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From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

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To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Subject: Proposal for a COUNCIL DECISION on the position to be taken on behalf of the European Union in the seventy-fourth session of the World Health Assembly

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Delegations will find attached document COM(2021) 233 final.

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Brussels, 3.5.2021  
COM(2021) 233 final

2021/0120 (NLE)

Proposal for a

**COUNCIL DECISION**

**on the position to be taken on behalf of the European Union in the seventy-fourth  
session of the World Health Assembly**

## EXPLANATORY MEMORANDUM

### **1. SUBJECT MATTER OF THE PROPOSAL**

This proposal concerns the establishment of the position to be taken on the Union's behalf at the seventy-fourth session of the World Health Assembly (WHA) in connection with the envisaged adoption of a Decision regarding the modalities/process for establishing an international treaty on the fight against pandemics.

### **2. CONTEXT OF THE PROPOSAL**

#### **2.1. The World Health Organisation**

The World Health Organisation (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<sup>1</sup> of the World Health Organisation 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 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<sup>2</sup>. 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 the WHO.

#### **2.2. The World Health Assembly**

The World Health Assembly is the main governing body of the WHO. The main functions of the World Health Assembly are to determine the policies of the WHO, appoint the Director-General, supervise financial policies, and review and approve the proposed programme budget.

The World Health Assembly is held annually in Geneva, Switzerland. The seventy-fourth session of the Assembly will take place virtually from 24 May to 1 June 2021.

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

Under Article 19 of the WHO Constitution, the World Health Assembly is given the authority to adopt conventions or agreements with respect to any matter within the competence of the Organization.

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<sup>1</sup> [BASIC DOCUMENTS \(who.int\)](https://www.who.int/about/who-constitution)

<sup>2</sup> [https://ec.europa.eu/health/sites/health/files/eu\\_world/docs/exchange\\_of\\_letters\\_2001.pdf](https://ec.europa.eu/health/sites/health/files/eu_world/docs/exchange_of_letters_2001.pdf)

### 2.3. The envisaged act of the seventy-fourth session of the World Health Assembly

In May 2021, during its seventy-fourth session, the World Health Assembly is expected to adopt a procedural Decision regarding modalities/process for establishing an international treaty on the fight against pandemics. More specifically, the purpose of the Decision is to establish an Intergovernmental Meeting to draft and negotiate a WHO Framework Convention on Pandemic Preparedness and Response for consideration by the Health Assembly under Article 19 of the WHO Constitution.

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

The EU and its Member States are leading international efforts to strengthen global health security and the World Health Organisation, in particular on preparedness and response to health emergencies, on the basis inter alia of Council Conclusions<sup>3</sup> of November 2020 on the EU's role in strengthening the WHO.

The proposal to conclude an international treaty on pandemics is currently discussed in the context of ongoing international efforts to reinforce global health security in light of lessons learnt from the pandemic. The overall aim of such a Treaty should be to secure political and legal commitment to an improved global health architecture.

Taking part in the development of such a treaty would be in line with Article 21(1) TEU that affirms that “The Union shall seek to develop relations and build partnerships with third countries, and inter-national, regional or global organisations which share the principles referred to in the first subparagraph. It shall promote multilateral solutions to common problems, in particular in the framework of the United Nations”. The European Council<sup>4</sup> in February 2021 reiterated its commitment to ‘advancing global health security, including by strengthening the World Health Organization and working towards an international treaty on pandemics within its framework’.

Although its exact scope is still not decided, the envisaged international Treaty is to address serious cross-border health threats. Such objective is likely to concern policy areas, which are rooted under Title XIV of Part III of the TFEU but also may possibly concern several other articles of the Treaty on the Functioning of the EU, for example:

- Prevention and management of zoonotic risks as part of a one-health approach, which requires linkages with environmental treaties on issues such as biodiversity and trade in endangered species, which could affect among others Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein;
- A structured system for the sharing of pathogens, genetic sequences and the resulting benefits for public health purposes (relevant EU legislation being Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union);

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<sup>3</sup> <https://data.consilium.europa.eu/doc/document/ST-12276-2020-INIT/en/pdf>

<sup>4</sup> Statement of the members of the European Council, 25-26 February 2021

- Human rights and privacy protection, particularly in light of surveillance technology, artificial intelligence and big data use for public health purposes (e.g. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data); and
- Measures to promote implementation and compliance, e.g., peer and expert review processes, mutual accountability mechanisms, verification and inspection arrangements, and dispute settlement processes.
- The Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and also the future Regulation on Cross-Border Health threats will also be affected by the future Treaty.

In view of the above and the likely affectation of the existing EU legislation in different areas of the EU's action, it is essential that the participation of the Union is assured alongside the Member States. The following principles should guide their position in the upcoming World Health Assembly discussions on a possible Decision establishing a process to draft and negotiate a WHO Framework Convention on Pandemic Preparedness and Response:

- a. The EU should be allowed to participate as contracting party to the Treaty in order to fully support the establishment of a WHO process for a new Framework Convention on Pandemic Preparedness and Response.
- b. The decision of the World Health Assembly setting out the procedural aspects of the negotiations should allow for the full participation of the EU in the negotiating process.
- c. A new Framework Convention must strengthen, be complementary to, and bring added value to the existing international framework for preventing and responding to health emergencies, taking into account the outcome of the forthcoming Global Health Summit on 21 May. In line with this, any new Framework Convention should complement and reinforce the implementation of the International Health Regulations (IHR), and address effectively any gaps in those Regulations.
- d. Discussions on a Framework Convention should take into account the outcome of the independent panels<sup>5</sup> reviewing the WHO-led international pandemic response, to ensure that it is firmly evidence-based and reflects the lessons learnt from the global experience in tackling the COVID-19 pandemic.

