Basic information

2024/0299(NLE) NLE - Non-legislative enactments	Awaiting final decision
International Health Regulations (2005): authorising Member States to accept the amendments contained in the Annex to Resolution WHA77. 17 and adopted on 1 June 2024 **Subject** 4.20 Public health 4.20.01 Medicine, diseases	

Key players

European Parliament	**Committee responsible**	**Rapporteur**	**Appointed**
	SANT Public Health	JARUBAS Adam (EPP)	19/02/2025
Council of the European Union			
European Commission	**Commission DG**	**Commissioner**	
	Health and Food Safety	VÁRHELYI Olivér	

Key events

Date	Event	Reference	Summary
13/11/2024	Preparatory document	COM(2024)0541	Summary
28/01/2025	Legislative proposal published	17046/2024	Summary
10/03/2025	Committee referral announced in Parliament		
09/04/2025	Vote in committee		
14/04/2025	Committee report tabled for plenary, 1st reading/single reading	A10-0064/2025	
06/05/2025	Decision by Parliament	T10-0073/2025	Summary
06/05/2025	Results of vote in Parliament		

Technical information

Procedure reference	2024/0299(NLE)
Procedure type	NLE - Non-legislative enactments
Procedure subtype	Consent by Parliament

Legal basis	Treaty on the Functioning of the European Union TFEU 218-p6a Treaty on the Functioning of the European Union TFEU 168-p5
Stage reached in procedure	Awaiting final decision
Committee dossier	SANT/10/02076

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE770.100	04/03/2025	
Amendments tabled in committee		PE771.852	28/03/2025	
Committee report tabled for plenary, 1st reading/single reading		A10-0064/2025	14/04/2025	
Text adopted by Parliament, 1st reading/single reading		T10-0073/2025	06/05/2025	Summary

Council of the EU

Document type	Reference	Date	Summary
Legislative proposal	17046/2024	28/01/2025	Summary

European Commission

Document type	Reference	Date	Summary
Preparatory document	COM(2024)0541	13/11/2024	Summary

Additional information

Source	Document	Date
European Commission	EUR-Lex	

International Health Regulations (2005): authorising Member States to accept the amendments contained in the Annex to Resolution WHA77.17 and adopted on 1 June 2024

2024/0299(NLE) - 13/11/2024 - Preparatory document

PURPOSE: to authorise Member States to accept, in the interest of the European Union, the amendments to the International Health Regulations contained in the Annex to Resolution WHA77.17 and adopted on 1 June 2024.

PROPOSED ACT: Council Decision.

ROLE OF THE EUROPEAN PARLIAMENT: Council may adopt the act only if Parliament has given its consent to the act.

BACKGROUND: on 1 June 2024, at the Seventy-seventh session of the World Health Assembly (WHA), the Member States of the World Health Organization (WHO) adopted by consensus the various amendments to the International Health Regulations of 2005 contained in the Annex to Resolution WHA77.17 and aimed at strengthening their effectiveness.

The purpose and scope of the International Health Regulations (2005), as amended through Resolution WHA77.17, 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. The amendments to the International Health Regulations (2005) adopted through Resolution WHA77.17 aim at strengthening further global preparedness, surveillance and response to public health emergencies.

On 3 March 2022, with the adoption of Council 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), the Council of the European Union authorised the Commission to negotiate on behalf of the Union, for matters falling within Union competence, an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the International Health Regulations (2005).

The majority of amendments adopted on 1 June 2024 concern matters for which the Union is competent on the basis of Article 168(5) TFEU and in relation to which Union rules exist, in particular in the field of serious cross-border threats to health. In addition, some amendments correspond to areas covered by Union law in relation to the supply of crisis-relevant medical countermeasures, protection of public health in the event of a public health emergency, free movement of persons, civil protection, or development cooperation.

The Member States remain competent for the definition of their health policy and for the organisation and delivery of health services and medical care in accordance with Article 168(7) TFEU.

In accordance with the principle of sincere cooperation, **Member States, acting in the interest of the Union, should accept the amendments** to the International Health Regulations (2005) contained in the Annex to Resolution WHA 77.17.

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).

In these circumstances, the Union's external competence may be exercised through the Member States acting as intermediaries.

CONTENT: under this draft Council Decision, Member States are authorised to accept, without reservations, the amendments to the International Health Regulations (2005) contained in the Annex to Resolution WHA 77.17 adopted on 1 June 2024, in the interest of the Union, for the parts falling within the competence of the Union.

The amendments to the International Health Regulations (2005) adopted through Resolution WHA 77.17 are fully in line with the negotiating directives as adopted by the Council and annexed to Council Decision (EU) 2022/451, as well as complementary amendments to the International Health Regulations (2005).

The amendments include, *inter alia*, the following modifications:

- introduction of a definition of "**pandemic emergency**" as well as a related declaration mechanism, to trigger more effective international collaboration in response to events that are at risk of becoming, or have become, a pandemic;

- introduction of an explicit reference to "**preparedness**" within the scope of the International Health Regulations (2005);

- provisions aimed at enhancing the commitment to solidarity and equity including the introduction of substantive provisions strengthening **access to medical products and financing**;

- provisions aimed at improving the **timely sharing of information** in case of public emergencies, between WHO and relevant intergovernmental organisations;

- introduction of a requirement for WHO, when issuing recommendations, to take into account the need to **facilitate international travel and maintain international supply chains**;

- provisions aimed at improving coordination between conveyance operators and port authorities, with a requirement for conveyances operators to prepare, as appropriate, for the application of health measures on board, as well as during embarkation and disembarkation;

- new provisions enabling the use of **digital health certificates**.

