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COVER NOTE

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

date of receipt: 5 March 2024

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

No. Cion doc.: C(2024) 1343 final

Subject: COMMISSION DELEGATED REGULATION (EU) .../... of 5.3.2024 supplementing Regulation (EU) 2022/2371 of the European Parliament and of the Council as regards assessments of the state of implementation of national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan

Delegations will find attached document C(2024) 1343 final.

Encl.: C(2024) 1343 final



Brussels, 5.3.2024
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COMMISSION DELEGATED REGULATION (EU) .../...

of 5.3.2024

supplementing Regulation (EU) 2022/2371 of the European Parliament and of the Council as regards assessments of the state of implementation of national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Prevention, preparedness, and response planning is essential to the effective monitoring, early warning and combatting of serious cross-border threats to health. Lessons learned from the COVID-19 pandemic revealed the importance of pandemic preparedness planning and broader reporting requirements. Access to timely and complete data is a precondition for prompt risk assessment and crisis mitigation. Article 7(1) of 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/EU¹ requires Member States to report on prevention, preparedness and response planning and implementation at national level and, where appropriate, cross-border interregional levels.

With the aim of supporting continuous improvement of Member States' capacities for prevention, preparedness and response planning, Regulation (EU) 2022/2371 provides for the European Centre for Disease Prevention and Control (ECDC) to conduct assessments in Member States of the state of prevention, preparedness and response in cooperation with the relevant EU agencies or bodies.

Pursuant to Article 8(1) of Regulation (EU) 2022/2371, the ECDC is to assess every 3 years the Member States' state of implementation of their national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan. Such assessments are to be based on a set of agreed indicators. The assessments are to aim to assess prevention, preparedness and response planning at national level with regard to the information referred to in Article 7(1). In accordance with Article 8(4), this delegated act supplements Regulation (EU) 2022/2371 concerning procedures, standards and criteria for the assessments to be carried out by the ECDC in accordance with Article 8(1) of Regulation (EU) 2022/2371.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In accordance with Article 31(4) of Regulation (EU) 2022/2371, the Commission, prior to adopting this delegated act, consulted experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. The Commission consulted the Expert Group on Public Health set up in accordance with Commission Decision C(2022)8816². The Expert Group on Public Health addressed this matter during two virtual meetings in the fourth quarter of 2023. The ECDC national focal points for preparedness and response and the ECDC advisory forum were also consulted.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act is consistent with the principles laid down in relevant EU legislation, in particular Regulation (EU) 2022/2371.

¹ OJ L 314, 6.12.2022, p. 26, ELI: <http://data.europa.eu/eli/reg/2022/2371/oj>

² Commission Decision of 7.12.2022 setting up a Commission expert group on public health and repealing Commission Decision setting up a Commission expert group 'Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases' OJ C, C/471, 12.12.2022, p. 8.

The delegated act should be applicable as of the date of its entry into force.

The delegated act has no additional financial implications in respect to the planned budgetary administrative provisions of the Commission and EU agencies, specifically the ECDC.

The ECDC's assessments will contribute to the Commission report on the state of play and progress on prevention, preparedness and response planning at Union level in accordance with Article 9 of Regulation (EU) 2022/2371.

COMMISSION DELEGATED REGULATION (EU) .../...

of 5.3.2024

supplementing Regulation (EU) 2022/2371 of the European Parliament and of the Council as regards assessments of the state of implementation of national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 1082/2013¹, and in particular Article 8(4) thereof,

Whereas:

- (1) Regulation (EU) 2022/2371 lays down mechanisms and structures for coordinating preparedness for and response to serious cross-border threats to health, including reporting on prevention, preparedness and response planning.
- (2) Pursuant to Article 7(1) of Regulation (EU) 2022/2371, Member States are to provide the Commission and relevant Union agencies and bodies with an updated report on prevention, preparedness, and response planning and implementation at national level, and where appropriate, cross-border interregional levels by 27 December 2023 and every 3 years thereafter. The information in that report is to be collected through responses provided using the template for the provision of information on prevention, preparedness and response planning set out in Implementing Regulation (EU) 2023/1808² and the European Centre for Disease Prevention and Control (ECDC) is to take account of that information when assessing the Member States' state of implementation of their national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan in accordance with Article 8(1) of Regulation (EU) 2022/2371. Such assessments are to be based on a set of agreed indicators and carried out in cooperation with the relevant Union agencies or bodies and aim to assess prevention, preparedness and response planning at national level regarding the information referred to in Article 7(1) of Regulation (EU) 2022/2371.
- (3) The ECDC assessment procedure should be organised in phases, which should include a desk review and a country visit, followed by an ECDC assessment report. In so far as the assessments cover areas within the remit of the Commission or of other Union

¹ OJ L 314, 6.12.2022, p. 26, ELI: <http://data.europa.eu/eli/reg/2022/2371/oj>.

² Commission Implementing Regulation (EU) 2023/1808 of 21 September 2023 setting out the template for the provision of information on prevention, preparedness and response planning in relation to serious cross-border threats to health in accordance with Regulation (EU) 2022/2371 of the European Parliament and of the Council (OJ L 234, 22.9.2023, p. 105, ELI: http://data.europa.eu/eli/reg_impl/2023/1808/oj).

agencies or bodies, the ECDC should closely cooperate with the Commission or those Union agencies or bodies. The ECDC may seek support of the Office for the European Region of the World Health Organization and experts from other Member States upon agreement with the assessed Member State.

- (4) The standards and criteria to be used for the ECDC's assessments should be based on the capacities referred to in the template for the provision of information on prevention, preparedness and response planning as set out in Implementing Regulation (EU) 2023/1808. Those capacities are needed to ensure adequate prevention, preparedness and response planning.
- (5) In carrying out its assessments, the ECDC should use the criteria with associated indicator levels and responses to the open questions provided in the template for the provision of information on prevention, preparedness and response planning as set out in Implementing Regulation (EU) 2023/1808.
- (6) The ECDC assessments should have a qualitative approach to the state of implementation of Member States' national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan.
- (7) In accordance with Article 8(2) of Regulation (EU) 2022/2371, the ECDC is to present to the Member States and to the Commission recommendations based on its assessments of the standards and criteria, addressed to Member States taking into account national respective circumstances. Those recommendations may contain recommended follow-up actions by the Member State. Those recommendations are to be addressed by the Member States in an action plan in accordance with Article 8(3) of that Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down procedures, standards and criteria for the assessments, in accordance with Article 8(1) of Regulation (EU) 2022/2371, of the Member States' state of implementation of their national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan.

Article 2

Procedures

The procedures for the assessments by ECDC of Member States' state of implementation of their national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan are set out in Annex I.

Article 3

Standards and criteria

The ECDC shall assess the Member States' state of implementation of their prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan against the standards and on the basis of the criteria set out in Annex II.

Article 4

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5.3.2024

For the Commission
The President
Ursula VON DER LEYEN