Proposed Amendments to the International Health Regulations: Details

You can find the current (2005, 3rd edition) version of the International Health Regulations here.

You can find the WHO's Article-by-Article Compilation of Proposed Amendments to those International Health Regulations here. This is the draft version of the proposed amendments that everyone outside the drafting process has been using to-date (October'23). But be aware that extensive negotiations have been taking place, as outlined in the blog article, so that these initial proposals will not be the final position. Indeed, they cannot be allowed to be as some proposals will conflict with others. This is inevitable as the proposals were submitted independently by 15 countries or groups of countries. (The WHO themselves submitted none).

Hence, we do not yet know what proposed amendments to the IHR will go forward to the World Health Assembly (WHA)

The <u>draft of initial amendments</u> comprises 15 sets of proposals, all either from nation states (11) or from groups of nation states making a joint submission (4), namely, Armenia; Bangladesh; Brazil; Czech Republic on behalf of the Member States of the European Union; Eswantini on behalf of the WHO African Region Member States; India; Indonesia; Malaysia; Namibia; New Zealand; Republic of Korea; the Russian Federation on behalf of the Member States of the Eurasian Economic Union; Switzerland; United States of America; and Uruguay on behalf of MERCOSUR. Hence 101 nations were represented in the submissions which form the initial compiled set of proposed amendments to the IHR.

The UK was not one of them.

I do not present all 307 proposed amendments but select those which appear most significant or of greatest concern. The country which has made the proposal is indicated in each case. The opinion of the process's own Review Committee is summarised where relevant (together with the page numbers in the <u>Review Committee's report</u>).

It is worth noting that the Review Committee's comments on the proposals I include below are generally negative, and that the Review Committee consists entirely of WHO staff.

I adopt the convention that red text is existing text from the existing 2005 IHR which is proposed to be removed, whereas *text in blue italics is proposed to be added*. For added clarity, red text is struck through.

The actual or proposed IHR text is given below as the bullet points. The rest is commentary.

I acknowledge <u>James Roguski</u> as a useful source of guidance. You may wish to also <u>read this</u> critique of the proposed changes to the IHR, written by two international human rights lawyers.

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; (page 12/197) (red text to be removed). Proposed by Bangladesh.
- "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; (page 12/197) (red text to be removed). Proposed by Bangladesh.

IHRRC (Review Committee) Technical Recommendation: "The proposed amendments to these definitions could be understood as aiming to change the nature of these recommendations from non-binding to binding, and giving a binding effect to WHO recommendations and requests as proposed in other articles. That change would require a fundamental reconsideration of the nature of recommendations and the process for their adoption and implementation. The Committee further notes that during a public health emergency of international concern the recommendations may work better if they are not mandatory and advises against changing the nature of recommendations." (page 26).

<u>My comment</u>: This is one of the key concerns as it would make most or all recommendations in the IHR mandatory.

Article 2 (Purpose and scope)

• 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 public health risk all risks with a potential to impact public health, and which avoid unnecessary interference with international traffic and trade. (blue text to be added). Proposed by India.

Other amendments by other countries to this para were proposed which I omit as (probably) benign.

<u>IHRRC</u> (Review Committee) <u>Technical Recommendation</u>: "The Committee considers that the proposed amendment to replace "public health risk" with "all risks with a potential to impact public health" may not increase the clarity of this Article." (page 27).

My comment: Concerns over this proposal are that "all risks with a potential to impact public health" is open-ended. Almost anything has that potential. For example, economic matters can affect public health. Some might argue that climate change also has such a potential. The concern is that all sorts of issues, including virtually all current hot political topics, would then be smuggled into the orbit of the WHO's new mandatory powers under these amended regulations. The concern is not so fanciful in view of the open espousing of the "One Health" ethos, which explicitly brings social and environmental factors into the remit of "health".

Article 3 (Principles)

• The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons 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. (red type to be removed, blue text to be added). Proposed by India.

*Other nations also added "solidarity" to this. People who have been paying attention will know that the words "equity", "inclusivity", "solidarity" and "coherence" have specific sociopolitical meanings which are belied by the cosy ambiance of these words' everyday meanings.

IHRRC Technical recommendations: "The Committee strongly recommends the retention of the existing text "full respect for the dignity, human rights and fundamental freedoms of persons" as an overarching principle in the first paragraph, and notes that the concepts of human rights, dignity and fundamental freedoms are clearly defined within the framework of treaties to which many of the States Parties to the Regulations have adhered. The inclusion of human rights in Article 3 of the current International Health Regulations (2005) was a major improvement on the previous 1969 Regulations.1 The reference to "respect for dignity, human rights and freedoms of persons" works not only as an overarching principle in Article 3, but also as a concrete reference point in the operationalization of all articles concerning public health response, response measures, additional health measures and recommendations.

