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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: COUNCIL DECISION on the position to be adopted on behalf of the European Union in the seventy-fifth session of the World Health Assembly as regards certain amendments to the International Health Regulations (2005)

COUNCIL DECISION (EU) 2022/...

of ...

**on the position to be adopted on behalf of the European Union in the seventy-fifth session
of the World Health Assembly as regards certain amendments
to the International Health Regulations (2005)**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular
Article 168(5), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) In the field of public health, Union action, which is to complement national policies, is to be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action is also to cover monitoring, early warning of and combating serious cross-border threats to health. To that effect, the Union and the Member States are to foster cooperation with third countries and the competent international organisations in the sphere of public health.
- (2) The International Health Regulations ('IHR') (2005) were adopted by the World Health Assembly of the World Health Organization ('WHO') on 23 May 2005 and entered into force on 15 June 2007.
- (3) On 3 March 2022, the Council adopted Decision (EU) 2022/451 authorising the opening of negotiations on behalf of the European Union for an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the International Health Regulations (2005)¹.
- (4) The World Health Assembly, during its seventy-fifth session starting on 22 May 2022, is to adopt a decision on the amendment of Article 59 of the IHR (2005), in order to shorten the period necessary to further amend the provisions of the IHR (2005), notably by reducing from twenty-four to twelve months the period for the entry into force of the amendments thereof, together with related amendments to Article 55(3), Articles 61 and 62 and Article 63(1), which are necessary to bring those articles in line with the envisaged amendments to Article 59 of the IHR (2005).

¹ OJ L 92, 21.3.2022, p. 1.

- (5) Pursuant to Article 60(b) of the WHO Constitution, the World Health Assembly may adopt decisions by a majority of the members of the WHO present and voting.
- (6) The Union supports the objective of shortening the period necessary to further amend the provisions of the IHR (2005), and considers that the amendments to Article 59 of the IHR (2005), as well as to Article 55(3), Articles 61 and 62 and Article 63(1) thereof, will allow addressing changing needs more rapidly in the areas covered by the IHR (2005).
- (7) It is appropriate to establish, for matters falling within Union competence, the position to be adopted on the Union's behalf in the World Health Assembly with respect to the decision, which the World Health Assembly is called upon to adopt, with a view to amending Article 59 of the IHR (2005), as well as Article 55(3), Articles 61 and 62 and Article 63(1) of the IHR (2005).
- (8) The Union's position is to be expressed by the Member States of the Union that are members of the WHO, acting jointly,

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on the European Union's behalf during the seventy-fifth session of the World Health Assembly as regards amendments to Article 59 of the IHR (2005), and related amendments to Article 55(3), Articles 61 and 62 and Article 63(1) thereof, shall be in accordance with the Annex to this Decision.

Adjustments to the amendments set out in the Annex to this Decision, which do not jeopardise the attainment of the objective of those amendments and do not result in shortening further the generally applicable periods indicated in the Annex, may be agreed by the Commission in consultation with the Member States and without further decision of the Council.

Article 2

The position referred to in Article 1 shall be expressed by the Member States of the Union that are members of the World Health Organization, acting jointly on behalf of the Union.

Article 3

This Decision shall enter into force on the date of its adoption.

Done at ...,

For the Council

The President

ANNEX

A. Amendments to Article 59 of the International Health Regulations (2005)

The Union supports the following amendments to Article 59 of the International Health Regulations (2005) (the deleted text is in square brackets and the new text is underlined):

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.

- 1bis. 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 9 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 12 months after the date of notification referred to in paragraph 1 bis of this Article, except for:
- (...)
- (b) a State that has made a reservation, for which these Regulations or an amendment thereto shall enter into force as provided in Article 62;
- (...)
3. If a State is not able to adjust its domestic legislative and administrative arrangements fully with these Regulations or an amendment thereto within the periods set out in paragraph 2 of this Article, as applicable, that State shall submit within the applicable period specified in paragraph 1 or 1 bis 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 and no later than 6 months after the entry into force of an amendment to these Regulations for that State Party.

B. Amendments to Article 55(3), Articles 61 and 62 and Article 63(1) of the International Health Regulations (2005)

The Union also supports the following technical amendments to Article 55(3), Articles 61 and 62 and Article 63(1) of the International Health Regulations (2005) (the deleted text is in square brackets and the new text is underlined):

Article 55 Amendments

(...)

