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Proposal for a

COUNCIL DECISION

**on the position to be taken on behalf of the European Union in the first meeting of the
States Parties Committee for the Implementation of 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 in the first meeting of the States Parties Committee for the Implementation of the International Health Regulations (2005) in connection with the envisaged adoption of the terms of reference for the Committee and its Subcommittee, which is to be established also during the meeting.

2. CONTEXT OF THE PROPOSAL

2.1. The International Health Regulations (2005)

The International Health Regulations (2005) constitute an instrument of international law, adopted pursuant to Article 21 of the Constitution of the World Health Organization (WHO) in 2005, replacing the Regulations adopted in 1969. They entered into force in June 2007. They are legally binding on all WHO Member States, as well as the Holy See, Liechtenstein and Palestine. The Regulations provide an overarching legal framework in the field of global health security and define the Parties' rights and obligations in handling public health events and emergencies that have a cross-border potential.

The International Health Regulations (2005) have been amended in 2014, 2022 and 2024. The amendments adopted by the World Health Assembly on 1 June 2024, which led to the most substantial revision of the instrument since its entering into force, aim at strengthening the International Health Regulations (2005) in light of the lessons learned from the COVID-19 crisis, as well as from previous outbreaks. They focus on improving international cooperation and collaboration in response to health threats and provide a framework for enhanced support to ensure stronger implementation of the International Health Regulations (2005).

The Commission negotiated the 2024 amendments to the International Health Regulations (2005) on behalf of the Union, for matters falling within Union competence, based on an authorisation from the Council set out in Council Decision (EU) 2022/451 of 3 March 2022¹. On 26 May 2025, the Council adopted a Decision inviting Member States to accept, in the interest of the European Union, the amendments to the International Health Regulations (2005) contained in the Annex to Resolution WHA77.17 and adopted on 1 June 2024².

The Union is not a party to the International Health Regulations (2005), as the Regulations do not provide for the possibility of accession by regional economic integration organisations³.

All Member States are parties to the International Health Regulations (2005). The Netherlands and Slovakia have however rejected both the 2022 and 2024 amendments to the International

¹ OJ L92, 21.3.2022, p. 1.

² OJ L, 2025/1129, 4.6.2025.

³ It should be noted that the Commission had put forward in 2022 a proposal to amend Article 64 of the International Health Regulations (2005) to allow regional economic integration organisation to become parties. Such proposal did not meet the agreement of some EU Member States and was therefore not included in the package of proposed amendments to the International Health Regulations (2005) submitted by the Czech Republic to the WHO on behalf of the Union and its Member States, on 30 September 2022.

Health Regulations (2005), while Italy, the Czech Republic and Austria⁴ rejected only the 2024 amendments.

2.2. The States Parties Committee for the Implementation of the International Health Regulations (2005)

The States Parties Committee for the Implementation of the International Health Regulations (2005) is established by Article 54 bis of the International Health Regulations (2005) to facilitate the effective implementation of the Regulations, in particular of Article 44 on Collaboration, assistance and financing and Article 44 bis on the Coordinating Financial Mechanism. Article 54 bis is a new article, introduced by the 2024 amendments to the International Health Regulations (2005).

Pursuant to Article 54 bis, paragraphs 1 and 2, the Committee shall, at its first meeting, establish a Subcommittee to provide technical advice and report to the Committee itself. In addition, the Committee shall adopt, by consensus, its terms of reference, including the way that the Committee conducts its business, and the terms of reference for its Subcommittee.

Pursuant to Article 54 bis, paragraph 4, the Committee shall also adopt, at its first meeting, by consensus, the terms of reference for the Coordinating Financial Mechanism, established in Article 44 bis of the Regulations, and modalities for its operationalization and governance. The Committee may also adopt necessary working arrangements with relevant international bodies, which may support the operation of the Coordinating Financial Mechanism.

No proposal for any such terms of reference is available. The first session of the Committee is scheduled to start on 31 August 2026.

