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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	General Secretariat of the Council
No. Cion doc.:	COM(2022) 214 final
Subject:	ANNEX to the Proposal for a Council Decision on the position to be taken 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)

Delegations will find attached document COM(2022) 214 final.

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EUROPEAN
COMMISSION

Brussels, 6.5.2022
COM(2022) 214 final

ANNEX

ANNEX

to the

Proposal for a Council Decision

on the position to be taken 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)

ANNEX

The Union supports the following amendments to Article 59 of the International Health Regulations (2005), indicated in bold face and strikeout:

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 1bis 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 1bis** 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**.

The Union also supports the technical amendments to Articles 55(3), 61, 62 and 63(1) of the International Health Regulations (2005). The amendments to these articles are indicated in bold face and strikeout:

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 paragraph**s** 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~~u**nless 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.**

(…)