes and reporting for the WHO Secretariat and Member States alike.</p>
<p>NEW Article 49.3 ter – Composition of Emergency Committee to be shared with Member States.</p>	

As always, New Zealand stands ready to assist the WGIHR Bureau, IHR Expert Review Committee and the WHO Secretariat to progress negotiations of amendments.

We look forward to collaborating with our fellow Member States within the WGIHR in due course, and to engaging on the pending report of the IHR Expert Review Committee at the 152nd Executive Board meeting in January 2023.



Ref.: C.L.2.2022

Proposal for amendments to the International Health Regulations (2005)

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

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

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

GENEVA, 20 January 2022

... ENCLS.: (2)



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

No. 4-22

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

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

Enclosed:

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

Geneva, 18 January 2022

World Health Organization



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

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

Article 5: Surveillance

1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1. **This capacity will be periodically reviewed through the Universal Health Periodic Review mechanism. Should such review identify resource constraints and other challenges in attaining these capacities, WHO and its Regional Offices shall, upon the request of a State Party, provide or facilitate technical support and assist in mobilization of financial resources to develop, strengthen and maintain such capacities.**

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

Article 6: Notification

1. Each State Party shall assess events occurring within its territory by using the decision instrument in Annex 2 **within 48 hours of the National IHR Focal Point receiving the relevant information.** Each State Party shall notify WHO, by the most efficient means of communication available, by way of the National IHR Focal Point, and within 24 hours of assessment of public health information, of all events which may constitute a public health emergency of international concern within its territory in accordance with the decision instrument, as well as any health measure implemented in response to those events. If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA), **the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (OIE), the UN Environment Programme (UNEP) or other relevant entities,** WHO shall immediately notify the ~~IAEA~~ **relevant entities.**

2. Following a notification, a State Party shall continue to communicate to **WHO, by the most efficient means of communication available,** timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including **genetic sequence data,** case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern.

Article 9: Other reports

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

Article 10: Verification

1. **Within 24 hours of receiving information,** WHO shall request, ~~in accordance with Article 9,~~ verification from a State Party of reports from sources other than notifications or consultations of events which may constitute a public health emergency of international concern allegedly occurring in the State's territory. In such cases, WHO shall inform the State Party concerned regarding the reports it is seeking to verify.
2. Pursuant to the foregoing paragraph ~~and to Article 9,~~ each State Party, when requested by WHO, shall verify and provide:
 - (a) within 24 hours, an initial reply to, or acknowledgement of, the request from WHO;
 - (b) within 24 hours, available public health information on the status of events referred to in WHO's request; and
 - (c) information to WHO in the context of an assessment under Article 6, including relevant information as described in **paragraphs 1 and 2 of** that Article.
3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall offer **within 24 hours** to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures. Such activities may include collaboration with other standard-setting organizations and the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments.

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

4. If the State Party does not accept the offer of collaboration **within 48 hours,** WHO ~~shall~~ **may,** when justified by the magnitude of the public health risk, **immediately** share with other States Parties the information available to it, whilst encouraging the State Party to accept the offer of collaboration by WHO, ~~taking into account the views of the State Party concerned.~~

Article 11: Provision of information by WHO

1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as appropriate, to relevant intergovernmental organizations, as soon as possible and by the most efficient means available, in confidence, such public health information which it has received under Articles 5 to 10 inclusive, **or which is available in the public domain,** and which is necessary to enable States Parties to respond to a public health risk. WHO **shall** communicate information to other States Parties that might help them in preventing the occurrence of similar incidents.
2. WHO shall use information received under Articles 6, ~~and 8 and paragraph 2 of Article 9~~ for verification, assessment and assistance purposes under these Regulations and, unless otherwise agreed with the States Parties referred to in those provisions, shall ~~not~~ **when until such time as:**
 - (a) the event is determined to constitute a public health emergency of international concern in accordance with Article 12; or
 - (b) information evidencing the international spread of the infection or contamination has been confirmed by WHO in accordance with established epidemiological principles; or
 - (c) there is evidence that:

(i) control measures against the international spread are unlikely to succeed because of the nature of the contamination, disease agent, vector or reservoir; or

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

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

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

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

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

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

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

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

2. If the Director-General considers, based on an assessment under these Regulations, that a **potential or actual** public health emergency of international concern is occurring, the Director-General shall **notify all States Parties and seek to** consult with the State Party in whose territory the event arises regarding this preliminary determination **and may, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the “Emergency Committee”)**. If the Director-General determines ~~and the State Party are in agreement regarding this determination~~ **that the event constitutes a public health emergency of international concern**, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the ~~Committee established under Article 48 (hereinafter the “Emergency Committee”)~~ on appropriate temporary recommendations.

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

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

(a) Information provided by the State Party, **by other States Parties, available in the public domain, or otherwise available under Articles 5-10;**

(b) The decision instrument contained in Annex 2;

(c) The advice of the Emergency Committee;

- (d) Scientific principles as well as available scientific evidence and other relevant information; and
- (e) An assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic.

5. If the Director-General, following consultations with the **Emergency Committee and relevant States Parties** ~~within whose territory the public health emergency of international concern has occurred~~, considers that a public health emergency of international concern has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49.

New 6. Where an event has not been determined to meet the criteria for a public health emergency of international concern but the Director-General has determined it requires heightened international awareness and a potential international public health response, the Director-General, on the basis of information received, may determine at any time to issue an intermediate public health alert to States Parties and may consult the Emergency Committee in a manner consistent with the procedure set out in Article 49.

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

Article 13: Public health response

3. ~~At the request of a State Party, WHO shall~~ **offer assistance** ~~collaborate to a State Party~~ in the response to public health risks and other events by providing technical guidance and assistance and by assessing the effectiveness of the control measures in place, including the mobilization of international teams of experts for on-site assistance, when necessary. **The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which WHO shall share with other States Parties.**

4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern is occurring, it ~~shall~~ **may** offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State Party, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer. **The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which WHO shall share with other States Parties. Regarding on-site assessments, in compliance with its national law, a State Party shall make reasonable efforts to facilitate short-term access to relevant sites; in the event of a denial, it shall provide its rationale for the denial of access.**

Article 15: Temporary recommendations

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

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

New 3. In developing temporary recommendations, the Director-General shall consult with relevant international agencies such as ICAO, IMO and WTO in order to avoid unnecessary interference with international travel and trade, as appropriate. Additionally, temporary recommendations should allow

for the appropriate exemption of essential health care workers and essential medical products and supplies from travel and trade restrictions.

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

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

Article 48: Terms of reference and composition

2. The Emergency Committee shall be composed of experts selected by the Director-General from the IHR Expert Roster and, when appropriate, other expert advisory panels of the Organization, **as well as Regional Directors from any impacted region.** The Director-General shall determine the duration of membership with a view to ensuring its continuity in the consideration of a specific event and its consequences. The Director-General shall select the members of the Emergency Committee on the basis of the expertise and experience required for any particular session and with due regard to the principles of equitable **age, gender, and** geographical representation, **and require training in these Regulations before participation.** ~~At least one member~~ **Members** of the Emergency Committee should ~~include~~ **be an at least one** expert nominated by ~~a~~ **the** State Party within whose territory the event arises, **as well as experts nominated by other affected States Parties.** **For the purposes of Articles 48 and 49, an “affected State Party” refers to a State Party either geographically proximate or otherwise impacted by the event in question.**

Article 49: Procedure

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

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

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

...