2.3. The envisaged act of the States Parties Committee for the Implementation of the International Health Regulations (2005)

During its first meeting, the States Parties Committee for the Implementation of the International Health Regulations (2005) is to adopt its own terms of reference, including the way that the Committee conducts its business, as well as the terms of reference for its Subcommittee ('the envisaged acts').

The terms of reference of the Committee and of its Subcommittee are envisaged to address various issues, such as the organisation and conduct of the meetings, the participation of observers, the preparation of the agendas, representation, or decision-making modalities, and as such they will encompass the rules of procedure for the Committee and its Subcommittee.

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

To support the proper functioning of the States Parties Committee for the Implementation of the International Health Regulations (2005) and of its Subcommittee, the Union should support the adoption of terms of reference that provide for the efficient, cost effective, transparent and orderly functioning and organisation of the meetings of the Committee and Subcommittee and that allow for the participation of the Union as an observer.

Allowing for the participation of the Union as an observer to the meetings of the States Parties Committee for the Implementation of the International Health Regulations (2005), and of its

⁴ The Netherlands, the Czech Republic and Austria indicated that they were not in a position to finalise their domestic procedure for the acceptance of the amendments by the time of their entering into force.

Subcommittee is of particular importance, as the International Health Regulations include a significant number of provisions that fall within matters for which the Union has competence on the basis of Article 168(5) of the Treaty on the Functioning of the European Union (TFEU), read together with Article 6 and Article 168(1) TFEU, to support, coordinate or supplement the actions of the Member States and in relation to which Union rules exist, in particular in the field of serious cross-border threats to health under Regulation (EU) 2022/2371.

4. LEGAL BASIS

4.1. Procedural legal basis

The States Parties Committee for the Implementation of the International Health Regulations is a body set up by an agreement, namely the International Health Regulations (2005).

The envisaged acts which the States Parties Committee for the Implementation of the International Health Regulations (2005) is called upon to adopt will produce legal effects under the International Health Regulations (2005) for the Union.

They will in particular determine whether regional economic integration organisations such as the Union can participate as observers to the States Parties Committee for the Implementation of the International Health Regulations (2005) and to its Subcommittee. Such organisational acts determining the participation of the Union in the meetings of the Committee and Subcommittee produce legal effects within the meaning of Article 218(9) TFEU.

In addition, the terms of reference to be adopted by the States Parties Committee for the Implementation of the International Health Regulations (2005), whose role is to facilitate the effective implementation of the International Health Regulations (2005), will determine the way in which decisions or recommendations will be adopted. Such decisions or recommendations are capable of affecting the interpretation or application of the provisions of the International Health Regulations (2005). In this regard, an important part of these provisions, which are legally binding for all Union Member States under international law, falls within matters for which the Union has exercised its competences on the basis of Article 168(5) TFEU, read together with Article 6 and Article 168(1) TFEU, to support, coordinate or supplement the actions of the Member States and in relation to which Union rules exist, in particular in the field of serious cross-border threats to health under Regulation (EU) 2022/2371. The States Parties Committee for the Implementation of the International Health Regulations (2005) and its Subcommittee have the competence to take decisions, which are capable to have an influence on the content of Union rules, in particular Regulation (EU) 2022/2371. Thus, the envisaged acts produce legal effects within the meaning of Article 218(9) TFEU.

The envisaged acts do not supplement or amend the institutional framework of the International Health Regulations (2005).

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

4.2. Substantive legal basis

The main objective and content of the envisaged acts relate to the establishment of a structured framework and relevant methods of work for the States Parties Committee for the Implementation of the International Health (2005) and its Subcommittee.

The purpose and scope of the International Health Regulations (2005) are “to prevent, prepare for, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade”.

Considering the objectives and substantive provisions of the International Health Regulations (2005), the substantive legal basis of the proposed decision is Article 168(5) TFEU, which provides that “the European Parliament and the Council, acting in accordance with the ordinary legislative procedure, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health”.

