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.**

(…)