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To: European Data Protection Supervisor
<EDPS@edps.europa.eu>
[REDACTED] SG DATA
PROTECTION OFFICER (EC) <DATA-PROTECTION-
[REDACTED]
[REDACTED]
CC: SANTE DATA PROTECTION COORDINATOR (EC) <SANTE-
DATA-PROTECTION-COORDINATOR@ec.europa.eu>;
[REDACTED]
[REDACTED]
[REDACTED]
Sent at: 30/07/15 09:30:21
Subject: Consultation on the COMMISSION IMPLEMENTING
DECISION with regard to procedures for the functioning
of the early warning and response system

Dear Mr Buttarelli,
Please find enclosed the letter from Mr John F. Ryan, Acting Director of the Public Health Directorate.

I would like to inform you that the draft COMMISSION IMPLEMENTING DECISION with regard to procedures for the functioning of the early warning and response system for notifying alerts in relation to serious cross border threats to health pursuant to Decision 1082/2013/EU of the European Parliament and of the Council and repealing Decision 2000/57/EC is still in the internal consultation within DG SANTE and we would appreciate to receive your approval of or comments on the implementing decision by 24 August.

Kind regards,

[REDACTED]
[REDACTED]



European Commission
DG Health and Food Safety
Directorate C - Public Health

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Director

Luxembourg,
sante.ddg1.c.3 (2015) 2709019

Mr Giovanni Buttarelli
Supervisor
European Data Protection
Supervisor
Brussels

Subject: Opinion of the European Data Protection Supervisor on the draft COMMISSION IMPLEMENTING DECISION with regard to procedures for the functioning of the early warning and response system for notifying alerts in relation to serious cross-border threats to health pursuant to Decision 1082/2013/EU of the European Parliament and of the Council and repealing Decision 2000/57/EC

Dear Mr Buttarelli,

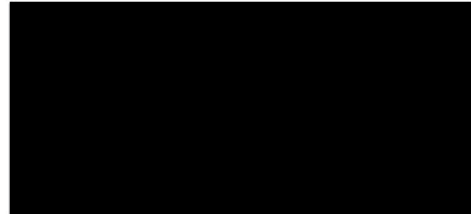
Please find enclosed the draft of the Commission Implementing Decision with regard to procedures for the functioning of the early warning and response system for notifying alerts in relation to serious cross-border threats to health pursuant to Decision 1082/2013/EU of the European Parliament and the Council on serious cross border threats to health, and repealing Commission Decision 2000/57/EC.

This decision addresses the procedures for the notification of alerts through the Early Warning and Response System (EWRS) taking into account the new provisions of Decision 1082/2013/EU. These procedures are deemed necessary in view of the wider scope of Decision 1082/2013/EU, which extends the application of the EWRS to threats caused by biological, chemical, environmental and unknown events. In addition, the implementing decision includes procedures which address the obligation of sharing risk assessment related to the events notified through the EWRS and the need to link the EWRS with other alerting systems of the Commission. Finally, it includes the procedures for personal data protection, in line with Commission Decision 2000/57/EC that will be repealed.

In case you need further information do not hesitate to contact [REDACTED]

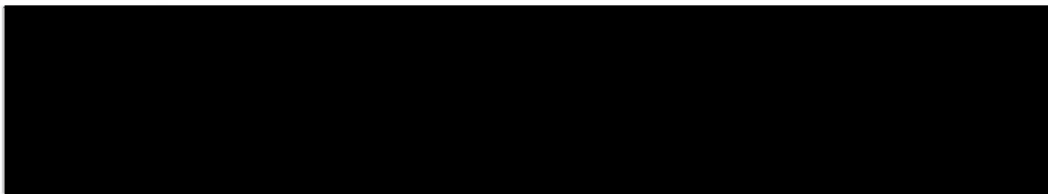
I would appreciate receiving your approval or comments within 10 working days from receipt of this note.

Thank you in advance for your cooperation.



Encl.: Draft commission implementing decision with regard to procedures for the functioning of the early warning and response system for notifying alerts in relation to serious cross-border threats to health pursuant to Art.8 par.2 of Decision 1082/2013/EU of the European Parliament and of the Council and repealing Decision 2000/57/EC

Cc:





EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Director

ANNEX

to the letter of 6 June 2015
Addressed to Mr Giovanni Buttarelli

European Data Protection Supervisor

Subject: Opinion of the European Data Protection Supervisor on the draft COMMISSION IMPLEMENTING DECISION with regard to procedures for the functioning of the early warning and response system for notifying alerts in relation to serious cross-border threats to health pursuant to Decision 1082/2013/EU of the European Parliament and of the Council and repealing Decision 2000/57/EC

The draft COMMISSION IMPLEMENTING DECISION with regard to procedures for the functioning of the early warning and response system for notifying alerts in relation to serious cross-border threats to health pursuant to Decision 1082/2013/EU of the European Parliament and of the Council and repealing Decision 2000/57/EC is still in the internal consultation within DG SANTE.