4.3. Conclusion

The legal basis of the proposed decision should be Article 168(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 first meeting of the States Parties Committee for the Implementation of 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) TFEU, in conjunction with Article 218(9), thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The International Health Regulations (2005) entered into force in June 2007, while the amendments to the International Health Regulations (2005) adopted on 1 June 2024 by the World Health Assembly entered into force on 19 September 2025, except for the States Parties that rejected those amendments.
- (2) The Union is not party to the International Health Regulations (2005), as only States can be Parties thereto. All Member States are parties to the International Health Regulations (2005).
- (3) Council Decision (EU) 2025/1129¹ invited Member States to accept, in the interest of the Union, without reservations, the amendments to the International Health Regulations (2005) adopted on 1 June 2024, to the extent that the Union has adopted common rules regarding the matters addressed in those amendments.
- (4) Those amendments led, among others, to the establishment of the States Parties Committee for the Implementation of the International Health Regulations (2005), with the objective of facilitating the effective implementation of the Regulations.
- (5) The States Parties Committee for the Implementation of the International Health Regulations (2005) is scheduled to adopt at its first meeting its terms of reference and the terms of reference for its Subcommittee.
- (6) The envisaged acts of the States Parties Committee for the Implementation of the International Health Regulations (2005) will, if adopted, produce legal effects for the Union, as they will determine whether regional economic integration organisations such as the Union can participate as observers to the States Parties Committee and to its Subcommittee. In addition, the envisaged acts will, if adopted, produce legal effects by determining the way in which future decisions of the States Parties Committee for the Implementation of the International Health Regulations (2005) and its Subcommittee are taken. Decisions and recommendations of the States Parties

¹ Council Decision (EU) 2025/1129 of 26 May 2025 inviting Member States to accept, in the interest of the European Union, the amendments to the International Health Regulations (2005) contained in the Annex to Resolution WHA77.17 and adopted on 1 June 2024 (OJ L, 2025/1129, 4.6.2025, ELI: <http://data.europa.eu/eli/dec/2025/1129/oj>).

Committee for the Implementation of the International Health Regulations (2005) and its Subcommittee concerning the application and interpretation of the International Health Regulations (2005), in particular of those amended provisions which were authorised pursuant to Council Decision (EU) 2025/1129, are capable of decisively influencing the content of Union rules, and in particular Regulation (EU) 2022/2371 of the European Parliament and of the Council², which provides the framework and mechanisms at the level of the Union for coordinating and strengthening prevention, preparedness and response to serious cross-border threats to health of biological, chemical, environmental and unknown origin.

- (7) It is therefore appropriate to establish the position to be taken on the Union's behalf during the States Parties Committee for the Implementation of the International Health Regulations (2005) with regard to the terms of reference for the Committee and its Subcommittee.
- (8) The Union's position is to be expressed by the Member States that are represented in the States Parties Committee for the Implementation of the International Health Regulations (2005), acting jointly, in the interest of the Union,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf in the first meeting of the States Parties Committee for the Implementation of the International Health Regulations (2005) shall be to support the adoption of the terms of reference for that Committee and for its Subcommittee provided that the final texts fulfil the following conditions:

- (a) they provide for the efficient, cost effective, transparent and orderly functioning and organisation of meetings of the Committee and its Subcommittee,
- (b) they allow for the participation of the Union to the Committee and to its Subcommittee as an observer.

Article 2

The position set out in Article 1 shall be expressed by the Member States that are represented in the States Parties Committee for the Implementation of the International Health Regulations (2005), acting jointly, in the interest of the Union.

Article 3

Minor technical changes to the position set out in Article 1 may be agreed upon without a further decision of the Council.

² Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26, ELI: <http://data.europa.eu/eli/reg/2022/2371/oj>).

Article 4

This Decision is addressed to the Member States.

Done at Brussels,

*For the Council
The President*