


Complementarity and coherence between
the International Health Regulations (2005), as amended in 2024,
and the proposal for the WHO Pandemic Agreement

WHO Pandemic Agreement, Briefing Session
Washington DC, United States, 30 September 2024

INB11, 9-20 September 2024

Information document A/INB/11/INF./2

■ How information is presented in the document - Example

 World Health Organization

ELEVENTH MEETING OF THE INTERGOVERNMENTAL NEGOTIATING BODY TO DRAFT AND NEGOTIATE A WHO CONVENTION, AGREEMENT OR OTHER INTERNATIONAL INSTRUMENT ON PANDEMIC PREVENTION, PREPAREDNESS AND RESPONSE
A/INB/11/INF./2
29 August 2024
Provisional agenda item 2

Information document on complementarity and coherence between the amended International Health Regulations (2005) adopted by the Seventy-seventh World Health Assembly, and the proposal for the WHO Pandemic Agreement

BACKGROUND

1. At its tenth meeting, as reflected in document A/INB/10/4, the Intergovernmental Negotiating Body (INB) to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response requested the preparation of "an information document on the complementarity and coherence between the amended International Health Regulations (2005) adopted by the Seventy-seventh World Health Assembly and relevant Articles in the proposal for the WHO Pandemic Agreement, which could include, as appropriate, relevant proposals". The present document responds to that request.

2. Each of the tables presented below present, juxtaposed, related provisions from each instrument. The first column presents relevant provisions from the International Health Regulations (2005), as amended through resolution WHA77.17 (2024) (hereinafter referred to as "IHR as amended in 2024"), and the second column those from the proposal for the WHO Pandemic Agreement, as contained in the Appendix to document A/77/10 Annex (hereinafter referred to as "proposal for the WHO Pandemic Agreement"). For the purposes of the present document, the excerpts of the text contained in document A/77/10 are presented without text highlighting. The considerations and proposals of the INB Bureau to further develop the proposal for the WHO Pandemic Agreement are presented in the bottom row of each table.

3. Decisions SSA2(5) (2021) and WHA75(9) (2022) established the INB and the Working Group on Amendments to the International Health Regulations (2005) (WGIHR), respectively, and set out the following mandates.

(a) INB, operative paragraph (OP)1(1) of decision SSA2(5) reads: "to establish, in accordance with Rule 41 of its Rules of Procedure, an intergovernmental negotiating body open to all Member States and Associate Members" (the "INB") to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, with a view

IHR as amended in 2024: <i>Article 1 Definitions</i> Proposal for the WHO Pandemic Agreement: <i>Article 1. Use of terms</i>	
Pandemic emergency	
Relevant text from the IHR as amended in 2024	Relevant text from the proposal for the WHO Pandemic Agreement
<p>"pandemic emergency" means a public health emergency of international concern that is caused by a communicable disease and:</p> <ul style="list-style-type: none"> (i) has, or is at high risk of having, wide geographical spread to and within multiple States; and (ii) is exceeding, or is at high risk of exceeding, the capacity of health systems to respond in those States; and (iii) is causing, or is at high risk of causing, substantial social and/or economic disruption, including disruption to international traffic and trade; and (iv) requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches; 	<p>The term "pandemic emergency(ies)" is mentioned in the following provisions of the proposal for the WHO Pandemic Agreement: Article 1(d) and 1(f); Article 7.1, 7.2(a) and 7.5; Article 9.2(a), 9.2(d) and 9.5; Article 10.1 and 10.2(f); Article 11.1(d), 11.1(f), 11.1 Alt(f) and 11.3; Article 12.4(b)(ii) and 12.5; Article 13.1, 13.1 Vice-chair proposal Art 1, 13.3 and 13.3 <i>Vice-chair Alt 3</i>; Article 13bis.4, 13bis.6 and 13bis.8 <i>Alt</i>; and Article 14.4 and 14.7(b).</p> <p>Of the provisions enumerated above, those "greened" in the proposal for the WHO Pandemic Agreement include Article 7.1, 7.2(a) and 7.5; Article 9.2(a) and 9.2(d); Article 10.1 and 10.2(f); Article 11.1(d); and Article 13.1 Vice-chair proposal Art 1 and 13bis.6.</p> <p>Article 9.2(a) ["greened"] and Article 12.4(b)(ii) [without highlighting] of the proposal for the WHO Pandemic Agreement explicitly apply "in the event of a pandemic emergency".</p>
<p>The INB may wish to consider the adoption of the definition of "pandemic emergency" from the IHR as amended in 2024, by adding this definition, including the reference to the IHR as amended in 2024, to <i>Article 1. Use of terms</i>, and replacing with "pandemic emergency(ies)" relevant references to "pandemic(s)", across the proposal for the WHO Pandemic Agreement, as a standalone noun.</p>	
<p>The INB may also wish to consider maintaining the response" or "to prevent, prepare for and respond to</p>	
<p>Considerations and rationale</p> <p>Rationale</p> <p>For the two instruments to be coherent, complementary and applicable in an effective manner, the consistent and unambiguous use of terms across them is necessary, where possible. For instance, the consistent use of terms would substantially clarify the context and timing for the application of some of the provisions where the term "pandemic(s)" is used.</p> <p>In that regard, it is further noted that, at their second joint plenary session, the INB and WGIHR decided that "public health alert – public health emergency of international concern (PHEIC) – pandemic continuum" would be primarily addressed through discussion and text negotiation in the WGIHR, and the INB process would make reference to the IHR as amended in 2024, as appropriate (see document A/INB/8/6, paragraph 6(a)).</p>	