3. Amendments to the Regulations adopted by the Health Assembly pursuant to this Article shall come into force for all States Parties on the same terms, and subject to the same rights and obligations, as provided for in Article 22 of the Constitution of WHO and Article 59 to 64 of these Regulations, subject to the periods provided for in those Articles with respect to amendments to these Regulations.

Article 61 Rejection

If a State notifies the Director-General of its rejection of these Regulations or of an amendment thereto within the applicable period provided in paragraph 1 or 1bis of Article 59, these Regulations or the amendment concerned shall not enter into force with respect to that State. Any international sanitary agreement or regulations listed in Article 58 to which such State is already a party shall remain in force as far as such State is concerned.

Article 62 Reservation

1. States may make reservations to these Regulations or an amendment thereto in accordance with this Article. Such reservations shall not be incompatible with the object and purpose of these Regulations.
2. Reservations to these Regulations or an amendment thereto shall be notified to the Director-General in accordance with paragraphs 1 and 1bis of Article 59 and Article 60, paragraph 1 of Article 63 or paragraph 1 of Article 64, as the case may be. A State not a Member of WHO shall notify the Director-General of any reservation with its notification of acceptance of these Regulations. States formulating reservations should provide the Director-General with reasons for the reservations.
3. A rejection in part of these Regulations or an amendment thereto shall be considered as a reservation.



4. The Director-General shall, in accordance with paragraph 2 of Article 65, issue notification of each reservation received pursuant to paragraph 2 of this Article. The Director-General shall:

(...)

(c) if the reservation was made to an amendment to these Regulations, request States Parties to notify him or her within three months of any objection to the reservation. States Parties objecting to a reservation to an amendment to these Regulations should provide the Director-General with reasons for the objection.

States objecting to a reservation should provide the Director-General with reasons for the objection.

5. After this period, the Director-General shall notify all States Parties of the objections he or she has received with regard to reservations. In the case of a reservation made to these Regulations, [U]unless by the end of six months from the date of the notification referred to in paragraph 4 of this Article a reservation has been objected to by one-third of the States referred to in paragraph 4 of this Article, it shall be deemed to be accepted and these Regulations shall enter into force for the reserving State, subject to the reservation. In the case of a reservation made to an amendment to these Regulations, unless by the end of three months from the date of the notification referred to in paragraph 4 of this Article a reservation has been objected to by one-third of the States referred to in paragraph 4 of this Article, it shall be deemed to be accepted and the amendment shall enter into force for the reserving State, subject to the reservation.
6. If at least one-third of the States referred to in paragraph 4 of this Article object to the reservation to these Regulations by the end of six months from the date of the notification referred to in paragraph 4 of this Article[;] or, in the case of a reservation to an amendment to these Regulations, by the end of three months from the date of the notification referred to in paragraph 4 of this Article, the Director-General shall notify the reserving State with a view to its considering withdrawing the reservation within three months from the date of the notification by the Director-General.

(...)

9. The Director-General shall submit the reservation, and the views of the Review Committee if applicable, to the Health Assembly for its consideration. If the Health Assembly, by a majority vote, objects to the reservation on the ground that it is incompatible with the object and purpose of these Regulations, the reservation shall not be accepted and these Regulations or an amendment thereto shall enter into force for the reserving State only after it withdraws its reservation pursuant to Article 63. If the Health Assembly accepts the reservation, these Regulations or an amendment thereto shall enter into force for the reserving State, subject to its reservation.

Article 63 Withdrawal of rejection and reservation

1. A rejection made under Article 61 may at any time be withdrawn by a State by notifying the Director-General. In such cases, these Regulations or an amendment thereto, as applicable, shall enter into force with regard to that State upon receipt by the Director-General of the notification, except where the State makes a reservation when withdrawing its rejection, in which case these Regulations or an amendment thereto, as applicable, shall enter into force as provided in Article 62. In no case shall these Regulations enter into force in respect to that State earlier than 24 months after the date of notification referred to in paragraph 1 of Article 59 and in no case shall an amendment to these Regulations enter into force in respect to that State earlier than 12 months after the date of notification referred to in paragraph 1bis of Article 59.

(...)