The introduction of the concept of common but differentiated responsibilities and respective capabilities in paragraphs 1 and 2 and new paragraph 5 should be analysed in depth and considered with care. ... The Committee acknowledges the origin of this concept in environmental law, in particular the international legal regime on climate change, and supports the spirit of the proposal, which is intended to give normative significance and implications to the profound differences between the respective resources and capacities of States Parties." (page 28)

My comment: The attempt to explicitly drop "full respect for the dignity, human rights and fundamental freedoms of persons" is the most disturbing of all the proposals and I'm glad the IHRRC strongly recommends its retention. What will ultimately be presented for approval we have yet to see. As for the words added by India, and similar words from other nations, it is easy to read into them a jockeying for national advantage as they see a potential to use the amended regulations as a means of drawing resources or financial benefits from "the collective" (us). Moreover, the IHRRC's observations in respect of the origins of the concept of "common but differentiated responsibilities and respective capabilities" in environmental law and the international legal regime on climate change adds weight to the concerns raised under Article 2, namely that the proposed text changes to "purpose and scope" do indeed have in mind the drawing into the orbit of the WHO's new global mandatory powers a huge swathe of non-health issues.

Article 4 (responsible authorities)

- Each State Party shall designate or establish *an entity with a role of* a National IHR Focal Point and the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations. Proposed by The Russian Federation.
- States Parties shall enact or adapt legislation to provide National IHR Focal Points (NFPs) with the authority and resources to perform their functions, clearly defining the tasks and function of the entity with a role of National IHR Focal Point in implementing the obligations under these Regulations. Proposed by The Russian Federation, new para.
- 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. Alternative/additional new para proposed by Switzerland.

<u>IHRRC Technical recommendations</u>: These proposals "would impose an obligation on States Parties to establish an entity responsible for the overall implementation of the Regulations, not only the 'health measures' as required of the 'competent authority'. The institutional positioning, organization and functioning of such an authority would be a matter of sovereignty…" (page 30)

<u>My Comments</u>: Note the Review Committee's warning that the proposed obligation would extend beyond health measures. Note also that Switzerland's proposal makes reference to a similar Recommendation made in the <u>Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response (who.int).</u>

Further evidence that some nation states are using the opportunity provided by these amendments to jockey for national advantage can be found in Malaysia's proposals. Under para 7 of Article 4, Malaysia makes a proposal which their own notes liken to a clause in the UNFCC (United Nations Framework Convention on Climate Change), specifically,

"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".

This is a flowery way of saying that some countries should be obliged to provide resources, know-how and cash to other countries, whereas the latter will have other priorities. This is, of course, what "equity" means, and equity, in this sense, is the declared ethos of this exercise.

Article 11 (Provision of information by WHO)

• 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:...(various conditions)...and proposed new condition WHO determines it is necessary that such information be made available to other States Parties to make informed, timely risk assessments. (Proposed by the USA).

<u>IHRRC Technical recommendations</u>: No comment, remarkably.

My Comment: The IHR requires a great deal of information to flow from nation states to the WHO. The existing IHR does not require the WHO to share information with other states until the event in question is determined to constitute a public health emergency of international concern (PHEIC). This proposal would give the WHO the right to withhold information for as long as they deemed necessary. In short, the WHO would be in a legal position to withhold information and information flows would potentially become one-way.

Article 12 (Determination of a public health emergency of international concern)

• 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 (PHEIC), the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the "Emergency Committee" on appropriate temporary recommendations. (page 189/197). Proposed by the USA. (red type to be removed).

<u>IHRRC Technical Recommendation</u>: "Proposed amendments...dilute the consultation requirements with the State Party in whose territory the event occurs, by removing the obligation of the Director-General to convene an Emergency Committee, and by removing the agreement between the Director-General and the State Party. It is unclear what the purpose is of the proposed amendments to eliminate the consultation with the State Party in whose territory the event occurs... Excluding this consultative step can result in sovereignty concerns from the State Party in whose territory the event occurs." (page 47)

My Comment: The ceding of power unilaterally to the WHO to declare a PHEIC clearly robs the nation in question of sovereignty. The nation in question may not agree that the situation even constitutes a national health emergency, let alone an international one, but will be obliged by the WHO to enact emergency measures despite this disagreement. This is clearly unacceptable, and may conflict with the national legislative conditions under which a state is permitted to invoke emergency powers.

