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From: Mr Wojciech Rafal WIEWIOROWSKI, European Data Protection Supervisor

date of receipt: 8 March 2021

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Subject: Formal comments of the European Data Protection Supervisor on the Proposal for a Regulation of the European Parliament and of the Council on establishing a European Centre for Disease Prevention and Control amending Regulation (EC) No 851/2004

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Delegations will find attached a letter and its annex, signed by Mr Wiewiorowski on the above.



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EUROPEAN DATA PROTECTION SUPERVISOR

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**Subject: Formal Comments<sup>1</sup> of the European Data Protection Supervisor on the  
Proposal for a Regulation of the European Parliament and of the Council on  
establishing a European Centre for Disease Prevention and Control amending  
Regulation (EC) No 851/2004**

Your Excellency,  
Mr Secretary-General,

Having regard to Article 42(1) of 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, please find enclosed Formal Comments on the Proposal for a Regulation of the European Parliament and of the Council on establishing a European Centre for Disease Prevention and Control amending Regulation (EC) No 851/2004.

We have sent a copy of these Formal Comments to the President of the European Commission and the President of the European Parliament.

Yours sincerely,

Wojciech Rafał WIEWIÓROWSKI  
*[e-signed]*

Encl.: Formal comments

Cc: Mr Ralph KAESSNER, Secretariat General of the Council

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<sup>1</sup>Article 20(1) of the EDPS Rules of Procedure provide that "In response to requests from the Commission pursuant to Article 42(1) of the Regulation, the EDPS shall issue opinions or formal comments."

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**EDPS Formal comments on the Proposal for a Regulation of the European Parliament and of the Council on establishing a European Centre for Disease Prevention and Control amending Regulation (EC) No 851/2004**

**1. Introduction and background**

- The Proposal for a Regulation of the European Parliament and of the Council on establishing a European Centre for Disease Prevention and Control amending Regulation (EC) No 851/2004 (the “**Proposal**”) provides for a reinforced mandate of the European Centre for Disease Prevention and Control (“**ECDC**”) addressing surveillance, preparedness, early warning and response under a strengthened EU health security framework.
- This Proposal intends to adapt the founding act of the ECDC to the new challenges brought by the COVID-19 pandemic, as well as to create synergies with other EU initiatives such as the EU Digital Single Market agenda and the European Health Data Space (“**EHDS**”). Moreover, the Proposal will facilitate information sharing including of real world evidence, and support the development of a Union-level IT infrastructure for surveillance and monitoring.
- The European Commission has presented the Proposal in conjunction with two other proposals, namely a Proposal for a Regulation on serious cross-border threats to health<sup>1</sup> and a Proposal on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices<sup>2</sup>.
- These comments are provided in reply to the request by the Commission of 13 January 2021 pursuant to Article 42(1) of Regulation (EU) 2018/1725 (“**the EUDPR**”) <sup>3</sup>. We limited our comments below to the provisions of the Proposal that are relevant from a data protection perspective.

**2. EDPS comments**

**2.1 General Comments**

- The EDPS **welcomes the efforts of the Commission in the harmonisation of the rules** around the EU health security framework as well as the review of the ECDC’s founding regulation in order to ensure consistency with the new EU instruments and its strengthened role. Moreover, the EDPS supports the development of initiatives for the prevention, preparedness and response planning, risk assessment and response, as

<sup>1</sup> 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 2020/0322 (COD).

<sup>2</sup> 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

<sup>3</sup> 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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the COVID-19 has demonstrated that the existence of adequate structures with the necessary capacities and interconnections is key to safeguarding public health.