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

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

1. The State Parties shall establish a Compliance Committee that shall be responsible for:
 - (a) Considering information submitted to it by WHO and States Parties relating to compliance with obligations under these Regulations;
 - (b) Monitoring, advising on, and/or facilitating assistance on matters relating to compliance with a view to assisting States Parties to comply with obligations under these Regulations;
 - (c) Promoting compliance by addressing concerns raised by States Parties regarding implementation of, and compliance with, obligations under these Regulations; and
 - (d) Submitting an annual report to each Health Assembly describing:
 - (i) The work of the Compliance Committee during the reporting period;
 - (ii) The concerns regarding non-compliance during the reporting period; and
 - (iii) Any conclusions and recommendations of the Committee.
2. The Compliance Committee shall be authorized to:
 - (a) Request further information on matters under its consideration;
 - (b) Undertake, with the consent of any State Party concerned, information gathering in the territory of that State Party;
 - (c) Consider any relevant information submitted to it;
 - (d) Seek the services of experts and advisers, including representatives of NGOs or members of the public, as appropriate; and
 - (e) Make recommendations to a State Party concerned and/or WHO regarding how the State Party may improve compliance and any recommended technical assistance and financial support.
3. The Members of the Compliance Committee shall be appointed by States Parties from each Region, comprising six government experts from each Region. The Compliance Committee shall be appointed for four-year terms and meet three times per year.

53 ter. Conduct of business

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

53 quater Reports

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

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

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

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

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

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

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

(a) a State that has rejected these Regulations or an amendment thereto in accordance with Article 61;

(b) a State that has made a reservation, for which these Regulations shall enter into force as provided in Article 62;

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

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

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

Republic of Korea

The Republic of Korea (“ROK”) welcomes constructive discussions and achievements for the resolution of the amendments to Article 59 of the IHR and its relevant paragraphs at the 75th World Health Assembly (WHA) held in May. However, to be better prepared for and respond to future pandemics, there is a need to amend not only Article 59 but also several Articles of the IHR. In particular, given that the ongoing discussion on the amendments to the IHR has progressed with the aim of the revised IHR being adopted at the 77th WHA in the same way as WHO CAII, the ROK wishes to reiterate that the two discussions need to be linked. In addition, we also emphasize that in consideration of the possibility of duplication or conflict between WHO CAII and the IHR, the relationship between them needs to be clearly defined. Along with that, the ROK presents the following suggestions.

Relationship between Universal Health and Preparedness Review (UHPR) and Joint External Evaluation (JEE)

The JEE has been conducted since 2016 following the amendment of the IHR in 2005. As the UHPR, which is even included in WHO CAII, is thought to be able to address the objective of the JEE of strengthening the implementation of the IHR, the ROK proposes that the UHPR replace the JEE in such a way that the two mechanisms are well integrated by fully reflecting the JEE into the UHPR, with the aim of alleviating the burden of the evaluation taken on WHO Member States and to avoid any duplication. In addition, incentives for support for capacity-building need to be provided to WHO Member States to help them to effectively participate in the UHPR and implement related policies smoothly.

Declaration of an intermediate health alert and a public health emergency of regional concern

In the early stage of emerging infectious disease outbreaks, including COVID-19 and Monkeypox, there is unclear or insufficient information available to determine whether an event constitutes a public health emergency of international concern (PHEIC). In that regard, the ROK proposes creating a system that declares an intermediate health alert and/or allows a Regional Director *to* declare a public health emergency of regional concern. To this end, the capacities of a Regional Office need to be strengthened so that the Office is able to provide advice, technical assistance and support for capacity-building to Member States in the region after a public health emergency of regional concern *is* declared.

Equity of access to resources and benefit-sharing

The ROK re-confirms that equitable access to resources is a foundation for preparedness

for future pandemics as being discussed in WHO CAII. Moreover, we strongly support the sharing of genetic information as we recognize the information as an essential factor to identify sequence variants and develop test kits. However, there is a need to review whether the sharing of such information is in accordance with the Nagoya Protocol currently stated in the WHO CAII draft. In addition, we emphasize that a benefit-sharing system for genetic information-sharing needs to be established.

Regulation on protection of human rights

The current IHR stipulates that health information which refers to personal data must be kept confidential and processed anonymously as required by relevant national law in its Article 45 as digital-based anti-epidemic policies have proven effective. In the context of epidemiological investigations using digital technologies, a review of ways to add a new regulation for protection of human rights and formulate guidance on collection of personal data needs to be conducted. Article 45 (Treatment of personal data) also needs to be supplemented, and applying the Siracusa Principles adopted in 1984 may be considered.

Proposal for targeted amendments to the International Health Regulations(IHR)(2005)

* Explanation of changes: The proposed new text is shown in bold.

Article 5 Surveillance

1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1. **This capacity will be periodically reviewed through the Universal Health Periodic Review mechanism in replacement of the Joint External Evaluation that began in 2016. Such review shall identify resource constraints and other challenges in attaining these capacities,** and WHO and its Regional Offices shall, upon the request of a State Party, provide or facilitate technical support and assist in mobilization of financial resources to develop, strengthen and maintain such capacities.

Article 12

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

New 6. Where an event has not been determined to meet the criteria for a public health emergency of international concern but the Director-General has determined it requires heightened international awareness and a potential international public health response, the Director-General, on the basis of information received, may determine at any time to issue an intermediate public health alert to States Parties and may consult the Emergency Committee in a manner consistent with the procedure set out in Article 49.

New 7. A Regional Director may determine that an event constitutes a public health emergency of regional concern 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. / END/

Russian Federation
on behalf of the Member States
of the Eurasian Economic Union (EAEU)



ПОСТОЯННОЕ ПРЕДСТАВИТЕЛЬСТВО
РОССИЙСКОЙ ФЕДЕРАЦИИ
ПРИ ОТДЕЛЕНИИ ООН И ДРУГИХ
МЕЖДУНАРОДНЫХ ОРГАНИЗАЦИЯХ
В ЖЕНЕВЕ

PERMANENT MISSION
OF THE RUSSIAN FEDERATION
TO THE UNITED NATIONS OFFICE AND
OTHER INTERNATIONAL ORGANIZATIONS
IN GENEVA

№ 4128

The Permanent Mission of the Russian Federation to the United Nations Office and other International Organizations in Geneva presents its compliments to the World Health Organization (WHO) and, referring to the Article 55(1) of the International Health Regulations (IHR) (2005) and to the decision WHA75(9) «Strengthening WHO preparedness for and response to health emergencies» of the 75th World Health Assembly, that invites Member-States to submit proposed amendments to IHR by 30 September 2022, has the honor to submit on behalf of the Eurasian Economic Union (EAEU) Member-States the text of the IHR amendments approved by the Council of Heads of Authorized Bodies in the Field of Sanitary and Epidemiological Welfare of the Population of the EAEU Countries.