The services agreed that **24 August** is a new date for receiving European Data Protection Supervisor approval of or comments on the implementing decision in question.



Brussels, **XXX**
[...](2015) **XXX** draft

COMMISSION IMPLEMENTING DECISION (EU) .../...

of XXX

with regard to procedures for the functioning of the early warning and response system for notifying alerts in relation to serious cross-border threats to health pursuant to Decision 1082/2013/EU of the European Parliament and of the Council and repealing Decision 2000/57/EC

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) .../...

of **XXX**

with regard to procedures for the functioning of the early warning and response system for notifying alerts in relation to serious cross-border threats to health pursuant to Decision 1082/2013/EU of the European Parliament and of the Council and repealing Decision 2000/57/EC

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Decision 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 2119/98/EC¹, and in particular Article 8(2) thereof,

Whereas:

- (1) Decision 2119/98/EC of the European Parliament and of the Council² set up an early warning and response system as a communication network between the Commission and the competent public health authorities of Member States for the prevention and control of certain categories of communicable diseases.
- (2) Commission Decision 2000/57/EC³ laid down procedures concerning the functioning of the early warning and response system set up by Decision 2119/98/EC.
- (3) Pursuant to Regulation (EC) 851/2004 of the European Parliament and of the Council⁴ the European Centre for Disease Prevention and Control (hereinafter "ECDC") has taken over the operation of the early warning and response system from the communication network set up under Decision No 2119/98/EC.
- (4) Decision 1082/2013/EU extended the scope of the existing communication network for communicable diseases to other categories of serious cross-border threats to health including threats of biological, chemical, environmental or unknown origin. Accordingly, that Decision established an Early Warning and Response System (hereinafter "EWRS") to enable the Commission and the competent public health authorities of Member States to be in permanent communication for the purposes of alerting, assessing public health risks and determining the measures that may be required to protect public health.

¹ OJ L 293, 5.11.2013, p. 1.

² Decision 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).

³ 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 021, 26.1.2000, p. 32).

⁴ 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, 30.04.2004, p. 1).

- (5) Communication within the EWRS should occur through national contact points set up within the relevant competent authorities designated by Member States pursuant to Article 15(1)(b) of Decision 1082/2013/EU (hereinafter "EWRS contact points").
- (6) EWRS plays a major role in facilitating the sharing of information among Member States, the Commission, ECDC and the World Health Organisation (hereinafter "WHO") to coordinate response to health events with impact on public health at the Union level.
- (7) EWRS should allow the transmission of alerts of and information on events which are or may pose a serious cross border threat to health to other relevant Union rapid alert and information systems, with the aim to avoid structural duplication of notifications.
- (8) In order to ensure effective contact tracing, it is appropriate to provide an indicative list of personal data to be communicated by the national competent authorities through EWRS pursuant to Article 9(3)(i) of Decision 1082/2013/EU.
- (9) Accordingly, Commission Decision 2000/57/EC should be repealed and replaced by this Decision.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Committee on serious cross-border threats to health.

HAS ADOPTED THIS DECISION:

Article 1

EWRS contact points

1. Member States shall communicate to the Commission information on the EWRS contact points set up by the competent authorities designated pursuant to Article 15(1)(b) of Decision 1082/2013/EU. It shall include the following:
 - (a) contact details of the EWRS contact point;
 - (b) indication of the categories of serious cross-border threats to health pursuant to Article 2(1) of Decision 1082/2013/EU that the EWRS contact point is to be informed of;
 - (c) indication whether 'write-and-read' or 'read-only' access to the EWRS informatics application should be granted to the EWRS contact point.
2. Member States shall immediately notify the Commission of any changes concerning the EWRS contact points.
3. The Commission shall grant access to the EWRS informatics application to the EWRS contact points notified in accordance with paragraph 1 through the European Commission Authentication Service arrangements.
4. The Commission shall maintain and update the list of EWRS contact points and make it immediately available through the EWRS informatics application to the national competent authorities and the Health Security Committee (hereinafter "HSC").
5. Member States and the Commission shall ensure the functional availability of an on-duty officer reachable outside office hours for emergency communications on a 24-hour/7-days-a-week basis. Member States shall communicate to the Commission contact details of the on-duty officer.

6. For the purpose of providing the information on EWRS contact points referred to in paragraph 1 and the contact details of the on-duty officer referred to in paragraph 5 Members States shall use the template laid down in Annex I.

Article 2

Alert notification

1. Alerts fulfilling the criteria laid down in Article 9(1) of Decision 1082/2013/EU shall be notified in the EWRS without undue delay and no later than 24 hours from the identification of the serious cross-border threat to health. The fact that not all relevant information as indicated in Article 9(3) of Decision 1082/2013/EU may be available shall not unduly delay notification of an alert.
2. The notification message posted through the EWRS in accordance with Article 9(1) of Decision 1082/2013/EU shall indicate how the criteria laid down in this provision are fulfilled.
3. Where, following an alert notification, a Member State provides through EWRS additional information for coordination purposes pursuant to Article 9(3) of Decision 1082/2013/EU, it shall use the *ad hoc* functionality of the EWRS as a 'comment' to the initial notification.
4. Member States shall ensure effective communication between the competent authorities designated pursuant to Article 15(1)(b) of Decision 1082/2013/EU 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 1082/2013/EU.