- The EDPS **welcomes the specific references** in Article 6(3) and in Article 11(2) of the Proposal **to the respect of data protection rules** by the ECDC in the performance of certain of its tasks, namely (1) the provision of analysis and recommendations for actions to prevent and control communicable disease threats, and (2) the development of solutions to access relevant health data made available or exchanged through digital infrastructures, respectively. At the same time, the EDPS notes that the new tasks of the ECDC cover a much broader range of activities in which processing of personal data is likely to occur, and that a number of exchanges of health data with Member States is foreseen within the Proposal through different channels (e.g. the European Surveillance System (TESSy) or the Early Warning and Response System of the European Union (EWRS)). The EDPS therefore recommends to include within the recitals of the Proposal the following statement: *“Where it is necessary for the purposes of this Regulation to process personal data, this should be carried out in accordance with Union law on the protection of personal data. Any processing of personal data based on this Regulation shall take place in accordance with Regulations (EU) No 2016/679<sup>4</sup> and (EU) No 2018/1725 and with Directive 2002/58/EC on privacy and electronic communications<sup>5</sup>.”*
- Moreover, similarly to other recent regulations founding EU agencies<sup>6</sup>, we suggest to include a provision within the operative part of the Proposal stating that *“This Regulation shall be without prejudice to the obligations of Member States relating to their processing of personal data under Regulation (EU) No 2016/679 and Directive 2002/58/EC on privacy and electronic communications, or the obligations of the ECDC and the Commission relating to their processing of personal data under Regulation (EU) No 2018/1725, when fulfilling their responsibilities”*.
- The EDPS recalls that, pursuant to Article 10 EUDPR, the processing of **special categories of personal data**, *inter alia*, data revealing racial or ethnic origin, genetic data, biometric data or data concerning health is prohibited, except when one of the **exceptions** of Article 10(2) EUDPR applies. Indeed, one of these exceptions relates to the processing of personal data that is necessary for reasons of **public interest in the area of public health**, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of healthcare and of medicinal products or medical devices. However, such processing is only possible **on the basis of (national or) Union law** which provides for suitable and specific **measures to safeguard** the rights and freedoms of the data subject, in particular professional secrecy<sup>7</sup>. As a result, the EDPS recommends to set out in the Proposal **the categories of data subjects** under the scope of the processing and the **categories of the personal data processed**, together with a description of the specific **measures to safeguard** the

<sup>4</sup> 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) (Text with EEA relevance), OJ L 119, 4.5.2016, p. 1–88.

<sup>5</sup> Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector, OJ L 201, 31.7.2002, p. 37–47

<sup>6</sup> See, for example, Article 89 of Regulation (EU) No 806/2014 of the European Parliament and of the Council of 15 July 2014 establishing uniform rules and a uniform procedure for the resolution of credit institutions and certain investment firms in the framework of a Single Resolution Mechanism and a Single Resolution Fund and amending Regulation (EU) No 1093/2010, OJ L 225, 30.7.2014, p. 1–90

<sup>7</sup> Article 10.2(i) EUDPR.

rights and freedoms of the data subjects involved in line with data protection legislation, particularly with regard to concrete safeguards to prevent abuse or unlawful access or transfer, and the storage periods.

- The Proposal intends to expand the mission and tasks of the ECDC in order to enhance its capacity to provide the required scientific expertise and to support actions which are relevant to the prevention, preparedness, response planning and combating serious cross-border threats to health in the Union<sup>8</sup>. To this purpose, the Proposal entrusts the ECDC with a broad range of powers, ranging from epidemiological-related tasks to coordination and cooperation tasks, including with third countries. The EDPS notes that the **Proposal should clearly identify those instances where the tasks entrusted to the ECDC will entail the processing of personal data**, particularly in the case of health data relating to identified or identifiable individuals.
- The EDPS recalls that where processing of personal data is not necessary to perform the activities of the ECDC, **measures should be put in place to ensure use of anonymous data** (and otherwise pseudonymous data) in line with the principle of data minimisation. Moreover, the EDPS recommends to amend to the Proposal to explicitly state that whenever possible, use shall be made of anonymous data. The anonymization shall consist on rendering personal data anonymous in such a manner that the data subject is not or no longer identifiable, through techniques such as the randomization (*altering the veracity of the data in order to remove the strong link between the data and the individual*) and/or generalization (*consisting on generalizing, or diluting, the attributes of data subjects by modifying the respective scale or order of magnitude*). In this context the EDPS draws attention to the Article 29 Working Party Opinion 5/2014 on Anonymisation Techniques<sup>9</sup> which describes the main techniques used thereto as well as the safeguards they provide.