The Permanent Mission respectfully requests the Director General of the WHO to communicate the amendments to all State Parties and initiate, as appropriate, consultations on a consolidated package of the amendments of all Member-States to the IHR (2005).

The Permanent Mission of the Russian Federation avails itself of this opportunity to renew to the World Health Organization the assurances of its highest consideration.

GA
Annex: 8 pp.

[Signature]
Geneva, « 30 » September 2022

WORLD HEALTH ORGANIZATION

Geneva





ЕВРАЗИЙСКАЯ ЭКОНОМИЧЕСКАЯ КОМИССИЯ

Выписка из Протокола

двадцать девятого заседания Совета руководителей уполномоченных органов в области санитарно-эпидемиологического благополучия населения государств – членов Евразийского экономического союза

28 февраля 2022 г.

г. Москва

ПРЕДСЕДАТЕЛЬСТВОВАЛ: Председатель Совета руководителей уполномоченных органов в области санитарно-эпидемиологического благополучия населения государств – членов Евразийского экономического союза (далее – Совет руководителей) Анна Юрьевна Попова.

ПРИСУТСТВОВАЛИ: представители уполномоченных органов государств-членов Евразийского экономического союза в области санитарно-эпидемиологического благополучия населения (далее – уполномоченные органы, государства-члены, Союз), представители Евразийской экономической комиссии (далее – Комиссия) (список прилагается).

2. О совместной работе государств-членов Евразийского экономического союза на площадке Всемирной организации здравоохранения

2.1. Принять к сведению информацию заместителя руководителя Федеральной службы по надзору в сфере защиты прав потребителей и благополучия человека В.Ю. Смоленского о том, что:

во исполнение договоренностей, достигнутых в ходе заседания Совета руководителей 17 января 2022 г., Роспотребнадзором был подготовлен и направлен в уполномоченные органы проект изменений в Международные медико-санитарные правила (2005 год) (далее – ММСП), получены комментарии Республики Армения, Республики Беларусь, Республики Казахстан, в соответствии с которыми проект предложений по изменению в ММСП доработан;

21-23 февраля текущего года состоялось 7-е заседание Рабочей группы Всемирной организации здравоохранения (далее – ВОЗ) по усилению готовности к чрезвычайным ситуациям в области здравоохранения и реагированию на них, в ходе которого странами-членами особое внимание уделено рекомендациям, связанным с изменением или дополнением ММСП (2005 г.);

Российской Федерацией анонсировано представление проекта точечных изменений в ММСП (2005 г.), который будет внесен от государств-членов Союза;

все предложенные членами ВОЗ по изменению в ММСП планируется рассматривать пакетным принципом в рамках подготовки к 75-ой сессии Всемирной ассамблеи здравоохранения (далее – ВА3), проведение которой планируется в конце мая 2022 г.

2.2. По итогам обсуждения Советом руководителей принято решение:

одобрить разработанный Роспотребнадзором с учетом мнения стран-членов ЕАЭС проект предложений по внесению точечных изменений в Международные медико-санитарные правила (2005 г.);

просить Роспотребнадзор направить в ВОЗ совместную позицию государств-членов ЕАЭС по внесению точечных изменений в ММСП (2005 г.).

**Председатель Совета руководителей
уполномоченных органов в области
санитарно-эпидемиологического
благополучия населения
государств – членов Евразийского
экономического союза**



А.Ю. Попова

Joint proposal by the member States of the Eurasian Economic Union for point amendments
to the International Health Regulations (2005):
Articles 4, 5, 6, 10, 12, 18, 23, 44 and Annex 1

Article 4 Responsible authorities

1. Each State Party shall designate or establish an entity with a role of National IHR Focal Point, and the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations).

NEW (Ibis). States Parties shall enact or adapt their legislation to provide National IHR Focal Points with the authority and resources to perform their functions, clearly defining the tasks and functions of the entity with a role of National IHR Focal Point in implementing the obligations under these Regulations.

2. National IHR Focal Points shall be accessible at all times for communications with the WHO IHR Contact Points provided for in paragraph 3 of this Article. The functions of National IHR Focal Points shall include:
 - (a) sending to WHO IHR Contact Points, on behalf of the State Party concerned, urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12; and
 - (b) disseminating information to, and consolidating input from, relevant sectors of the administration of the State Party concerned, including those responsible for surveillance and reporting, points of entry, public health services, clinics and hospitals and other government departments.
3. WHO shall designate IHR Contact Points, which shall be accessible at all times for communications with National IHR Focal Points. WHO IHR Contact Points shall send urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12, to the National IHR Focal Point of the States Parties concerned. WHO IHR Contact Points may be designated by WHO at the headquarters or at the regional level of the Organization.
4. States Parties shall provide WHO with contact details of their National IHR Focal Point and WHO shall provide States Parties with contact details of WHO IHR Contact Points. These contact details shall be continuously updated and annually confirmed. WHO shall make available to all States Parties the contact details of National IHR Focal Points it receives pursuant to this Article.

Article 5 Surveillance

1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1.
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 capacities referred to in paragraph 1 of this Article.
4. WHO shall collect information regarding events through its surveillance activities and assess, on the basis of risk assessment criteria regularly updated and agreed with States Parties, their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Articles 11 and 45 where appropriate.

Article 6 Notification

1. Each State Party, within 48 hours after the Focal Point receives information about the event, 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), WHO shall immediately notify the IAEA.
2. Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, genome sequencing data, if available, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern.).

Article 10 Verification

1. WHO shall request, in accordance with Article 9, as soon as possible or within a specific time, verification from a State Party of reports from sources other than notifications or consultations of events which may constitute a public health emergency of international concern allegedly occurring in the State's territory. In such cases, WHO shall inform the State Party concerned regarding the reports it is seeking to verify.
2. Pursuant to the foregoing paragraph and to Article 9, each State Party, when requested by WHO, shall verify and provide:
 - (a) within 24 hours, an initial reply to, or acknowledgement of, the request from WHO;

- (b) within 24 hours, available public health information on the status of events referred to in WHO's request; and
 - (c) information to WHO in the context of an assessment under Article 6, including relevant information as described in that Article.
3. When WHO receives 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**, 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, when justified by the magnitude of the public health risk, share with other States Parties the information available to it, whilst encouraging the State Party to accept the offer of collaboration by WHO, taking into account the views of the State Party concerned.