## **4. LEGAL BASIS**

### **4.1. Procedural legal basis**

#### *4.1.1. Principles*

Article 218(9) of the Treaty on the Functioning of the European Union (TFEU) provides for decisions establishing *'the positions to be adopted on the Union's behalf in a body set up by*

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<sup>5</sup> Notably the Independent Panel on Pandemic Preparedness and Response, the IHR Review Committee and the Independent Oversight and Advisory Committee of the WHO Health Emergencies Programme

*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<sup>6</sup>.

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*’<sup>7</sup>.

#### *4.1.2. Application to the present case*

The World Health Assembly is a body set up by an agreement, namely the Constitution of the World Health Organization, signed at New York on 22 July 1946.

The decision on modalities which the World Health Assembly is called upon to adopt constitutes an act having legal effects. The envisaged act will be binding under international law for the Members of the World Health Organization in accordance with Articles 18 and 60 of the Constitution of the World Health Organization. The envisaged act also has legal effects because it will determine the ability of the European Union to participate fully in the drafting and negotiation of a WHO framework convention on pandemic preparedness and response for consideration by the World Health Assembly under Article 19 of the WHO Constitution and to become party to this Convention as a Regional Economic Integration Organization.

The Framework Convention will have an impact on the exercise of Union competences and, depending on its scope, on the EU legislation in areas such as health, trade, free movement, data protection, internal market, development cooperation, all of which might become relevant under the Framework Convention.

The envisaged act does not supplement or amend the institutional framework of the Agreement.

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

## **4.2. Substantive legal basis**

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

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<sup>6</sup> Judgment of the Court of Justice of 7 October 2014, Germany v Council, C-399/12, ECLI:EU:C:2014:2258, paragraph 64.

<sup>7</sup> Judgment of the Court of Justice of 7 October 2014, Germany v Council, C-399/12, ECLI:EU:C:2014:2258, paragraphs 61 to 64.

#### 4.2.2. *Application to the present case*

The main objective and content of the envisaged act relate to increasing international cooperation in the field of pandemic preparedness and response within the United Nation system, with the aim to “promote multilateral solutions to common problems, in particular in the framework of the United Nations.” In particular, its principal aim is to combat major cross-border health scourges and serious cross-border threats to health.

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

#### **4.3. Conclusion**

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

Proposal for a

## **COUNCIL DECISION**

**on the position to be taken on behalf of the European Union in the seventy-fourth session of the World Health Assembly**

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

Whereas:

- (1) Article 21, paragraph 1, TEU, states that the Union shall seek to develop relations and build partnerships with third countries, and international, regional or global organisations which share the principles referred to in the first subparagraph. It shall promote multilateral solutions to common problems, in particular in the framework of the United Nations.
- (2) The Constitution of the World Health Organization ('the Agreement') entered into force on 7 April 1948.
- (3) Pursuant to Article 60 of the Agreement, the World Health Assembly may adopt decisions by a majority of the World Health Organisation (WHO) Members present and voting.
- (4) The World Health Assembly, during its seventy-fourth session starting on 24 May 2021, is to adopt a decision on the establishment of an Intergovernmental Meeting to draft and negotiate a WHO Framework Convention on Pandemic Preparedness and Response.
- (5) It is appropriate to establish the position to be taken on the Union's behalf in the World Health Assembly, as the decision of the World Health Assembly will determine the ability of the European Union to participate in the drafting and negotiation of a WHO Framework Convention on Pandemic Preparedness and Response and to potentially become a party to it as a Regional Economic Integration Organisation.
- (6) The European Union's full participation in the drafting and negotiation of a WHO Framework Convention on Pandemic Preparedness and Response and its possible accession to the Convention will contribute to increasing international cooperation in response to pandemics within the United Nations system.



- (7) The Union's position is to be expressed by the Member States of the Union that are members of the World Health Assembly,

HAS ADOPTED THIS DECISION:

*Article 1*

The position to be taken on the Union's behalf in the seventy-fourth session of the World Health Assembly shall be the following:

The European Union supports the establishment of a World Health Organisation process for a new Framework Convention on Pandemic Preparedness and Response and must be allowed to participate as contracting party to such a treaty.

The decision of the World Health Assembly setting out the procedural aspects of the negotiations must allow for the full participation of the Union in the negotiating process, in view of the Union's possible accession to the Convention as a Regional Economic Integration Organisation.

This should be achieved through the inclusion of specific references in the body text of the decision clarifying that any intergovernmental body set up to draft and negotiate the Convention shall be open to the participation of Regional Economic Integration Organisations.

*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*