## 2.2 Specific comments

### 2.2.1 Data governance within ECDC

- The EDPS considers that a **strong governance mechanism** within the ECDC is crucial for its correct functioning, including the establishment of the necessary protocols and procedures describing its data governance system. This is particularly relevant with regard to the processing operations involving personal data arising from new powers of the agency. The EDPS highlights that the ECDC's data governance mechanism must provide for sufficient **assurances for the lawful, responsible and ethical use of the data**, as well as to ensure the respect of the **fundamental rights** to data protection and privacy as set by Articles 7 and 8 of the Charter of Fundamental Rights of the European Union. In this regard, the EDPS draws attention to its preliminary opinion 8/2020 on the European Health Data Space<sup>10</sup> with respect to its recommendations for the setting up of a new governance system. As explained in this opinion, a strong governance system requires the **clear identification of the main actors involved in the processing of personal data within it**, including the definition of their role as data controller, processor or joint controller. Moreover, the governance

<sup>8</sup> See recital 6 of the Proposal

<sup>9</sup> Available at [https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2014/wp216\\_en.pdf](https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2014/wp216_en.pdf)

<sup>10</sup> Available at [https://edps.europa.eu/sites/default/files/publication/20-11-17\\_preliminary\\_opinion\\_european\\_health\\_data\\_space\\_en.pdf](https://edps.europa.eu/sites/default/files/publication/20-11-17_preliminary_opinion_european_health_data_space_en.pdf)

system should foresee **mechanisms and procedures to assess the validity and quality of the sources of the data.**

- The EDPS notes that some of the tasks set out in the mission<sup>11</sup> of the ECDC may imply the carrying out of processing operations involving sensitive data (i.e. health data), for example, the “*search for, collect, collate, evaluate and disseminate relevant scientific and technical data and information, considering the latest technologies*”; “*provide analyses [...] on cross-border health threats, including risk assessments, analysis of epidemiological information, epidemiological modelling, anticipation and forecast [...]*” and “*coordinate the European networking of bodies operating in the fields within the Centre’s mission, including networks arising from public health activities supported by the Commission and operating the dedicated surveillance and other networks*”. Due to the sensitive nature of the health data, the ECDC must ensure that it has in place **procedures and data protection safeguards** designed to guarantee that its processing operations rigorously respect the data protection principles of lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality. More specifically, with respect to the new tasks that the ECDC would acquire following the adoption of the Proposal, the EDPS wishes to recall the importance of the **principles of data protection by design and by default** as defined in Article 27 of Regulation (EU) 2018/1725 EUDPR, while also determining appropriate technical and organisational security measures in accordance with Article 33 EUDPR.
- The EDPS notes that the current formulation of **Article 6(3) and of Article 11.2(d)** of the Proposal is not fully aligned with the principle of **purpose limitation**. In particular, these two provisions would allow the ECDC to have access to (and develop solutions to access) relevant health data made available or exchanged through digital infrastructures and applications “*in accordance with data protection rules, allowing for the health data to be used for healthcare, research, policy making and regulatory purposes*”. In the EDPS’s view, the current formulation would potentially allow the ECDC to **use sensitive health data for purposes that are described in very broad terms**. Furthermore, we note that the possibility to relate health data with socio-economic elements increases the risk of identification of the data subjects and of discrimination based on environmental factors. Therefore, the EDPS recommends to amend Article 6(3) and Article 11.2(d) of the Proposal to **narrow down and define more precisely the specific purposes for which the ECDC would be able to process health data.**

### 2.2.2 New tasks of the ECDC regarding digital platforms and applications supporting epidemiological surveillance

- Pursuant to Article 5(2)(a) of the Proposal, the ECDC shall “*ensure the further development of the digital platforms and applications supporting epidemiological surveillance at Union level, supporting Member States with technical and scientific advice to establish integrated surveillance systems **enabling real-time surveillance** where appropriate, benefiting from existing EU space infrastructures and services*”<sup>12</sup>.
- The EDPS recalls that certain applications supporting epidemiological surveillance, such as contact tracing applications, entail data protection risks as they provide for preventive contact recording of a very large number of the population in public and private spaces. These applications are therefore likely to result in a high risk to the

<sup>11</sup> See Article 3(2) of the Proposal

<sup>12</sup> Article 5.2(a) of the Proposal

rights and freedoms of natural persons and thus, **require a data protection impact assessment (DPIA)** to be conducted prior to their deployment<sup>13</sup>. In this context, the EDPS draws attention to the EDPB Guidelines 04/2020 on the use of location data and contact tracing tools in the context of the COVID-19 outbreak, which provide useful guidance and clarification on the conditions and principles for the proportionate use of location data and contact tracing tools, including as regards the legal basis or legislative measure that provides the lawful basis for the use of contact tracing applications<sup>14</sup>.