Article 12 Determination of a public health emergency of international concern

1. The Director-General shall determine, on the basis of the information received, in particular from the State Party within whose territory an event is occurring, whether an event constitutes a public health emergency of international concern in accordance with the criteria and the procedure set out in these Regulations.
2. If the Director-General considers, based on an assessment under these Regulations, that a public health emergency of international concern is occurring, the Director-General shall and consult with the State Party in whose territory the event arises regarding this preliminary determination. If the Director-General and the State Party are in agreement regarding this determination, the Director-General shall **notify all the States Parties**, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the "Emergency Committee") on appropriate temporary recommendations.
3. If, following the consultation in paragraph 2 above, the Director-General and the State Party in whose territory the event arises do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern, a determination shall be made in accordance with the procedure set forth in Article 49.

...

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 the States Parties in accordance with the procedure set out in Article 49

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.

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

Article 23 Health measures on arrival and departure

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

(a) with regard to travellers:

- (i) information concerning the traveller's destination so that the traveller may be contacted;
- (ii) information concerning the traveller's itinerary to ascertain if there was any travel in or near an affected area or other possible contacts with infection or contamination prior to arrival, as well as review of the traveller's health documents if they are required under these Regulations, **including documents containing information on a laboratory test for a pathogen and / or information on vaccination against a disease, including those provided at the request of the State Party in digital / electronic form; and/or**
- (iii) a non-invasive medical examination which is the least intrusive examination that would achieve the public health objective;

Article 44 Collaboration and assistance

1. States Parties shall undertake to collaborate with each other, to the extent possible, in:

- (a) the detection and assessment of, and response to, events as provided under these Regulations;
- (b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health capacities required under these Regulations;
- (c) **(New) building capacity to identify emerging public health threats, including through laboratory methods and genome sequencing;**
- (d) (c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and
- (e) **(New) collaborating with each other, with WHO, the medical and scientific community, laboratory and surveillance networks, to facilitate the timely, safe, transparent and rapid exchange of specimens and genetic sequence data for pathogens with the potential to cause pandemics and epidemics or other high-risk situations, given the relevant national and international laws, regulations, commitments and principles, including, as appropriate, the Convention on Biological Diversity, the Pandemic Influenza Preparedness Framework, and the importance of rapidly securing access to human pathogens for public health preparedness and taking response measures;**
- (f) **(New) strengthening cooperation and establishing mechanisms for upgrading, coordinating and explaining in contiguous territories programs on health issues**

that are recognized as being of common interest in terms of an appropriate response to health risks and emergencies of international concern;

(g) (New) developing recommendations and guidance on the use of digital technologies to improve and modernize communication for preparedness and response to health emergencies, including to better meet the obligations of these Rules;

(h) (New) in countering the dissemination of false and unreliable information about public health events, preventive and anti-epidemic measures and activities in the media, social networks and other ways of disseminating such information

(i) (d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations,

1. WHO shall collaborate with States Parties, upon request, to the extent possible, in:

(a) the evaluation and assessment of their public health capacities in order to facilitate the effective implementation of these Regulations;

(b) the provision or facilitation of technical cooperation and logistical support to States Parties; and;

(c) (New) implementation of the timely, secure and transparent exchange of samples and genetic sequence data of pathogens capable of causing pandemics and epidemics or other high-risk situations, taking into account relevant national and international legal provisions, rules, obligations and principles, including , these Regulations, as appropriate, the Convention on Biological Diversity, and the importance of rapid access to information on human pathogens for public health preparedness and response;

(d) (New) application of digital technologies to improve and upgrading communications for health emergency preparedness and response, including through the development of an interoperability mechanism for secure global digital exchange of health information,

(e) (New) countering the dissemination of false and unreliable information about public health events, preventive and anti-epidemic measures and activities in the media, social networks and other ways of disseminating such information;

(f) (c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1;

(g) (New) support to States Parties in enhancing reporting capabilities in accordance with the requirements of these Regulations, including the simplification and harmonization of reporting processes by States Parties;

(h) (New) facilitation of the development of national public health emergency response plans by developing, disseminating and updating policy documents and technical guidance, training materials, data and science to enable response;

(i) (New) strengthening the capacity of Focal Points, including through regular and targeted training events and workshops, consultations;

(j) (New) ensuring that differences in contexts and priorities among different States Parties, respect for their sovereignty, including health system strengthening, are taken into account when developing recommendations and supporting their implementation by WHO in order to improve pandemic preparedness and effective response for public health emergencies.

3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies.

ANNEX 1

A. CORE CAPACITY REQUIREMENTS FOR SURVEILLANCE AND RESPONSE

...

6. At the national level

...

Public health response. The capacities:

- (a) to determine rapidly the control measures required to prevent domestic and international spread;
- (b) to provide support through specialized staff, laboratory analysis of samples, **genome sequencing** (domestically or through collaborating centres) and logistical assistance (e.g. equipment, supplies and transport);

Switzerland



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

**Mission permanente de la Suisse auprès de l'Office des Nations
Unies et des autres organisations internationales à Genève**

Réf. : 852-05-05-02 MOS/AEE

The Permanent Mission of Switzerland to the United Nations Office and other International Organizations in Geneva presents its compliments to the World Health Organization (WHO) and has the honor to refer to the International Health Regulations (IHR) (2005).

In accordance with the decision WHA75(9) of 27 May 2022 and referring to the Article 55(1) of the IHR (2005), Switzerland is proposing amendments to the IHR (2005). The Mission, by means of this note, has the honor to submit the proposal and respectfully requests the Director-General of the WHO to communicate the proposed amendments to all States Parties in accordance with Article 55(2) of the IHR (2005).

The Permanent Mission of Switzerland to the United Nations Office and other International Organizations in Geneva avails itself of this opportunity to renew to the World Health Organization (WHO) the assurances of its highest consideration. *L.A*

Geneva, 26 September 2022



World Health Organizations (WHO)
Health Regulations (IHR)

GENEVA



Submission by Switzerland

Proposal for targeted amendments to the International Health Regulations (2005)

I. Amendments to Article 4 (National IHR Competent Authority)

Article 4 Responsible authorities :

“1. Each State Party shall designate or establish a National IHR Focal Point and the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations.

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.¹

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

(a) sending to WHO IHR Contact Points, on behalf of the State Party concerned, urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12; and

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

3. WHO shall designate IHR Contact Points, which shall be accessible at all times for communications with National IHR Focal Points. WHO IHR Contact Points shall send urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12, to the National IHR Focal Point of the States Parties concerned. WHO IHR Contact Points may be designated by WHO at the headquarters or at the regional level of the Organization.

4. States Parties shall provide WHO with contact details of their National IHR Focal Point and **National IHR Competent Authority** 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.”

¹ see recommendation (1) at page 53 of the Review Committee on Covid-19 report (<https://www.who.int/publications/m/item/a74-9-who-s-work-in-health-emergencies>)

Rationale:

The lack of compliance with certain obligations under the IHR and the issue of national responsible authority has been discussed extensively by the IHR Review Committee on COVID-19, and the committee made several recommendations on that in the context of improved compliance and accountability. Among others, it was recommended that the responsibility for implementing the IHR needs to be elevated to the highest level of government [page 10, key message (2)]. Although Article 4 already has the provision for State Parties to establish this authority, this has never been implemented. The full rationale and discussion about this are on pp. 52-54, section 3.10, of the Review Committee report. The above-proposed amendment takes up from recommendation (1) on page 53 of the report of the Review Committee. In our view, it is not a matter of creating a new entity, but of ensuring that the designated national competent authority can assume political responsibility in addition to the technical responsibility of the IHR focal point.