	International Health Regulations (2005) (IHR) (as amended through resolution WHA77.17)	Draft WHO Pandemic Agreement (after INB11, 9-20 September 2024)
	Article 1 <i>Definitions</i>	Article 1 <i>Use of terms</i>
1	<ul style="list-style-type: none"> ▪ Pandemic emergency 	<ul style="list-style-type: none"> ▪ Multiple terms used, incl. internal inconsistencies
	<ul style="list-style-type: none"> ▪ Public health emergency of international concern 	
	<ul style="list-style-type: none"> ▪ Public health risk 	
	<ul style="list-style-type: none"> ▪ Relevant health products 	
2	Article 13 <i>Public health response, including equitable access to relevant health products</i>	Articles 13 <i>Supply chain and logistics</i> [Article 13 bis <i>Procurement and distribution</i>]
	<ul style="list-style-type: none"> ▪ “work to remove barriers” 	<ul style="list-style-type: none"> ▪ “unimpeded”, “unhindered”, or related
3	Article 13 <i>Public health response, including equitable access to relevant health products</i>	Article 9 <i>Research and development</i>
4	Article 44 <i>Collaboration, assistance and financing</i>	Article 20 <i>Sustainable financing</i>
	<ul style="list-style-type: none"> ▪ Paragraphs 2.(c), 2 bis., 2.ter 	<ul style="list-style-type: none"> ▪ Paragraphs 2.(a), 2.(b), 2.(d)
	Annex 1 <i>Core capacities</i>	
	<ul style="list-style-type: none"> ▪ Paragraphs 1, 4 	
5	Article 44 bis <i>Coordinating Financial Mechanism</i>	Article 20 <i>Sustainable financing</i>
		<ul style="list-style-type: none"> ▪ Paragraphs 3, 3 bis., 4
6	Article 54 bis <i>States Parties Committee for the Implementation of the International Health Regulations (2005)</i>	Article 21 <i>Conference of the Parties</i>
		<ul style="list-style-type: none"> ▪ “Sub-committee on Implementation established under the IHR”
[7]	Article 2 <i>Purpose and scope</i>	Article 2 <i>Objective</i>
	Article 5 <i>Surveillance</i>	Article 4 <i>Pandemic prevention and surveillance</i>
	Article 13 <i>Public health response, including equitable access to relevant health products</i>	Article 5 <i>One Health approach for Pandemic Prevention, Preparedness and Response</i>
	Article 19 <i>General obligations (Part IV Points of entry)</i>	
	Annex 1 <i>Core capacities</i>	

1. Use of terms – In general...

- Joint INB-WGIHR meeting, 23 February 2024: “pandemic continuum” addressed by the WGIHR, with INB process making reference to the amended IHR (document [A/INB/8/6](#))
- For the two instruments, IHR, as amended in 2024, and the WHO Pandemic Agreement, to be coherent, complementary, and applicable in an effective manner, the consistent and unambiguous use of terms across them is necessary
- The consistent use of terms would substantially clarify the context and timing for the application of some of the provisions
- Limiting the variety of terms used would facilitate the understanding of the text of the WHO Pandemic Agreement
- Textual options to reflect the adoption of the terms defined in the IHR in the text of the WHO Pandemic Agreement