Article 13 (Public health response)

• 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. Proposed by Eswatini on behalf of the Member States of the WHO African Region.

<u>IHRRC Technical Recommendation</u>: "The proposal in paragraph 1 would impose a new obligation on developed States Parties to offer assistance. ... high- or even middle-income countries may also have concerns about such an open-ended obligation, which may imply that all developed States Parties must offer assistance to all developing States Parties." (page 50)

"The obligation for States Parties to accept or justify rejecting WHO's offer of assistance may undermine the sovereignty of the State Party concerned and risks undermining the purpose and spirit of genuine collaboration and assistance. It is the prerogative of States Parties to request or accept assistance, not to be the recipient of unsolicited offers, accompanied by an obligation to justify the refusal and an unrealistic time frame in which to respond. Furthermore, the proposal that WHO share the rationale for rejection, while intended to promote transparency, may not be conducive to an atmosphere that fosters collaboration. It could be interpreted as a default approach of mistrust to States Parties that reject offers of assistance." (page 50). "...some Committee members also consider that this amendment poses challenges for the sovereignty of States Parties." (page 51)

My Comment: What the African proposal embodies is, of course, exactly that "equity" means, and this has been declared to be the ruling ethos behind the amendments. It remains to be seen whether amendments like this remain in what is ultimately presented for approval by the WHA. This will depend, not only on pressure from developing countries, driven by national self-interest, but also on whether there is robust push-back from developed nations. It is easy to envisage that developed nations might be more than happy to accede to these proposals if their representatives are driven by an ideology which aligns with the "One Health" / "equity" ethos. This will depend upon one or two individual persons per country who are the representatives on the negotiation or drafting working groups, individuals whose identity we are not permitted to know.

New Article 13A (WHO Led International Public Health Response)

Several new paras, of which I focus on one...

• 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 the allocation plan. Proposed by Bangladesh and the nations of the African Region, and similar proposals by Malaysia.

<u>My Comment</u>: This is another proposal by poorer nations under the equity category, essentially a redistribution charter. The IHRRC savaged these new proposals...

<u>IHRRC Technical Recommendation</u>: "WHO recommendations, as currently stated under Articles 15 and 16, were not envisioned for the purposes of establishing a medicines allocation mechanism or otherwise directing States Parties on increasing access to health products." (page 52)

"The Committee has concerns regarding the proposal in paragraph 1 to use Article 15 (temporary recommendations) for the purposes of establishing an 'allocation mechanism'. Temporary recommendations, as (currently) defined under Article 1, are 'non-binding advice and do not authorize WHO to direct States'" (page 53).

"This proposal also renders mandatory the temporary and standing recommendations addressed under Articles 15 and 16. The State Party making this proposal has also provided corresponding proposals to change the definitions of temporary and standing recommendations under Article 1." (page 55/97) (This refers to the proposed deletion of 'non-binding' from the definitions in Article 1 which would be required for consistency).

"More fundamentally, it remains unclear how WHO could discharge the unprecedented set of new responsibilities attributed to it relating to health products and know-how under this proposed amendment, as these may arguably exceed its constitutional mandate. In order to be legally feasible, this amendment will require coherence with States Parties' relevant national laws and other international obligations." (page 55). (My comment: The proposal is effectively suggesting central planning of worldwide production. It would be unworkable).

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

The concern here relates to the proposed changes to make Recommendations mandatory rather than non-binding, as at present. The following, currently non-binding Recommendations, would become obligatory if this view prevails...

- 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.

<u>My Comment</u>: The above, if mandatory and imposed by WHO upon all member states, are one of the key concerns. These are clearly totalitarian powers.

Article 23 (Health measures on arrival and departure)

- ...a State Party may require for public health purposes, whether in paper based or digital format, on arrival or departure:... 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 including documents containing information on a laboratory test for a pathogen and/or information on vaccination against a disease, ... Proposed by India.
- Documents containing information concerning traveller's destination (hereinafter Passenger Locator Forms, PLFs) should preferably be produced in digital form...
 Documents meeting such requirements shall be recognized and accepted by all Parties.
 Proposed by the Czech Republic and Member States of the EU.

<u>IHRRC Technical Recommendation</u>: "Regarding the proposal to introduce the possibility for health documents to include information related to laboratory tests... the Committee is concerned that such a requirement may overburden travellers, and may even raise ethical and discrimination-related concerns." (page 62)

My Comment: The proposed additions again include an open-ended obligation that "lower-income countries shall receive assistance", another levering of the equity ethos. The issue here, as always, is not the desirability of assisting those nations less able to help themselves, but the replacement of (arguably) ethical obligations with legal ones. There is a profound issue here: if the opportunity to behave ethically is denied by making behaviours compulsory, morality itself is denied. Compulsion leads to demoralisation.