N.B. The amendments II, III and IV proposed below take up or are based on some recommendations elaborated during a technical consultation on the implementation of the IHR 2005 (Emergency Committees and Public Health Emergencies of International Concern) which was held in Geneva on 7 and 8 November 2019².

II. Amendment to Article 12.5 IHR (standing recommendations by the IHR Review Committee)

Article 12.5 IHR:

“If the Director-General, following consultations with the **Emergency Committee and relevant States Parties** ~~within whose territory the public health emergency of international concern has occurred~~ **[amendments as proposed by the U.S., also supported by Switzerland]**, 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.**”

Rationale:

This recommendation originates from the above-mentioned technical consultation on the

² The final meeting report of that consultation was e-mailed to the attending experts but was not published. It remains an internal document of the WHO IHR Secretariat and is among the background documents considered by the IHR Review Committee for its review on the functioning of the IHR (2005) during the COVID-19 response. See IHR Review Committee’s report, p. 68: “WHO technical consultation on the implementation of the IHR, Emergency Committees and public health emergencies of international concern, November 2019, final meeting report (unpublished)”

Implementation of the IHR (2005):

When an event has turned into a long-term term or endemic situation, the WHO should carefully consider the utility of a continued PHEIC according to Article 12.5 and consult the Emergency Committee. If the PHEIC is determined to be over, but there is still a need for recommendations, the DG should consider convening a Review Committee to advice on issuing standing recommendations, in accordance with Articles 16 and 53.

At the meeting the experts considered that the criteria defining a PHEIC were difficult to apply over a prolonged period of time when substantial response efforts are already in place, such as in the PHEIC ongoing since 2014 for poliomyelitis. Temporary recommendations cannot be maintained upon termination of a PHEIC (Articles 15.3 and 49.6 IHR), but standing recommendations may be indicated in such situations. The emergency committee, however, cannot issue any standing recommendations.

III. Amendment to Article 48.1 (a) (wider set of criteria at the disposal of the Emergency Committee to determine whether an event constitutes a PHEIC)

Article 48.1 (a):

“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 **based on Articles 1, 2 and 12.4.**”
- (b) (...)

Rationale:

As per definitions in Article 1 the PHEIC “means an extraordinary event which is determined, as provided in these regulations:

- (i) to constitute a public health risk to other States through the international spread of disease and
- (ii) to potentially require a coordinated international response.”

Particularly during the Ebola outbreak in the Democratic Republic of Congo (DRC) 2018-2020, the WHO and the Emergency Committee were criticized for not declaring a PHEIC earlier. It was argued that “a PHEIC declaration only requires the potential for international spread of the virus” [Green A. Lancet. 2019 Apr 20; 393(10181):1586.]. Others claimed that there was a sustained and heated controversy over declaring a PHEIC, complaining that “the [emergency] committee did not ... expressly conclude that the ‘conditions for a PHEIC have not been met.’” [Fidler DP. AJWH. 2019; 14:287-330.] Such a challenge has also been recorded by the Review Committee in its report (page 37, para 75) under Chapter 3.6 on the “COVID-19

Emergency Committee and the determination of a Public Health Emergency of International Concern”.

In contrast to the simplistic approach only based on Article 1 for the declaration of a PHEIC the Director-General according to Article 12.4 shall consider a wider set of criteria in determining whether an event constitutes a PHEIC:

- (a) information provided by the State Party;
- (b) the decision instrument contained in Annex 2;
- (c) the advice of the emergency committee;
- (d) scientific principles as well as the scientific evidence and other relevant information;
- (e) an assessment of the risk to human health, of the risk of international spread of disease and the risk of interference with international traffic.

The Ebola Emergency Committee concluded it would be misleading the Director-General if considering only Article 1. Contradictions between Emergency Committee and Director General would often result if they are obliged to base their determination on different set of Articles for the same issue, whether or not to decide for a PHEIC.

This was one of the main reasons to convene the above-mentioned Technical Consultation on the Implementation of the IHR 2005 in November 2019. There it was recommended that:

When convening an EC, the DG should specify the reasons why he/she convened the Committee (which are based on the risk assessment conducted by WHO for each event), the scope of the EC deliberations, and the advice that she/he is expecting from the EC, including whether the EC should give its views on the possible social and economic consequences of a PHEIC determination, as per Article 2 or Annex 2 of the IHR.

In the context of the 2018-2020 Ebola outbreak in the Democratic Republic of Congo, the debate during that technical consultation has focused on what constitutes “extraordinary” (in a country that has multiple such outbreaks), what is the meaning of “international spread” and how we should interpret “requires a coordinated international response”, particularly when such a response is already in place. The questions were raised, whether the Emergency Committees should only consider the three specific criteria set out in Article 1 of the IHR or should they also consider wider aspects, such as the political and security situation on the ground and whether the declaration of a PHEIC will help improve the response or perhaps hinder it. The experts considered the definitions flexible enough for an all-hazards approach, but insufficiently explicit to easily make a yes or no determination.

IV. Proposal of an Article 12.4 bis IHR (new) (PHEIC declaration not designed to mobilise funds)

(New) Article 12.4 *bis*:

“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.”

Rationale:

In the debate about the determination of the PHEIC in the 10th Ebola outbreak in the DRC, it was suggested that a PHEIC should be used to help mobilize resources for the response in the country. In contrast, the Director-General repeatedly underlined that the IHR should not become just a tool to generate funding. Also, the experts in the 2019 Technical Consultation concluded, that while the human and financial resources may be relevant to their risk assessment, the potential consequences of the PHEIC declaration are not within the legitimate purpose of the Emergency Committee as a public health risk assessment mechanism. Thus, resulted the following recommendation:

It should be made clear that the IHR are not designed to mobilise funds in the case of an emergency event, and that the DG should use other mechanisms for this purpose.

Actually, this issue has also been considered by the Review Committee on COVID-19 in its report (p. 37, para 76). We believe it is important that scientific independence be guaranteed in the determination of a PHEIC.

United States of America



No. 29-22

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

The Permanent Mission of the United States of America to the United Nations and Other International Organizations in Geneva presents its compliments to the World Health Organization (WHO) and refers to the International Health Regulations (IHR) (2005). The Mission, by means of this note, and in response to the invitation found in WHA75(9), “Strengthening WHO preparedness for and response to health emergencies,” respectfully requests the Director-General of the WHO to communicate the text of the attached proposed IHR amendments to all States Parties without delay. The Mission is also transmitting via this note a letter to WHO Director-General Tedros Adhanom Ghebreyesus from the HHS Director of Multilateral Affairs Mara Burr and a rationale for the proposed amendments.