1. Use of terms – Pandemic emergency

- Replacing with “pandemic emergency” relevant references to “pandemic(s)”, across the WHO Pandemic Agreement, as a standalone noun
- Maintaining the use of the term “pandemic(s)” when this is used in the context of the expression “pandemic prevention, preparedness and response” or “to prevent, prepare for and respond to pandemic(s)”, as well as in the shortened title of the instrument (“WHO Pandemic Agreement”)



1. Use of terms – Relevant health products/pandemic-related health products

- Article-by article discussions in the INB on the appropriateness of adopting (or not) the term “relevant health products” as defined in IHR, instead of “pandemic-related health products”
- Article 12.4.(b) refers to “vaccines, therapeutics and diagnostics”. This terminology is more specific with regard to the products that are covered under the benefit sharing component of the Pathogen Access and Benefit-Sharing System (PABS)
- Through that lens it may be applicable and appropriate for Articles 9 and 11 as well, given the intention of those articles and the relevance of this component

2. Terminology “work to remove barriers”

- Article 13.1 and 13.[Alt] 3 include the terminology “facilitate work to remove barriers” which is consistent with the term “work to remove barriers” used in Article 13 of the IHR, as amended in 2024
- Discussions on Articles 13 and 13 bis ongoing in the INB

3. Research and development

- IHR: Article 13.9.(c)

“[...] States Parties shall undertake [...] to [...] **making available**, as appropriate, relevant **terms of their research and development agreements** for relevant health products related to promoting equitable access to such products during a public health emergency of international concern, including a pandemic emergency.”

- Draft WHO Pandemic Agreement: Article 9.5

“Each Party shall **develop and implement** [...] **policies** regarding the inclusion of **provisions in research and development agreements** [...] **for the development** of pandemic-related health products, that promote timely and equitable access to such products, particularly for developing countries, during public health emergencies of international concern including pandemic emergencies, **and the [publication of] such [terms or provisions].** [...]”

- Discussions on this Article ongoing in the INB

4. Financing

- Substantial coherence
 - IHR: *Article 44 Collaboration, assistance and financing* - Paragraphs 2.(c), 2 bis., 2.ter; and *Annex 1 Core capacities* - Paragraphs 1, 4
 - Draft WHO Pandemic Agreement: *Article 20 Sustainable financing* - Paragraphs 2.(a), 2.(b), 2.(d)

5. Financing – “Coordinating Financial Mechanism”

- Operative paragraph 2.(3) of resolution WHA77.17 (2024), adopting the amendments to the IHR, states:

“The Seventy-seventh World Health Assembly, [...] 2. DECIDES: [...] (3) that future instruments on public health emergencies or pandemic prevention, preparedness and response, adopted pursuant to the Constitution of the World Health Organization, may utilize the Coordinating Financial Mechanism contained in Article 44 bis of the amended International Health Regulations (2005) to serve the implementation of such instruments;”

- INB to consider whether changes to *Article 20 Sustainable financing* are needed to ensure alignment with the IHR and avoid a situation that may result in the establishment of parallel “coordinating financial mechanisms”

6. “(Sub)committee” for implementation

- Article 54 bis of the IHR establishes a “States Parties Committee for the Implementation of the International Health Regulations (2005)”, with the mandate to establish a “Subcommittee to provide technical advice and report” to it
- INB to consider whether *Article 21 Conference of the Parties* should include provisions to promote coherence in the implementation of the two instruments – possible differences in membership of the instruments and their governance body
 - IHR: All WHO Member States (at least) and governed by World Health Assembly
 - WHO Pandemic Agreement: “greened” text establishes a Conference of the Parties

