# EDPS Formal comments on the Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU

## 1. Introduction and background

- The Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU[1] (the 'Proposal') provides a stronger and more comprehensive legal framework within which the Union can react rapidly and trigger the implementation of preparedness and response measures to cross-border threats to health across the EU in the form of a Regulation.

- In particular, this Proposal aims to:

  1) set out a comprehensive legislative framework to govern action at Union level on preparedness, surveillance, risk assessment, and early warning and responses; and

  2) enhance the Union's guidance in the adoption of common measures at EU level to face a future cross-border health threat.

- The European Commission has presented the Proposal in conjunction with two other proposals, namely a Proposal for a Regulation of the Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices[2] and a Proposal to extend the mandate of the European Centre for Disease Prevention and Control ('ECDC')[3], with the aim of improving EU-level protection, prevention, preparedness and response against human health hazards.

- These comments are provided in reply to the request by the Commission of 5 January 2021 pursuant to Article 42(1) of Regulation (EU) 2018/1725 ('the EUDPR')[4] on the Proposal. We limited our comments below to the provisions of the Proposal that are relevant from a data protection perspective.

[1] Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU COM(2020)727 final

[2] Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices COM(2020) 725 final

[3] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control, COM(2020) 726 final.

[4] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (Text with EEA relevance), OJ L 295, 21.11.2018, p. 39–98.

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## 2. EDPS comments

### 2.1 General Comments

- The EDPS welcomes the Commission Proposal which aims to provide for a stronger and more comprehensive legal framework for the Union to prepare and respond to health crises. In particular, it is important for the Union to rapidly act and trigger the implementation of preparedness and response measures across the EU in the form of a Regulation.

- The EDPS also welcomes the specific references in the Recital 20 and in Article 26 of the Proposal to the applicability of the Regulation (EU) 2016/679 ('GDPR')[5] and of the EUDPR.

- At the same time, the EDPS notes that the Proposal does not specify the roles and responsibilities of the parties involved in the various systems that it aims to set up. This is in particular important as regards the identification of controllers, before whom individuals are able to exercise their data protection rights. Consequently, **we recommend to provide in the Proposal for further implementing or delegated acts that would lay down the roles of the actors involved in the processing of personal data through the IT tools and systems contemplated by the proposal**.

### 2.2 Specific comments

#### 2.2.1 Setting up a digital platform for epidemiological surveillance by the European Centre for Disease Prevention and Control

- Pursuant to Article 14 of the Proposal, the European Centre for Disease Prevention and Control ('ECDC') shall set up and manage a digital platform through which data is managed and automatically exchanged, to establish integrated surveillance systems enabling real-time surveillance where appropriate, for the purpose of supporting communicable disease prevention and control.

- Moreover, in line with Article 14 of the Proposal *"the digital platform shall:*

  *(a) enable the automated collection of surveillance and laboratory data, make use of information from electronic health records and apply artificial intelligence for data validation, analysis and automated reporting;*

  *(b) allow for the computerised handling and exchange of information, data and documents."*

- The deployment of artificial intelligence technology will, most likely, meet at least one of the criteria set in Article 39 (3) EUDPR[6]. Considering the potential risks

[5] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016.

[6] Article 39 (3) EUDPR provides that *"A data protection impact assessment referred to in paragraph 1 shall in particular be required in the case of:*
*(a) a systematic and extensive evaluation of personal aspects relating to natural persons which is based on automated processing, including profiling, and on which decisions are based that produce legal effects concerning the natural person or similarly significantly affect the natural person;*
*(b) processing on a large scale of special categories of data referred to in Article 10, or of personal data relating to criminal convictions and offences referred to in Article 11; or*
*(c) a systematic monitoring of a publicly accessible area on a large scale."*

associated to the use of the surveillance system and artificial intelligence[7], the **EDPS recommends the ECDC to conduct a DPIA prior to the deployment of a digital platform.** The EDPS also points out that, if a DPIA shows that the processing would entail a high risk for the rights and freedoms of the data subjects, unless the data controller takes measures to mitigate the risk, **there is an obligation to consult the supervisory authority under Article 40 EUDPR.**

- Finally, the EDPS notes that the Commission will adopt implementing acts for the functioning of the surveillance platform[8]. In this regard, **the EDPS recalls the legal obligation under Article 42(2) EUDPR to be consulted when such legislative acts will be prepared.**

### 2.2.2 Early warning and response system

- Article 18 of the Proposal describes the early warning and response system ('EWRS') and states *that "[t]he ECDC shall continuously update the EWRS allowing for the use of modern technologies, such as digital mobile applications, artificial intelligence models, space enabled applications, or other technologies for automated contact tracing".*

- The EDPS recalls **the need to conduct a DPIA before processing data** using innovative technologies such as artificial intelligence if the processing is likely to result in high risk to the rights and freedoms of the individuals. Moreover, the EDPS would like to draw attention to the **EDPB Guidelines 04/2020 on the use of location**

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4. *The European Data Protection Supervisor shall establish and make public a list of the kind of processing operations which are subject to the requirement for a data protection impact assessment pursuant to paragraph 1.*

*5. The European Data Protection Supervisor may also establish and make public a list of the kind of processing operations for which no data protection impact assessment is required.*

*6. Prior to the adoption of the lists referred to in paragraphs 4 and 5 of this Article, the European Data Protection Supervisor shall request that the European Data Protection Board set up by Article 68 of Regulation (EU) 2016/679 examine such lists in accordance with point (e) of Article 70(1) of that Regulation where they refer to processing operations by a controller acting jointly with one or more controllers other than Union institutions and bodies.*

[7] A DPIA is mandatory before processing data using innovative technologies if the processing is likely to result in high risk to the rights and freedoms of the individuals See: European Data Protection Board, *Guidelines on Data Protection Impact Assessment (DPIA) and determining whether processing is "likely to result in a high risk" for the purposes of Regulation 2016/679*, WP 248 rev.01.