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

Attachments:

1. Letter from HHS Director of Multilateral Affairs Mara Burr
2. Proposed IHR amendments
3. Rationale for proposed amendments



Geneva, 28 September 2022

World Health Organization

In Geneva



Excellency Tedros Adhanom Ghebreyesus
Director-General
World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland

September 21, 2022

Dear Director-General Tedros:

On January 14, 2022, the United States of America submitted a package of proposed targeted amendments to the International Health Regulations 2005 (IHR) pursuant to IHR Article 55(2). The Seventy-fifth World Health Assembly (WHA) adopted the proposed amendment to Article 59, and the necessary technical adjustments to Articles 55, 61, 62 and 63 of the IHR (Resolution WHA75.12). There were other amendments submitted by the United States that were not able to be taken up by the Health Assembly and pursuant to Resolution WHA75(9) will need to be resubmitted and considered by the Working Group on the International Health Regulations (WGIHR).

Pursuant to WHA Decision 75(9) “to invite proposed amendments to be submitted by 30 September 2022, with all such proposed amendments being communicated by the Director-General to all States Parties without delay,” please find attached the proposed amendments submitted by the United States of America updated primarily to: 1) exclude Article 59 and the technical adjustments necessary for that amendment; and 2) include a technical adjustment to paragraphs 2 and 4 of Article 11 to account for the proposed amendments to Article 12. A rationale for the proposed amendments is also provided.

The United States of America looks forward to engaging with Member States, the IHR Review Committee, and the WGIHR on the proposed targeted amendments.

Thank you for your kind consideration.

Sincerely,

Mara M. Burr, JD, LLM
Director of Multilateral Affairs
Office of the Secretary
Office of Global Affairs

Attachments

Submission of the United States of America

Proposed Amendments to the International Health Regulations (2005)

Rationale

The United States proposal for targeted amendments to the International Health Regulations addresses the need for amendments in the following areas:

- 1) Establishing early warning triggers for action;
- 2) Enabling rapid sharing of information;
- 3) Strengthening implementation and compliance with the IHR;
- 4) Strengthening rapid assessments and responses; and
- 5) Improving decision-making around PHEIC determinations and WHO-provided guidance to Member States.

The following table presents proposed solutions and specific points in the text where these could be addressed.

Issue	Proposed solution	Targeted text
States Parties (SPs) improve early warning triggers for action and guidance	<ul style="list-style-type: none"> - Allow WHO Regional Directors to propose a regional intermediate health alert - Include a global intermediate or graded health alert to trigger necessary actions by States Parties and WHO to respond to events that may not constitute a PHEIC but do require action or to spur rapid action when facing a potential pandemic threat. Also include a pandemic declaration. - Explore ways to pair alerts with clear triggers and recommendations for States Parties action, so that future alerts would be responded to in a manner that is commensurate with the risks, including exploring ideas for how Art 11 could be used to start certain triggers; whether Art 13 could be involved for implementing control measures; and how the DG's authority to make determinations of PHEICs is tied in. 	Articles 5, 11, 12, 13
Information is not shared rapidly enough, and this slows both WHO and Member State responses.	<ul style="list-style-type: none"> - Add a requirement that where an event that may constitute a PHEIC is identified, an SP shall consult immediately with WHO – at all three levels (CO to RO to HQ) 	Articles 6, 9, 10, 11

	<ul style="list-style-type: none"> - Expand the criteria in Art. (11)(2) that, when met, allow WHO to share information regarding events that are determined to be a public health emergency of international concern, a public health emergency of regional concern, or that warrant an intermediate public health alert that States Parties need to respond to a public health risk. - Add a requirement that WHO inform all SP of the available event-related information and data, and the expected timeline for a response as well as the WHO’s risk assessment. - Provide a timeline of action and inform all SP. - Allow for rapid information sharing needed for intermediate/graded health alerts requiring regional action. - Provide more reasonable timelines for event notification to WHO and SP. 	
<p>General lack of implementation and compliance with the IHR</p>	<ul style="list-style-type: none"> - Periodic review through Universal Health Periodic Review (UHPR), with facilitation of technical and financial assistance. - Establish a compliance and accountability committee to meet annually at the regional level, and on a biennial basis in Geneva. Such a committee could be charged with promoting compliance, addressing issues of non-compliance, assisting countries without sufficient core capacities, and providing guidance for implementation as well as reporting to the Universal Health Periodic Review Mechanism. It could also review textual understandings and assess developments, progress, and gaps, and make recommendations for action. - Affirmative obligation for SP to share information on compliance with IHR to WHO and SP. 	<p>Article 5, New article [53]</p>
<p>Early detection and containment of outbreaks to prevent spread</p>	<ul style="list-style-type: none"> - Develop warning criteria for risk assessment. - Encourage WHO to aid and deploy expert teams to outbreak areas when an event is notified or to 	<p>Articles 5,10, 13, 15</p>

	<p>request SP to update based on publicly available information.</p> <ul style="list-style-type: none"> - Affirmative obligation on SP to respond in a timely manner to requests for information or offers of assistance. 	
<p>Improved decision-making around PHEIC determinations and evidence-based guidance from WHO to Member States during emergencies</p>	<ul style="list-style-type: none"> - Address the transparency of the IHR Emergency Committee (composition and process), including by ensuring that the process is not controlled by the SP in whose territory the event occurs. - Ensure that relevant agencies such as ICAO, WTO, IATA, and IMO are involved in the development of recommendations with appropriate flexibility to assess and minimize negative impacts on trade or travel. - Increase flexibility to tailor recommendations to avoid negative impacts on trade or travel. 	<p>Articles 48, 49</p>

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

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

Article 5: Surveillance

1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1. **This capacity will be periodically reviewed through the Universal Health Periodic Review mechanism. Should such review identify resource constraints and other challenges in attaining these capacities, WHO and its Regional Offices shall, upon the request of a State Party, provide or facilitate technical support and assist in mobilization of financial resources to develop, strengthen and maintain such capacities.**

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

Article 6: Notification

1. Each State Party shall assess events occurring within its territory by using the decision instrument in Annex 2 **within 48 hours of the National IHR Focal Point receiving the relevant information.** Each State Party shall notify WHO, by the most efficient means of communication available, by way of the National IHR Focal Point, and within 24 hours of assessment of public health information, of all events which may constitute a public health emergency of international concern within its territory in accordance with the decision instrument, as well as any health measure implemented in response to those events. If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA), **the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (WOAH), the UN Environment Programme (UNEP) or other relevant entities.** WHO shall immediately notify the IAEA **relevant entities.**
2. Following a notification, a State Party shall continue to communicate to WHO, **by the most efficient means of communication available,** timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including **genetic sequence data,** case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when

necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern.