7. Prevention and surveillance – IHR

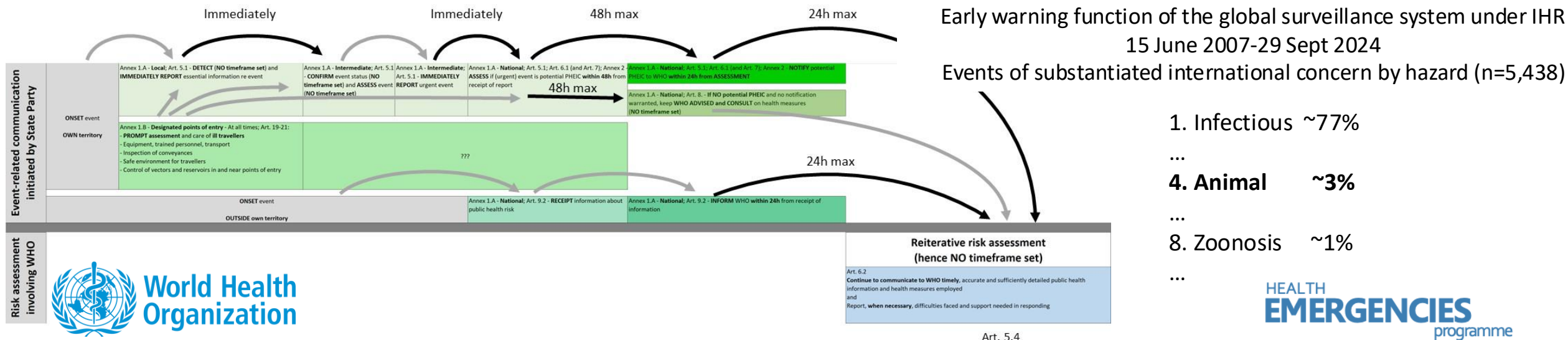
- **Article 21** of the **Constitution of the World Health Organization** - *“The Health Assembly [...] adopt **regulations** concerning: (a) sanitary and quarantine requirements and other procedures designed **to prevent** the international spread of disease”*
- **Article 2 Purpose and scope** - *“The purpose and scope of these Regulations are **to prevent**, prepare for, protect against, control and provide a public health response to the international spread of **disease** in ways that [...]”*
- **Term “prevention/prevent” used in 13 additional provisions specifically related to:**
 - **Core capacities** - Across territory of State Party to prevent the international spread of disease / reducing the risk thereof
 - **Recommendations** (“standing” and “temporary”) - Issued by the Director-General to States Parties and signal potential/actual failure in the implementation of core capacities, thus need for specific non-binding advice to prevent, inter alia, the (further) international spread of disease

7. Prevention and surveillance – IHR

- Provisions **amended** in 2024 through references to **“prevention/prevent”**
 - *Article 5 Surveillance*
 - *Article 13 Public health response, including equitable access to relevant health products*
 - *Annex 1 Core capacities*
- **“Prevention”** intended in its **multifaceted aspects** (see rationales of WGIHR Bureau’s text proposals), according to the definition of **“prevention”** in *A Dictionary of Epidemiology*, Sixth edition, 2014 (primordial, primary, secondary, tertiary, quaternary)
- Amendments considered the following under *Article 1 Definitions*
 - **“disease”**: “an illness or medical condition, **irrespective of origin or source**, that presents or could present significant harm to humans”
 - **“infection”**: “the entry and development or multiplication of an infectious agent in the body of **humans and animals** that may constitute a **public health risk**”
 - Make explicit that core capacities apply to **“pandemic emergencies”** (Articles 13.1, 44 bis.2.(d) and (e))

7. Prevention and surveillance – IHR

- Joint INB-WGIHR meeting, 23 February 2024: “public health surveillance” addressed by the WGIHR, with INB process making reference to the amended IHR (document [A/INB/8/6](#))
- “surveillance” specifically addressed in:
 - Definition** of surveillance under *Article 1*
 - Part II – Information and public health response* (Articles 5 to 14)
 - Article 5 Surveillance – Obligations for States Parties and WHO**
 - Annex 1 Core capacities – Part A. Core capacities requirements for prevention, surveillance, preparedness and response – Obligations for States Parties**



7. Prevention and surveillance – Draft WHO Pandemic Agreement

Article 4 Pandemic prevention and surveillance

[Hybrid] Informal meeting of members of the [INB] drafting group

Friday, 4 October 2024, 09:00-13:00 CEST

7. Prevention and surveillance – Draft WHO Pandemic Agreement

Article 4. Pandemic prevention and surveillance (“yellow” and “white”)

1. The Parties shall [...] progressively strengthen **pandemic prevention** and **surveillance capacities**, **consistent** with the **IHR** [...]”

