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

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2022/0152 (NLE)

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)

EXPLANATORY MEMORANDUM

1. SUBJECT MATTER OF THE PROPOSAL

This proposal concerns the decision establishing the position to be taken on the Union's behalf at the seventy-fifth session of the World Health Assembly in connection with the envisaged adoption of a decision related to the amendment of Article 59 of the International Health Regulations ('IHR') (2005). The decision, which the World Health Assembly is called upon to adopt, also covers related technical amendments to Articles 55(3), 61, 62 and 63(1) of the IHR (2005), which are necessary to bring these articles into conformity with the envisaged amendments to Article 59.

2. CONTEXT OF THE PROPOSAL

2.1. The World Health Organization

The World Health Organization ('WHO') was established as a specialized United Nations health agency within the terms of Article 57 of the Charter of the United Nations. The Constitution[1] of the World Health Organization entered into force on 7 April 1948 and defines the main objective of the organization to be the "attainment by all peoples of the highest possible level of health".

The European Union ('Union') has an informal observer status at the WHO. This status has been established through an exchange of letters published in the Official Journal on 4 January 2001[2]. The exchange included a "Memorandum concerning the framework and arrangements for cooperation between the World Health Organization and the Commission of the European Communities". All EU Member States are members of WHO.

2.2. The World Health Assembly

The World Health Assembly is the main governing body of the WHO. It is held annually in Geneva, Switzerland. The seventy–fifth session of the World Health Assembly will take place from 22 to 28 May 2022.

According to Article 59 of the WHO Constitution, each member of WHO has one vote in the World Health Assembly. Decisions are made by a majority of members of WHO present and voting, except a few situations outlined in Article 60 of the WHO Constitution, where a two-thirds majority is needed. In practice, every effort is made to reach agreement by consensus. The Union has no voting rights.

Under Article 21 of WHO Constitution, the World Health Assembly has authority to adopt regulations concerning inter alia sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease.

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1 BASIC DOCUMENTS (who.int).

2 OJ C 1, 4.1.2001, p. 7–11.

2.3. The IHR (2005) and their proposed revision through potential amendments

The IHR were adopted by the World Health Assembly in 1969[3], having been preceded by the International Sanitary Regulations adopted in 1951. The 1969 Regulations, which initially covered six "*quarantinable diseases*" were amended in 1973[4] and 1981[5], primarily to reduce the number of covered diseases from six to three (yellow fever, plague and cholera) and to mark the global eradication of smallpox.

Following the emergence of severe acute respiratory syndrome, consensus emerged on the need to review the IHR. The IHR (2005) were adopted by the World Health Assembly on 23 May 2005[6]. They entered into force on 15 June 2007.

In recent years, following first the Ebola outbreak, and then the COVID-19 pandemic, several independent review committees and panels have pointed out the need to strengthen the implementation of, compliance with, and modernization of the IHR (2005)[7].

Under Article 55 of the IHR (2005), amendments to the Regulations may be proposed by any State Party or by the WHO Director-General and shall be submitted to the World Health Assembly for consideration. The text of any proposed amendment shall be communicated to all State Parties by the Director-General at least four months before the World Health Assembly at which it is proposed for consideration.

On 20 January 2022, the Director-General of the WHO communicated to the State Parties to the IHR (2005) an amending proposal put forward by the United States of America pursuant to Article 55(1) of the IHR (2005). The proposal concerns amendments to Articles 5, 6, 9, 10, 11, 12, 13, 15, 18, 48, 49, 53 and 59 of the IHR (2005).

On 26 January 2022, with the adoption of Decision EB150(3)[8], the WHO Executive Board urged members of WHO and, where applicable, regional economic integration organisations, such as the Union, to take all appropriate measures to consider potential amendments to the IHR (2005).

On 3 March 2022, with the adoption of Council Decision 2022/451[9], the Council of the European Union authorised the opening of negotiations on behalf of the Union for an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the IHR (2005). The Decision appoints the

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3 See WHO Official Records, No. 176, 1969, resolution WHA22.46 and Annex I.

4 See WHO Official Records, No. 209, 1973, resolution WHA26.55.

5 See document WHA34/1981/REC/1 resolution WHA34.13; see also WHO Official Records, No. 217, 1974, resolution WHA27.45, and resolution EB67.R13, Amendment of the International Health Regulations (1969).

6 See resolution WHA56.28.

7 In particular in relation to the COVID-19 pandemic: the Independent Panel for Pandemic Preparedness and Response, the Review Committee on the Functioning of the International Health Regulations (2005), the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme, and the Global Preparedness Monitoring Board.

8 Strengthening of the International Health Regulations (2005) through a process for revising the Regulations through potential amendments (who.int).

9 OJ L 92, 21.3.2022, p. 1–2.

Commission as negotiator on behalf of the Union for matters falling within Union competence and sets out the negotiating directives for the conduct of the negotiations.

Following the submission of the proposed amendments by the United States, a consultative process has taken place within the WHO, in particular through informal negotiation sessions held on 16 March, 5 April and 3 May 2022, to which the European Commission participated as Union negotiator. In the course of these discussions, a consensus has emerged among members of WHO to proceed with the adoption of the amendments to Article 59 of the IHR (2005) at the seventy-fifth session of the World Health Assembly, which will start on 22 May 2022. The proposed amendments to Article 59 also require technical amendments to additional articles of the IHR (2005), i.e. Articles 55(3), 61, 62 and 63(1), which are necessary to bring these articles into conformity with the envisaged amendments to Article 59.