Article 9: Other Reports

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

Article 10: Verification

1. **Within 24 hours of receiving information,** WHO shall request, ~~in accordance with Article 9,~~ verification from a State Party of reports from sources other than notifications or consultations of events which may constitute a public health emergency of international concern allegedly occurring in the State's territory. In such cases, WHO shall inform the State Party concerned regarding the reports it is seeking to verify.
2. Pursuant to the foregoing paragraph ~~and to Article 9,~~ each State Party, when requested by WHO, shall verify and provide:
 - a. within 24 hours, an initial reply to, or acknowledgement of, the request from WHO;
 - b. within 24 hours, available public health information on the status of events referred to in WHO's request; and
 - c. information to WHO in the context of an assessment under Article 6, including relevant information as described in **paragraphs 1 and 2 of** that Article.
3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall offer **within 24 hours** to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures. Such activities may include collaboration with other standard-setting organizations and the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments.

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

4. If the State Party does not accept the offer of collaboration **within 48 hours,** WHO ~~shall~~ ~~may,~~ when justified by the magnitude of the public health risk, **immediately** share with other States Parties the information available to it, whilst encouraging the State Party to accept the offer of collaboration by WHO, ~~taking into account the views of the State Party concerned.~~

Article 11: Provision of information by WHO

1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as appropriate, to relevant intergovernmental organizations, as soon as possible and by the most efficient means available, in confidence, such public health information which it has received under Articles 5 to 10 inclusive, **or which is available in the public domain**, and which is necessary to enable States Parties to respond to a public health risk. WHO **shall** communicate information to other States Parties that might help them in preventing the occurrence of similar incidents.
2. WHO shall use information received under Articles 6, ~~and 8 and paragraph 2 of Article 9~~ for verification, assessment and assistance purposes under these Regulations and, unless otherwise agreed with the States Parties referred to in those provisions, shall ~~not~~ make this information generally available to other States Parties, ~~when~~**until such time as:**
 - a. the event is determined to constitute a public health emergency of international concern, **a public health emergency of regional concern, or warrants an intermediate public health alert**, in accordance with Article 12; or
 - b. information evidencing the international spread of the infection or contamination has been confirmed by WHO in accordance with established epidemiological principles; or
 - c. there is evidence that:
 - i. control measures against the international spread are unlikely to succeed because of the nature of the contamination, disease agent, vector or reservoir; or
 - ii. the State Party lacks sufficient operational capacity to carry out necessary measures to prevent further spread of disease; or
 - d. the nature and scope of the international movement of travellers, baggage, cargo, containers, conveyances, goods or postal parcels that may be affected by the infection or contamination requires the immediate application of international control measures; or
 - e. **WHO determines it is necessary that such information be made available to other States Parties to make informed, timely risk assessments.**
3. WHO shall **inform** ~~consult with~~ the State Party in whose territory the event is occurring as to its intent to make information available under this Article.
4. When information received by WHO under paragraph 2 of this Article is made available to States Parties in accordance with these Regulations, WHO **shall** make it available to the public if other information about the same event has already become publicly available and there is a need for the dissemination of authoritative and independent information.

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

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

1. The Director-General shall determine, on the basis of information received, in particular from the State Party within whose territory an event is occurring, whether an event constitutes a

public health emergency of international concern in accordance with the criteria and the procedure set out in these Regulations.

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

New 6. Where an event has not been determined to meet the criteria for a public health emergency of international concern but the Director-General has determined it requires heightened international awareness and a potential international public health response, the Director-General, on the basis of information received, may determine at any time to issue an intermediate public health alert to States Parties and may consult the Emergency Committee in a manner consistent with the procedure set out in Article 49.

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

Article 13: Public health response

3. ~~At the request of a State Party, WHO shall offer assistance—collaborate to a State Party~~ in the response to public health risks and other events by providing technical guidance and assistance and

by assessing the effectiveness of the control measures in place, including the mobilization of international teams of experts for on-site assistance, when necessary. **The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which WHO shall share with other States Parties.**

4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern is occurring, it **shall** ~~may~~ offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State Party, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer. **The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which WHO shall share with other States Parties. Regarding on-site assessments, in compliance with its national law, a State Party shall make reasonable efforts to facilitate short-term access to relevant sites; in the event of a denial, it shall provide its rationale for the denial of access.**

Article 15: Temporary recommendations

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

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

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

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

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

Articles 48: Terms of reference and composition

2. The Emergency Committee shall be composed of experts selected by the Director-General from the IHR Expert Roster and, when appropriate, other expert advisory panels of the Organization, **as well as Regional Directors from any impacted region**. The Director-General shall determine the duration of membership with a view to ensuring its continuity in the consideration of a specific event and its consequences. The Director-General shall select the members of the Emergency Committee on the basis of the expertise and experience required for any particular session and with due regard to the principles of equitable **age, gender, and** geographical representation, **and require training in these Regulations before participation**. ~~At least one member~~ **Members** of the Emergency Committee should ~~include~~ **be at least one** expert nominated by ~~a~~ **the** State Party within whose territory the event arises, **as well as experts nominated by other affected States Parties**. **For the purposes of Articles 48 and 49, an “affected State Party” refers to a State Party either geographically proximate or otherwise impacted by the event in question.**

Article 49: Procedure

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

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

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

...

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

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

53 bis Terms of reference and composition

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

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

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

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

53 ter Conduct of business

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

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

53 quater Reports

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

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

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

Uruguay
on behalf of the Member States
of the Southern Common Market (MERCOSUR)

MERCOSUR – Setiembre 2022
Propuestas de Enmiendas al RSI 2005

En el marco del proceso de enmiendas al RSI 2005 definido durante la celebración de la 75ª AMS, los Estados Parte del MERCOSUR acuerdan elevar las siguientes propuestas:

TÍTULO II - INFORMACIÓN Y RESPUESTA DE SALUD PÚBLICA

Artículo 5 Vigilancia

SUBITEM 4

4. (Nueva redacción) – “La OMS recopilará información sobre eventos a través de sus actividades de vigilancia y evaluará, a partir de criterios de evaluación de riesgos actualizados periódicamente y acordados con los Estados Miembros, su potencial de provocar una propagación internacional de enfermedades y su posible interferencia con el tráfico internacional. La información que la OMS reciba en virtud de este párrafo se manejará de conformidad con lo dispuesto en los artículos 11 y 45 cuando proceda”; (Estados miembros de la Unión Económica Euroasiática)”

AGREGAR UN APARTADO 5

5 - “Fortalecer el papel central de las autoridades sanitarias nacionales en el proceso de gestión y articulación con los niveles jerárquicos político, intersectorial, interministerial y multinivel para una vigilancia y respuesta oportuna y coordinada según el enfoque de riesgo internacional de salud pública establecido por el RSI, afianzando el rol central de las autoridades sanitarias nacionales en el proceso de conducción y articulación multinivel”.