2. Each Party shall [...] develop, strengthen and implement, comprehensive **multisectoral** national **pandemic prevention** and **surveillance plans** [...] **consistent** with the **IHR** and that **cover**, inter alia:

- | | |
|---|---|
| a) prevention of the emergence and re-emergence of infectious diseases; | f) infection prevention and control; |
| b) coordinated multi-sectoral surveillance and risk assessment; | g) prevention of infectious disease transmission between animals and humans, including zoonotic disease spill-over; |
| c) early detection and control measures including at community level; | h) vector-borne disease surveillance and prevention; |
| d) water, sanitation and hygiene; | i) laboratory biological risk management; |
| e) routine immunization; | j) prevention of antimicrobial resistance” |

2 bis. The Parties recognize that a range of environmental, climatic, social, anthropogenic and economic factors may increase the risk of pandemics[...]

Paragraph: 3, [3 Alt Bureau proposal], 3 Alt Bureau proposal – with revisions: instrument

Paragraph: 3 Alt: Annex

<p>Paragraph 2 of Article 4. Pandemic prevention and surveillance Draft WHO Pandemic Agreement (after INB11)</p>	<p>Provisions of the International Health Regulations (2005) (IHR) (as amended through resolution WHA77.17)</p>
(a) prevention of the emergence and re-emergence of infectious diseases	Entire Annex 1 Core capacities
(b) coordinated multi-sectoral surveillance and risk assessment	Entire Annex 1 Core capacities, and specifically: <ul style="list-style-type: none"> ■ Local level: A.1.(a) and (e) ■ Intermediate level: A.2.(c).(i) and (ii) ■ National level: A.3.Assessment and notification.(a) and A.3.Public health prevention, preparedness and response.(b),(c), (f), (k), (m) Article 4.2 Responsible authorities
(c) early detection and control measures including at community level	Entire Annex 1 Core capacities, where detection and control, core capacities at community level are specifically addressed under Section A.1 Article 4 Responsible authorities; Article 6 Notification
(d) water, sanitation and hygiene	Annex 1 Core capacities: No explicitly mentioned, but following provisions applies: <ul style="list-style-type: none"> ■ Local level: A.1.(c) ■ Intermediate level: A.2.(c).(iv) and (vii) ■ National level: A.3.Public health prevention, preparedness and response.(e) and (n) ■ Designated points of entry: B.1.(d) Article 22.1.(e) and 22.1.(f); Article 25(a) and 25.(c); Article 27.2; Article 28.2; Article 32.(c)
(e) routine immunization	Not addressed

<p>Paragraph 2 of Article 4. Pandemic prevention and surveillance Draft WHO Pandemic Agreement (after INB11)</p>	<p>Provisions of the International Health Regulations (2005) (IHR) (as amended through resolution WHA77.17)</p>
<p>(f) infection prevention and control</p>	<p>Annex 1 Core capacities: Specifically addressed in:</p> <ul style="list-style-type: none"> ▪ Local level: A.1.(c) ▪ Intermediate level: A.2.(c).(iv), (v) and (vii) ▪ National level: A.3.Public health prevention, preparedness and response. (a), (c), (e), (g), (h), (j), (l), (n) ▪ Points of entry: 1.(a).(ii) and 1.(b), 2.(b),(c), (d) and (g)
<p>(g) prevention of infectious disease transmission between animals and humans, including zoonotic disease spill-over</p>	<p>Virtually entire Annex 1 Core capacities, although “spill-over” not mentioned Article 1 Definitions (“infection”, “contamination”, “decontamination”, “deratting”, “disinfection”, “goods”, “reservoir” “vector”); Article 22.1.(e); Article 33</p>
<p>(h) vector-borne disease surveillance and prevention</p>	<p>Virtually entire Annex 1 Core capacities Article 1 Definitions (“deratting”, “disinsection”, “relevant health products”, “vector”); Article 9; Article 11; Article 18; Article 19; Article 22; Article 24; Article 34; Article 39; Annex 3; Annex 5</p>
<p>(i) laboratory biological risk management</p>	<p>Annex 1 Core capacities: Not explicitly mentioned, but following strictly related provisions applies:</p> <ul style="list-style-type: none"> ▪ Local level: A.1.(b) ▪ Intermediate level: A.2.(a) and (A.2.(c).(iii) ▪ National level: A.3.Public health prevention, preparedness and response.(d) ▪ Designated points of entry: 1.(a).(i) and B.2.(b)
<p>(j) prevention of antimicrobial resistance</p>	<p>No explicitly mentioned, but Annex 1 core capacities applies, inferable by example for the application of Annex 2 (“new or emerging antibiotic resistance”)</p>

Thank you