Article 3

Public health risk assessment

1. In addition to public health risk assessment referred to in Article 10(1) of Decision 1082/2013/EU, the Commission shall promptly circulate to the national competent authorities through the EWRS and to the HSC any other information related to public health measures which may be relevant for coordination purposes through the EWRS.
2. Where the risk assessment carried out pursuant to Article 10(1) or (2) of Decision 1082/2013/EU indicates that the event will deserve specific follow-up and data gathering, the Commission shall ensure that special arrangements of the EWRS informatics application will support the consolidation and gathering of the information provided to facilitate easy access and interpretation of data and information provided by the EWRS contact points.

Article 4

Other Union alerting systems

1. Member States or the Commission, as appropriate, shall indicate in the EWRS that a particular alert or message communicated in the EWRS has previously been submitted through another alerting system at Union level, so that national EWRS contact points are aware that such information has already been received by the competent authorities.

2. In order to avoid double notification through the EWRS and another Union alerting system, the Commission shall ensure that special arrangements of the EWRS informatics application allow availability of the information communicated through the EWRS in another Union alerting system. If the event which is the origin for a serious cross border health threat is communicated through more than one Union alerting system, the Commission shall indicate the leading system.
3. The Commission shall ensure that notifications from the other alert systems existing at Union level and under the Euratom Treaty are communicated through the EWRS, if they may require or they may be useful for a coordination of response to a serious cross-border threat to health.
4. An indicative list of other alerting systems at Union level to be progressively linked with the EWRS is laid down in Annex II.

Article 5

Transmission of personal data through the selective messaging functionality of EWRS

1. When communicating personal data through the EWRS system, the EWRS contact points shall use the EWRS selective messaging functionality, referred to in Article 16(2) of Decision 1082/2013/EU.
2. An indicative list of personal data for contact tracing purposes as laid down in Article 16 of Decision 1082/2013/EU is provided in Annex III.

Article 6

Repeal of Commission Decision 2000/57/EC

Commission Decision 2000/57/EC is repealed.

Article 7

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,

For the Commission
The President

ANNEX I

See template attached

ANNEX II

List of alert and information systems at Union level to be progressively linked with EWRS. This list indicates rapid alert and information systems which are currently in place at Union level 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:

- 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;
- 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;
- Rapid Alert for Blood and Blood Components (RAB), for the exchange of information to prevent or contain cross-border incidents linked to blood transfusions;
- European Information Network on Drugs and Drug Addiction (REITOX), to collect and report information on the drug phenomenon across Europe;
- Animal Disease Notification System (ADNS), to register and document the situation of important infectious animal diseases;
- 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;
- 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 EU or being traded within the EU;
- European Community Urgent Radiological Information Exchange (ECURIE), to notify counter-measures to protect against the effects of a radiological or nuclear accident;
- Rapid Alert System for Food and Feed (RASFF) platform, for the notification of risks to human health deriving from food or feed.

ANNEX III

Indicative list of personal data for the purpose of contact tracing

1. PERSONAL INFORMATION

- Name and given names,
- Nationality, date of birth, sex,
- Country of residence,
- ID type, number and issuing authority,
- Current home address (street name and nr, city, country, postal code),
- Telephone numbers (mobile, residential, business),
- E-mail (private, business).

2. TRAVEL SPECIFICATIONS

- Conveyance data (e.g. flight number, date of flight, ship name, plate number),
- Seat number(s),
- Cabin number(s).

3. CONTACT INFORMATION

- Names of visited persons/places of stay,
- Dates and addresses of the places of stay (street name and nr, city, country, postal code),
- Telephone numbers (mobile, residential, business),
- E-mail (private, business).

4. INFORMATION ON ACCOMPANYING PERSONS

- Name and given names,
- Nationality,
- Personal information as laid down in point 1, indents 3-6.

5. EMERGENCY CONTACT DETAILS

- Name of person to be contacted,
- Address (street name and nr, city, country, postal code),
- Telephone numbers (mobile, residential, business),
- E-mail (private, business).



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Early Warning Response System user registration form

Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health

Print Form

Account type

Read and write function

Read-only function

First Name

Last Name /
Functional
Name

Organisation

Email

24h/7 Contact
Max 249 cha.

Country

Telephone

Fax

GSM

Address
Max 299 cha.

Date

03/01/2023

Signature :

For the EWRS controller in DG SANCO:

**Please send by e-mail the scanned document to :
SANCO-EWRS@ec.europa.eu**

Personal data shall be processed in compliance with the European Union legislation on the protection data, in particular 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 each data.

In compliance with Regulation 1049/2001/EC regarding public access to European Parliament, Council and Commission documents, it is requested that the information contained here be not disclosed for purposes other than those established by decision No 1082/2013/EU without prior consultation with the Commission services and the Member State which provided the information.