

**COMMISSION IMPLEMENTING DECISION (EU) 2017/253****of 13 February 2017****laying down procedures for the notification of alerts as part of the early warning and response system established in relation to serious cross-border threats to health and for the information exchange, consultation and coordination of responses to such threats pursuant to Decision No 1082/2013/EU of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to 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 repealing Decision No 2119/98/EC <sup>(1)</sup>, and in particular Articles 8(2) and 11(5) thereof,

Whereas:

- (1) Decision No 2119/98/EC of the European Parliament and of the Council <sup>(2)</sup> established an early warning and response system ('EWRS') as a permanent communication network between the Commission and the competent public health authorities of the Member States for the prevention and control of certain categories of communicable diseases (the 'permanent communication network'). The procedures governing the functioning of the EWRS were laid down in Commission Decision 2000/57/EC <sup>(3)</sup>.
- (2) Regulation (EC) No 851/2004 of the European Parliament and of the Council <sup>(4)</sup> established the European Centre for Disease Prevention and Control ('ECDC'). In accordance with Article 8 of that Regulation, the ECDC supports and assists the Commission by operating the EWRS. In particular, the ECDC performs daily operations and maintenance of the early warning and response system information technology application ('EWRS IT application').
- (3) Decision No 2119/98/EC was repealed and replaced by Decision No 1082/2013/EU. The new Decision re-enacted the EWRS. It also extended the scope of the permanent communication network to cover other types of biological threats, and other categories of serious cross-border threats to health including threats of chemical, environmental or unknown origin. In addition, it laid down rules on epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health.
- (4) Having regard to the revisions made to the EWRS, it is appropriate to revise and update the procedures governing its operation. In order to ensure the proper functioning and uniform application of the EWRS, it is necessary to lay down detailed procedures for information exchange. Such procedures should prevent overlapping activities or conflicting actions with existing structures and mechanisms for monitoring, for the provision of early warning and combating serious cross-border threats to health.
- (5) Pursuant to Article 15(1)(b) of Decision No 1082/2013/EU, Member States are required to designate competent authorities responsible for the notification of alerts and for the determination of response measures (EWRS competent authorities). In order to ensure coordination and consistency in communications, Member States should notify the contact details of the EWRS competent authorities to the Member States and the Commission as well as any subsequent changes to the competent authorities.
- (6) The effectiveness of the EWRS is dependent on the timely communication and exchange of appropriate information relating to the emergence or development of serious cross-border threats to health. It is therefore appropriate to specify clear time-frames in which alerts are notified and the information to be communicated.

<sup>(1)</sup> OJ L 293, 5.11.2013, p. 1.

<sup>(2)</sup> Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (OJ L 268, 3.10.1998, p. 1).

<sup>(3)</sup> Commission Decision 2000/57/EC of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council (OJ L 21, 26.1.2000, p. 32).

<sup>(4)</sup> Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

- (7) In order to avoid structural duplication of alert notifications and conflicting actions, it should be possible for other relevant rapid alert and information systems, established under other Union law provisions or the Euratom Treaty to use the EWRS to transmit alerts and information on events, which are or may pose a serious cross-border threat to health. Such a possibility should be subject to the requirement that the connection from other systems does not compromise the security of the EWRS and respects applicable data protection rules. In addition, the EWRS should be compatible with the system of data fields, workflows, and access rights of any other alert and information systems to which it is connected. The EWRS IT application should be adapted in order to allow such interoperability between different alert and information systems.
- (8) Pursuant to Article 11(1) of Decision No 1082/2013/EU, in the event of an alert being notified, Member States are to consult each other within the Health Security Committee ('HSC'), with a view to coordinating national responses and to providing risk and crisis communication. In order to facilitate the coordination of such responses and effective communication, it is appropriate to specify the procedures by which Member States coordinate responses as well as the procedures for communicating effectively to the general public and/or to healthcare professionals.
- (9) The European Data Protection Supervisor was consulted in accordance with Article 28(1) of Regulation (EC) No 45/2001 of the European Parliament and of the Council. <sup>(1)</sup>
- (10) Directive 95/46/EC of the European Parliament and of the Council <sup>(2)</sup> and Regulation (EC) No 45/2001 should be applied in the context of the operation of the EWRS.
- (11) The measures provided for in this Decision are in accordance with the opinion of the Committee on serious cross-border threats to health set by Article 18 of Decision No 1082/2013/EU.
- (12) Decision 2000/57/EC should therefore be repealed and replaced,

HAS ADOPTED THIS DECISION:

#### *Article 1*

#### **EWRS competent authorities**

1. The Commission shall grant to the EWRS competent authorities, designated in accordance with Article 15(1)(b) of Decision No 1082/2013/EU, access to the early warning and response system established pursuant to Article 8 of Decision No 1082/2013/EU.
2. Member States shall ensure that effective communication channels are established between the EWRS competent authorities and any other relevant competent authorities within their jurisdiction in order to promptly identify serious cross-border threats to health fulfilling the criteria laid down in Article 9(1) and (2) of Decision No 1082/2013/EU.

#### *Article 2*

#### **Alert notifications in the EWRS**

1. Where a Member State or the Commission becomes aware of the emergence or development of a serious cross-border threat to health within the meaning of Article 9(1) of Decision No 1082/2013/EU, it shall introduce the alert referred to in that Article without delay and in any event no later than 24 hours from when it first became aware of the threat.