International Health Regulations (2005): authorising Member States to accept the amendments contained in the Annex to Resolution WHA77.17 and adopted on 1 June 2024

2024/0299(NLE) - 06/05/2025 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 514 votes to 126, with 6 abstentions, a legislative resolution on the draft Council 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 2024.

The European Parliament **gave its consent** to the draft Council decision.

The International Health Regulations (2005) are the primary international legal instrument for notifying the World Health Organization (WHO) of disease outbreaks and defining the rights and obligations of parties in managing public health events and emergencies with transboundary potential. They are legally binding on 196 countries.

The Commission negotiated the amendments to the International Health Regulations (2005) on behalf of the European Union, for matters falling within the competence of the Union, on the basis of an authorisation from the Council of the European Union set out in Council Decision (EU) 2022/451 of 3 March 2022.

The amendments to the International Health Regulations (2005) adopted by Resolution WHA77.17 contribute to strengthening global public health emergency preparedness, response and surveillance and take into account lessons learned from the COVID-19 pandemic, two key priorities for EU action in the field of global health.

The majority of the amended provisions concern issues that have been regulated at EU level, in particular in the areas of serious cross-border threats to health, cooperation with competent public health organisations and the protection of public health in the event of a public health emergency.

The Council decision does not make use of the possibility for the Union to exercise its external competence in areas for which Union rules do not already exist. Member States should retain competence in respect of the matters covered by the amendments, provided that they do not affect Union rules or alter their scope or foreseeable future development.

Furthermore, in accordance with Article 168(7) of the Treaty on the Functioning of the European Union, Member States remain solely responsible for defining their health policy and for the organisation and provision of health services and medical care. Furthermore, the Council Decision does not create additional financial obligations for Member States. None of the amendments are contrary to Union law and therefore there is no need to enter reservations to amendments falling within Union competence.

International Health Regulations (2005): authorising Member States to accept the amendments contained in the Annex to Resolution WHA77.17 and adopted on 1 June 2024

2024/0299(NLE) - 28/01/2025 - Legislative proposal

PURPOSE: to invite Member States to accept, in the interest of the European Union, the amendments to the International Health Regulations contained in the Annex to Resolution WHA77.17 and adopted on 1 June 2024.

PROPOSED ACT: Council Decision.

ROLE OF THE EUROPEAN PARLIAMENT: Council may adopt the act only if Parliament has given its consent to the act.

BACKGROUND: on 3 March 2022, with the adoption of Decision (EU) 2022/4512, the Council authorised the Commission to negotiate on behalf of the Union, for matters falling within Union competence, an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the International Health Regulations (2005).

On 1 June 2024, at the Seventy-seventh session of the World Health Assembly (WHA), the Members of the World Health Organization (WHO) adopted by consensus the various amendments to the International Health Regulations (2005) contained in the Annex to Resolution WHA77.17 and aimed at strengthening their effectiveness.

Pursuant to Article 22 of the Constitution of the WHO, the amendments are to enter into force for all Members of the WHO except for such Members that have notified the Director-General of rejection or reservations within the period stated in the notice of adoption of those amendments.

A significant number of the amendments concern matters for which the Union has competence 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. In addition, some of the amendments correspond to areas covered by Union law in relation to the supply of crisis-relevant medical countermeasures as laid down in Regulation (EU) 2022/2372, to the protection of public health in the event of a public health emergency as laid down in Regulation (EU) 2022/123 of the European Parliament and of the Council, to the free movement of persons as laid down in Directive 2004/38/EC of the European Parliament and of the Council, to civil protection as set out in Decision No 1313/2013/EU of the European Parliament and of the Council, or to development cooperation as set out in Regulation (EU) 2021/947 of the European Parliament and of the Council

This Decision does not make use of the possibility for the Union to exercise its external competence with regards to areas in relation to which Union rules do not already exist. The Member States remain competent in respect of the matters covered by the amendments, in so far as the amendments do not affect Union rules or alter the scope thereof, including foreseeable future developments of those rules. In addition, Member States remain solely responsible for the definition of their health policy and for the organisation and delivery of health services and medical care, in accordance with Article 168(7) TFEU. Furthermore, this Decision does not create additional financial obligations for Member States.

None of the amendments are contrary to Union law, and it is therefore not necessary to make reservations in respect of the amendments falling within the competence of the Union.

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).

In these circumstances, and in accordance with the principle of sincere cooperation, the Union’s competence should be exercised externally through the Member States acting as intermediaries.

CONTENT: under this draft Council Decision, Member States are invited to accept, without reservations, the amendments to the International Health Regulations (2005) contained in the Annex to Resolution WHA 77.17 adopted on 1 June 2024, in the interest of the Union, for the parts falling within the competence of the Union.

The text of the amendments to the International Health Regulations (2005) is attached to this Decision.