Negotiations on the other amendments proposed by the United States, and any additional proposals thereof, should continue after May 2022, in view of their possible adoption at the seventy-sixth session of the World Health Assembly in May 2023.

2.4. The envisaged act of the seventy-fifth session of the World Health Assembly

In May 2022, during its seventy-fifth session, the World Health Assembly is expected to adopt a decision related to the amendment of Article 59 of the IHR (2005). The amendments to Article 59 have the objective to shorten the period necessary to amend the provisions of the IHR (2005), notably by reducing the period for their entry into force from twenty-four to twelve months.

This would allow for the IHR (2005) to be amended more rapidly in the future.

The introduction of a new paragraph in Article 59, which provides for a period for rejection of, or reservations to, an amendment to the IHR (2005), also requires technical amendments to be made to Articles 55(3), 61, 62 and 63(1), which are necessary to bring these articles into conformity with the envisaged amendments to Article 59.

The envisaged act will become binding on the State Parties in accordance with Article 55(3) of the IHR (2005)[10].

3. POSITION TO BE TAKEN ON THE UNION'S BEHALF

The Union supports the proposed amendments to Article 59 of the IHR (2005), which are procedural in nature and which would allow to further amend the IHR (2005) more rapidly in order to address changing needs in the areas covered by them. The Union also supports the proposed technical amendments to Articles 55(3), 61, 62 and 63(1) of the IHR (2005), which are necessary to bring these articles into conformity with the proposed amendments to Article 59.

[10] According to Article 55(3) of the IHR (2005), "Amendments to these 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 Articles 59 to 64 of these Regulations."

3.1. Procedural legal basis

3.1.1. Principles

Article 218(9) of the Treaty on the Functioning of the European Union (TFEU) provides for the adoption of decisions establishing '*the positions to be adopted on the Union's behalf in a body set up by an agreement, when that body is called upon to adopt acts having legal effects, with the exception of acts supplementing or amending the institutional framework of the agreement*.'

Article 218(9) TFEU applies regardless of whether the Union is a member of the body or a party to the agreement[11].

The concept of '*acts having legal effects*' includes acts that have legal effects by virtue of the rules of international law governing the body in question. It also includes instruments that do not have a binding effect under international law, but that are '*capable of decisively influencing the content of the legislation adopted by the EU legislature*'[12].

3.1.2. Application to the present case

The World Health Assembly is a body set up by an agreement, namely the WHO Constitution, signed at New York on 22 July 1943.

The decision related to the amendments to Article 59 of the IHR (2005), as well as to the incidental technical amendments to Articles 55(3), 61, 62 and 63(1) thereof, which the World Health Assembly is called upon to adopt, constitutes an act having legal effects. In line with Article 22 of the WHO Constitution, the IHR (2005) are a legally binding instrument under international law. The envisaged act of the World Health Assembly, which aims at amending the IHR (2005) will be binding under international law for all State Parties of the WHO in accordance with Article 55(3) of the IHR (2005).

The envisaged act does not supplement or amend the institutional framework of the IHR (2005).

Therefore, the procedural legal basis for the proposed decision is Article 218(9) TFEU.

3.2. Substantive legal basis

3.2.1. Principles

The substantive legal basis for a decision under Article 218(9) TFEU depends primarily on the objective and content of the envisaged act in respect of which a position is taken on the Union's behalf. If the envisaged act pursues two aims or has two components and if one of those aims or components is identifiable as the main one, whereas the other is merely incidental, the decision under Article 218(9) TFEU

[11] Judgment of the Court of Justice of 7 October 2014, Germany v Council, C-399/12, ECLI:EU:C:2014:2258, paragraph 64.

[12] Id. at paragraphs 61 to 64.

must be founded on a single substantive legal basis, namely that required by the main or predominant aim or component.

3.2.2. Application to the present case

The main objective and content of the envisaged act aims at introducing a faster amendment procedure to the IHR (2005), allowing for the IHR (2005) to be amended according to changing needs in a more timely manner. The purpose and scope of the IHR (2005) are "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."

Therefore, the substantive legal basis of the proposed decision is Article 168(1), (3) and (5) TFEU.

3.3. Conclusion

The legal basis of the proposed decision should be Article 168(1), (3) and (5) TFEU, in conjunction with Article 218(9) TFEU.

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(1), (3) and (5), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) 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.

(2) Pursuant to Article 60(b) of the WHO Constitution, the World Health Assembly may adopt decisions by a majority of the members of WHO present and voting.

(3) The World Health Assembly, during its seventy-fifth session starting on 22 May 2022, is to adopt a decision related to the amendment of Article 59 of the IHR (2005) together with related amendments to Articles 55(3), 61, 62 and 63(1), which are necessary to bring these articles into conformity with the envisaged amendments to Article 59 of the IHR (2005).

(4) It is appropriate to establish the position to be taken 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, aimed at amending 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. This decision also covers related amendments to Articles 55(3), 61, 62 and 63(1) of the IHR (2005), which are necessary to bring these articles into conformity with the envisaged amendments to Article 59.

(5) The Union supports this objective, which will allow addressing changing needs more rapidly in the areas covered by the IHR (2005).

(6) The Union's position is to be expressed by the Member States of the Union that are members of WHO, acting jointly.

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf in the seventy-fifth session of the World Health Assembly as regards certain amendments to the IHR (2005) shall be in accordance with the Annex to this Decision.

Changes to the amendments set out in the Annex to this Decision, which do not jeopardize the attainment of the objective of the same amendments, may be agreed by the Commission in consultation with the Member States of the Union 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 is addressed to the Member States.

Done at Brussels,

For the Council
The President