<sup>(1)</sup> Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

<sup>(2)</sup> Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

2. The Member State or the Commission may inform the Health Security Committee ('HSC') of the introduction of an alert.
3. The notification obligation referred to in paragraph 1, shall not affect the notification obligation laid down in Article 9(2) of Decision No 1082/2013/EU.
4. The fact that not all relevant information, as indicated in Article 9(3) of that Decision, may be available shall not delay the notification of an alert.
5. The alert referred to in paragraph 1 shall specify how the criteria laid down in Article 9(1) of Decision No 1082/2013/EU are fulfilled.
6. Where, following an alert notification, a Member State or the Commission wishes to communicate available relevant information for coordination purposes pursuant to Article 9(3) of Decision No 1082/2013/EU, it shall use the ad hoc functionality of the EWRS to post a 'comment' in reply to the initial notification message.

#### *Article 3*

### **Other Union rapid alert and information systems**

1. The alert notification referred to in Article 2(1) shall specify whether the threat identified has previously been notified through other alert or information systems at Union level or under the Euratom Treaty.
2. Where a serious cross-border threat to health is communicated through more than one Union alert or information system, the Commission shall indicate through the EWRS the lead system for the specific type of information exchange.
3. For the purposes of this Article, other alert and information systems at Union level or under the Euratom Treaty shall include the systems set out in the Annex.

#### *Article 4*

### **Coordination of national responses to serious cross-border threats to health**

1. Where a request for consultation is made under Article 11(1)(a) of Decision No 1082/2013/EU for the purposes of coordinating the response to a serious cross-border threat to health, the Commission shall arrange for the consultation to be held within the HSC within 2 working days of the request depending on the urgency related to the severity of that threat.
2. The Commission shall inform the HSC of the request and make available to the HSC any information relevant to the threat in addition to that already communicated through the EWRS.
3. Member States shall also provide in writing any available information relevant to the threat, in addition to that already communicated through the EWRS including public health measures, or other measures, that have been taken or are intended to be taken.
4. The HSC shall examine all the information available relating to the particular threat, including alert notifications, risk assessments, and other information communicated by Member States or the Commission either through the EWRS or the HSC, including information about public health measures that have been taken or are intended to be taken. Such an examination shall be concluded without delay.
5. Member States when considering or taking public health measures to combat serious cross-border threats to health shall take account of the outcome of examination carried out within the framework of the consultation of the HSC.

*Article 5***Risk and crisis communication**

1. Following a request for consultation under Article 11(1)(b) of Decision No 1082/2013/EU, Member States shall consult each other within the HSC and develop and suggest the content and form of risk and crisis communications to be provided by the Member States to the general public and/or to healthcare professionals. Member States may adapt the communications according to their needs and circumstances.
2. Member States that have already conveyed risk and crisis communications relating to a serious cross-border threat to health shall inform the HSC and the Commission, in writing, of the content of such communications.

*Article 6***Deactivation of the alert notification**

Where the conditions which justified the introduction of an alert pursuant to Article 9(1) of Decision No 1082/2013/EU cease to exist, the alert shall be deactivated by the Member State that introduced the alert, or by the Commission in the event that the alert was introduced by the Commission. Deactivation of an alert shall only take place after all the Member States concerned by the alert have agreed to such deactivation.

*Article 7***Repeal of Decision 2000/57/EC**

1. Decision 2000/57/EC is repealed.
2. References to the repealed Decision shall be construed as references to this Decision.

*Article 8***Entry into force**

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

Done at Brussels, 13 February 2017.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

## ANNEX

**Non-exhaustive list of alert and information systems at union level to be progressively linked with EWRS**

This Annex lists rapid alert and information systems which are currently in place at Union level or under the Euratom Treaty and which may be relevant for receiving alerts of and information on events which are or may pose a serious cross border threat to health:

- Animal Disease Notification System (ADNS), to register and document the situation of important infectious animal diseases;
  - Commission's cross sectoral warning system (ARGUS), a Commission internal Rapid Alert System allowing all Commission Directorate-Generals to share key information in the event of an emergency/crisis and to enable internal coordination;
  - Common Emergency Communication and Information System (CECIS), for civil protection and marine pollution accidents;
  - European Community Urgent Radiological Information Exchange (ECURIE), to notify counter-measures to protect against the effects of a radiological or nuclear accident;
  - Major Accident Reporting System (EMARS), to facilitate the exchange of lessons learned from accidents and near misses involving dangerous substances in order to improve chemical accident prevention and mitigation of potential consequences;
  - European Notification System for Plant Health Interceptions (EUROPHYT), dealing with interceptions for plant health reasons of consignments of plants and plant products imported into the Union or being traded within the Union;
  - Rapid Alert for Blood and Blood Components (RAB), for the exchange of information to prevent or contain cross-border incidents linked to blood transfusions;
  - Rapid Alert System for Non-food Dangerous Products (RAPEX), for the exchange of information on products posing a risk to health and safety of consumers;
  - Rapid Alert System for Food and Feed (RASFF) platform, for the notification of risks to human health deriving from food or feed;
  - Rapid Alert for Tissues and Cells (RATC) platform for the exchange of information and measures related to human tissues or cells transferred across borders for patients;
  - European Information Network on Drugs and Drug Addiction (Reitox), to collect and report information on the drug phenomenon across Europe.
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