[8] Article 14(6) of the Proposal states that: *"The Commission shall adopt implementing acts for the functioning of the surveillance platform which lay down:*

*(a) the technical specifications of the platform, including the electronic data exchange mechanism for exchanges with existing national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures;*

*(b) the specific rules for the functioning of the platform to ensure protection of personal data and security of exchange of information;*

*(c) the specific rules for the functioning and use of the platform;*

*(d) contingency arrangements to be applied in the event of unavailability of any of the functionalities of the platform;*

*(e) the cases where, and the conditions under which, the third countries and international organisations concerned may be granted partial access to the functionalities of the platform and the practical arrangements of such access;*

*(f) the cases where, and the conditions under which, the data, information and documents referred to in Article 13 are to be transmitted using the platform and the list of such data, information and documents; and*

*(g) the conditions under which ECDC can participate and be granted access to health data accessed or exchanged through the digital infrastructures referred to in paragraph 5."*

**data and contact tracing tools in the context of the COVID-19 outbreak**[9], which provide useful guidance and clarifications on the conditions and principles for a proportionate use of location data and contact tracing tools. In line with the EDPB Guidelines, the EDPS stresses that in order to ensure **accountability**, the controller of any contact tracing tool should be clearly defined. In addition, with regard to the **principle of purpose limitation**, the purposes must be specific enough to exclude further processing for purposes unrelated to the management of the COVID- 19 health crisis. Once the objective has been clearly defined, it will be necessary to ensure that the use of personal data is **adequate, necessary and proportionate**.

- The EDPS welcomes Article 26 of Proposal, which contains provisions on the protection of personal data, mainly in the context of the EWRS. In particular, we welcome the provision that requires an automatic deletion of the messages containing personal data from the selective message functionality 14 days after the date of their posting[10]. The EDPS also wishes to stress that concerning contact tracing tools, careful consideration should be given to the principle of data minimisation and data protection by design and by default.

- Finally, the EDPS notes that the Commission will adopt implementing acts on, *inter alia*, the procedures related to EWRS and the modalities for processing automated contract tracing applications and interoperability of these applications[11]. In this regard, **the EDPS recalls one more time the legal obligation under Article 42(2) EUDPR to be consulted when such legislative acts are prepared.**

### 2.2.3 Transfers of personal data to third countries

- In line with Recital 19 of the Proposal *"[c]ooperation with third countries and international organisations in the field of public health should be fostered and it is particularly important to ensure the exchange of information with the WHO on the measures taken pursuant to this Regulation."* Also in the context of the epidemiological surveillance network[12] and the functioning of the surveillance

[9] Guidelines 04/2020 on the use of location data and contact tracing tools in the context of the COVID-19 outbreak, adopted on 21 April 2020

[10] Article 26(5) of the Proposal states that: *"Messages containing personal data shall automatically be erased from the selective message functionality 14 days after the date of their posting."*

[11] Article 26(7) of the Proposal states that: *"The Commission shall, by means of implementing acts, adopt:*
*(a) procedures necessary to ensure that the operation of the EWRS and the processing of data complies with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725;*
*(b) procedures for the interlinking of EWRS with contact tracing systems at EU level;*
*(c) an indicative list of the personal data that may be exchanged for the purpose of the coordination of contact tracing measures;*
*(d) the modalities for processing automated contract tracing applications and interoperability of these applications, as well as the cases where, and the conditions under which, the third countries and international organisations concerned may be granted access to contract tracing interoperability and the practical arrangements of such access.*
*These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2)."*

[12] Article 13 of the Proposal states that: *"The epidemiological surveillance network shall aim to:*
*(a) monitor trends in communicable diseases over time and across Member States and in third countries to assess the present situation, respond to rises above warning thresholds and facilitate appropriate evidence-based action;(...)"*

platform[13] the third countries and international organisation are covered by the Proposal.

- In this regard, **the EDPS recalls that transfers of personal data to third countries or international organisations must comply with Chapter V of the EUDPR** (Articles 46 and following) and the applicable case law of the Court of Justice[14]

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*(e-signed)*

[13] Article 14(6) of the Proposal states that: *"The Commission shall adopt implementing acts for the functioning of the surveillance platform which lay down:(...) (e) the cases where, and the conditions under which, the third countries and international organisations concerned may be granted partial access to the functionalities of the platform and the practical arrangements of such access;(...)"*

[14] The EDPS would also like to draw attention to its recently published 'Strategy for Union institutions, offices, bodies and agencies to comply with the Schrems II Ruling' (https://edps.europa.eu/sites/edp/files/publication/2020-10-29_edps_strategy_schremsii_en_0.pdf) as well as the 'EDPB Recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data' (https://edpb.europa.eu/sites/edpb/files/consultation/edpb_recommendations_202001_supplementarymeasurestransferstools_en.pdf).