Article 35 (General rule)

 Health documents meeting the conditions approved by the Health Assembly shall be recognized and accepted by all Parties. Proposed by the Czech Republic and Member States of the EU.

<u>IHRRC Technical Recommendation</u>: "Introducing an obligation for States Parties to recognize the health documents of other States Parties may pose many practical difficulties, especially considering that domestic legislation concerning privacy and personal information protection differs from one State Party to the next. Another concern, depending on how the amendments are implemented, is the appropriate level of protection of personal data under the applicable regional and international instruments." (page 66)

My Comment: Quoting from Roguski, under this proposal, "nations would be authorized to infringe upon the rights of citizens from other nations. Our unalienable right to privacy, especially in regards to health issues, would clearly be violated by the digitization of medical records and an ever-increasing assault on bodily autonomy".

Article 42 Implementation of health measures

• Health measures taken pursuant to these Regulations, including the recommendations made under Article 15 and 16, shall be initiated and completed without delay by all State Parties, and applied in a transparent, equitable and non-discriminatory manner. State Parties shall also take measures to ensure Non-State Actors operating in their respective territories comply with such measures. Proposed by Malasia. (My comment: Note that Articles 15 and 16 relate to Recommendations, which would become mandatory under the proposed changes to Article 1).

<u>IHRRC Technical Recommendation</u>: "The proposed amendment to include a reference to temporary and standing recommendations seems to make application of these recommendations obligatory... The Committee is concerned that the proposed amendment goes too far in implying that States Parties must oblige, through legislation or other regulatory measures, non-State actors to comply with measures under the Regulations. While the reference to compliance by non-State actors strengthens the spirit of Article 42, there may be feasibility limits due to the regulatory powers of States under national and international law." (page 67).

<u>My Comment</u>: Note the proposed insertion of the word "equitable" by Malaysia, indicating a knowing attitude to the meaning this term now carries. Most importantly, this is another instance of Recommendations being converted into legally-binding orders.

Article 43 (Additional health measures)

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.

• 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. Proposed by Eswatini on behalf of the Member States of the WHO African Region.

<u>IHRRC Technical Recommendation</u>: "This Committee is concerned that these proposals may unduly impinge on the sovereignty of States Parties and give binding effects to what are supposed to be recommendations." (page 68)

My Comment: Yet again the issue of loss of sovereignty, and yet again the levering of "equity" for national advantage. In the case of the second proposal, above, poorer nations, via the WHO, would be able to frustrate other nations implementing "additional health measures" by obliging them to give priority to resourcing poorer nations. It is not fanciful to envisage this preventing states from implementing achievable and beneficial measures in their own territory. This is the unacceptable face of "equity".

Proposed New Article 44A (Financial Mechanism for Equity in Health Emergency Preparedness and Response)

• A mechanism shall be established for providing the financial resources on a grant or concessional basis to developing countries... The World Health Assembly shall make arrangements to implement the above-mentioned provisions, within 24 months of the adoption of this provision. Proposed by Eswatini on behalf of the Member States of the WHO African Region.

<u>IHRRC Technical Recommendation</u>: "The Committee notes a divergence of views as to whether WHO has a financing function... The Committee... cautions against creating an explicit financing function for WHO under the Regulations." (page 71).

My Comment: This is the levering of "equity" again. Well, it's not as if financial aid to African nations is ever misappropriated by corrupt authorities, is it?

Proposed New Chapter IV Article 53 (The Compliance Committee)

The State Parties shall establish a Compliance Committee that shall be responsible for...(a long list of issues)...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. Proposed by the USA.

<u>IHRRC Technical Recommendation</u>: "The proposal to establish a 'compliance committee' seems to give significant powers to 36 appointed government experts, without clearly explaining the rules under which such a committee would function... In addition, the Committee notes that the potential power given to the 'compliance committee' proposed in Article 53 to freely gather and use information, is far-reaching." (page 76)

Annexes

In proposals to amend the Annexes, e.g., Annex 1 and Annex 10, can be found further specifics regarding the expectations on "developed countries" under "equity". Despite providing no definition of "developed nations" versus "developing nations", the former would be obligated to provide substantial assistance to the latter. Perhaps Italy would be required to provide free resources to China, for example? And this is potentially to be made mandatory for unspecified problems and against no provided metrics of need or efficacy.