Artículo 9 Otros informes

3. (Nueva redacción) En las recomendaciones que formule a los Estados Partes con respecto a la recolección, procesamiento y difusión de la información sanitaria, la OMS podrá aconsejar lo siguiente:

(a) seguir orientaciones de la OMS sobre criterios y modos análogos de procesamiento y tratamiento de la información sanitaria

Artículo 13 Respuesta de salud pública (VIGENTE)

3. (Nueva redacción). A petición de un Estado Parte, la OMS colaborará en la respuesta a los riesgos para la salud pública y otros eventos proporcionando orientación y asistencia técnica y evaluando la eficacia de las medidas de control adoptadas, incluida la movilización de equipos de expertos internacionales para que presten asistencia in situ, si procede, y si fuera necesario cooperará con dicho Estado Parte en la búsqueda de apoyo y **asistencia financiera internacional para facilitarle la contención del riesgo en la fuente.**

Título III – Recomendaciones

Artículo 18 Recomendaciones con respecto a las personas, equipajes, cargas, contenedores, medios de transporte, mercancías y paquetes postales

SUBITEM 2- **Nueva redacción:** - asegurar los mecanismos para el desarrollo y aplicación de una declaración de salud del viajero ante situaciones de emergencia de salud pública internacionales (ESPII) para proporcionar una mejor disponibilidad de información sobre el itinerario realizado, los síntomas que pudiera presentar o las medidas de prevención que hubiera cumplido así como para facilitar el rastreo de contactos, cuando proceda

Título VI - Documentos Sanitarios

Artículo 35 Disposición general

Se sugiere agregar: Los documentos de salud digitales deben tener una función para verificar su autenticidad recuperando el documento en un sitio web oficial, como un código QR

Propuesta al Título X – Disposiciones generales

Artículo 56 Solución de controversias

Agregar apartados **6, 7 y 8**

6. La OMS deberá comunicar todas las reclamaciones de los Estados Miembros sobre medidas adicionales no informadas por alguno de ellos o recomendadas por dicha Organización;

7. Los Estados Miembros que apliquen las medidas referidas en el apartado anterior deberán informar a la OMS la justificación científica de su implantación y sostenimiento en el tiempo y la OMS deberá difundir esa información;

8. La Asamblea Mundial de la Salud podrá analizar los informes del Comité de Examen sobre la pertinencia y duración de las medidas y demás datos aludidos en los puntos a) y b) comprendidos en este apartado 6 y efectuar recomendaciones respecto a la pertinencia de la continuidad de las medidas sanitarias adicionales.

ANEXO 3

MODELO DE CERTIFICADO DE EXENCIÓN DEL CONTROL DE SANIDAD A BORDO / CERTIFICADO DE CONTROL DE SANIDAD A BORDO

(...)

Para conferir la autenticidad, escanee en sitio oficial o como el código QR.

Imagen del código QR u otra aplicación de validación

Se sugiere incorporar “*embarcaciones fluviales internacionales*”, en:

- I. El acápite de los certificados de sanidad a bordo y certificados de exención
- II. Los artículos y anexos y que hacen referencia a declaración marítima
- III. En todos los espacios que incorpora la palabra marítima

ANEXO 6

VACUNACIÓN, PROFILAXIS Y CERTIFICADOS CONEXOS

Propuesta de redacción¹:

Cuando fuera declarada una Emergencia de Salud Pública de Importancia Internacional, para el ingreso o egreso de los viajeros internacionales, en el caso de vacunaciones voluntarias con productos en fase de investigación o con muy limitada disponibilidad, a considerar las certificaciones de vacunas aprobadas según el marco normativo del país de origen, incluyendo lo referido al modelo/formato de certificación y el esquema de vacunación (tipo de vacuna y esquema).

¹ **Fundamentación:** Necesaria flexibilización del régimen de emergencia, requiere considerar la Certificación de vacunas aprobadas según marco normativo del país de origen en casos de vacunación voluntaria con productos en fase de investigación aprobados por OMS o de muy limitada disponibilidad mundial, en caso de una ESPII declarada por la misma, para la circulación de viajeros internacionales

Condiciones de los documentos digitales:

Los certificados analógicos deben ser asignados por el médico clínico que indica la administración de vacuna u otra profilaxis o por otro profesional de salud debidamente autorizado. Los certificados digitales deben poseer un recurso de verificación de autenticidad en sitios oficiales en redes, como el código QR.²

MODELO DE CERTIFICADO INTERNACIONAL DE VACUNACIÓN O PROFILAXIA

Se sugiere modificar redacción de apartado:

“Para conferir autenticidad cuando proceda escanee el en sitio oficial, como el código QR u otro método de verificación.

Imagen del código QR”

² Certificación de vacunación para el ingreso y egreso al territorio nacional:

Sobre los datos de los certificados se plantean dos escenarios:

Escenario de mínima:

Se aceptará la presentación de certificado/carné/constancia en formato papel.

Independientemente del diseño, se deberán consignar los siguientes datos:

1. Apellido y nombre
2. N° de DNI/Pasaporte
3. Tipo de vacuna: por ejemplo vacuna contra la fiebre amarilla / vacuna antipoliomielítica, vacuna contra el sarampión.
4. Lote de la vacuna (opcional, si se cuenta con la información)
5. Fecha de aplicación
6. Lugar de aplicación (efector)
7. Sello oficial (del profesional que intervino o de la institución)

Escenario de máxima:

Certificación del antecedente de vacunación mediante código QR

1. El antecedente de vacunación se acredita en formato digital o papel, mediante código QR
2. La lectura de código QR direcciona al sitio oficial del país de origen para levantar la información de su antecedente de vacunación.

Enfermedades en eliminación y/o erradicación:

Esto podría citarse para el INB: Respecto a la enfermedades en eliminación y en vías de erradicación, tales como la poliomiélitis, el sarampión, rubéola y el síndrome de rubéola congénita, y entendiendo el esfuerzo que representa para la región de las Américas sostener los objetivos definidos en este sentido, y ante la persistencia de brotes de sarampión en diferentes regiones del mundo, la circulación de poliovirus salvaje tipo 1 en dos países y el incremento de casos de poliovirus circulantes derivados de la vacuna (cVDPV), consideramos que resulta necesario plantear una estrategia global respecto a los recomendación y/o requerimientos de vacunación de viajeros

ANEXO 8

MODELO DE DECLARACIÓN MARÍTIMA Y FLUVIAL INTERNACIONAL DE SANIDAD

Cuestionario de sanidad

Se sugiere incorporar:

10) ¿Hay un viajero sin la vacunación requerida en el Anexo 7? Sí..... No.....

En caso afirmativo, proporcione los detalles en el formulario adjunto.

“Para verificar la autenticidad al escanear el sitio oficial, como el código QR u otro método de verificación

Imagen del código QR

PLANILLA ADJUNTA AL MODELO DE DECLARACIÓN MARÍTIMA DE SANIDAD

Incluir la columna “**Vacunación conforme al Anexo 7**”

PROPUESTA PARA ENMIENDA DEL RSI 2005 EN RELACIÓN A PLANES DE CONTINGENCIA

Propuesta:

Artículo 19 - Obligaciones generales

- d) **Nueva propuesta:** La elaboración de planes de contingencia “binacionales” con contenidos mínimos a ser incluidos en los planes de acción en casos de fronteras compartidas para emergencias en salud pública de importancia internacional (ESPII).