- Moreover, the EDPS insists that contact tracing applications use **privacy-enhancing technologies** and be designed in line with the principles of data minimisation, purpose limitation and storage limitation, i.e. determining in advance for which specific purposes the personal data may be used, and by whom and for how long it may be stored. Thus, the EDPS recommends **adding to Article 5.2(a) of the Proposal** the following wording: “*The digital platforms and applications shall be implemented with privacy-enhancing technologies taking into account the state of the art*”.
- In accordance with the Proposal, **the ECDC shall develop** digital platforms and applications with a focus to **enabling the use of digital technologies, such as artificial intelligence** (see recital 9, 15 and Article 8(3) of the Proposal). The EDPS highlights that pursuant to the Decision of the EDPS on DPIA lists issued under Articles 39(4) and (5) of Regulation (eu) 2018/1725<sup>15</sup>, applying technological or organisational solutions that involve novel forms of data collection and usage requires the prior elaboration of a DPIA, since the processing of personal data is likely to result in a high risk to the rights and freedoms of natural persons.
- Moreover, the EDPS draws attention to its Opinion 4/2020 on the European Commission’s White Paper on Artificial Intelligence<sup>16</sup>, and particularly the references to the risks posed by AI (e.g. *biased datasets, flawed AI system design, lack of data quality, overreliance on automated decision-making ect.*), and the need to establish safeguards to mitigate these risks both at the design and at the implementation phases of AI technological solutions<sup>17</sup>.
- The Proposal also brings under the umbrella of the ECDC the new responsibility of coordinating with the hosts of relevant databases other than the database(s) for epidemiological surveillance, and work towards harmonised approaches to data collection and modelling<sup>18</sup>. In this context, the EDPS highlights that the principle of data quality is of particular importance, since inaccurate data in one database is likely to have a multiplier effect on the others. Therefore, the EDPS recommends that the Proposal provides for the adoption of specific measures for **minimising risks that may emerge from the transference of inaccurate or incomplete data from one database to another, as well as the establishment of procedures for data quality review**.

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<sup>13</sup> See Article 39 of the EUDPR

<sup>14</sup> See

[https://edpb.europa.eu/sites/edpb/files/files/file1/edpb\\_guidelines\\_20200420\\_contact\\_tracing\\_covid\\_with\\_annex\\_en.pdf](https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_guidelines_20200420_contact_tracing_covid_with_annex_en.pdf), in particular at paragraph 31.

<sup>15</sup> [https://edps.europa.eu/sites/default/files/publication/19-07-16\\_edps\\_dpia\\_list\\_en.pdf](https://edps.europa.eu/sites/default/files/publication/19-07-16_edps_dpia_list_en.pdf)

<sup>16</sup> [https://edps.europa.eu/sites/default/files/publication/20-06-19\\_opinion\\_ai\\_white\\_paper\\_en.pdf](https://edps.europa.eu/sites/default/files/publication/20-06-19_opinion_ai_white_paper_en.pdf)

<sup>17</sup> See paragraph 20 and following of the EDPS Opinion 4/2020 on the European Commission’s White Paper on Artificial Intelligence

<sup>18</sup> Article 5.2(c) of the Proposal

- The Proposal also assigns to the ECDC new obligations relating to ensuring the **interoperability** of automated applications, including for contact tracing, developed at national level<sup>19</sup> and the interoperability of the digital infrastructures allowing for the health data to be used for certain (broad) purposes, with a view to integrate those platforms and infrastructures in the EHDS<sup>20</sup>. The EDPS would like to draw attention to its recommendations set in the Preliminary Opinion 8/2020 on the European Health Data Space<sup>21</sup>, and in particular, to the need to establish a thought-through legal basis for the processing operations in line with Article 6(1) GDPR. In the same line, the EDPS notes that the integration into the EHDS of the data from automated applications and digital infrastructures under the management of the ECDC constitutes a disclosure of personal data. The EDPS highlights that such disclosure will be lawful only if it is based on one of the legal basis set by the GDPR and the EUDPR, or if the legal basis of the previous processing operation allows for a compatible further processing of the data within the EHDS.
- The EDPS notes that the Proposal provides for a new role of the ECDC in the **definition of the functional requirements** for contract tracing applications and their interoperability in the framework of the Early Warning and Response System (EWRS), and the EWRS itself. In particular, Article 8(5) of the Proposal specifies that the ECDC will act as “processor” and in this capacity, it will have *“the responsibility to ensure the security and confidentiality of the processing operations of personal data carried out within the EWRS and in the context of interoperability of contact tracing applications, in accordance with the obligations laid down in Articles 33, 34(2) and 36 of Regulation (EU) 2018/1725 of the European Parliament and of the Council”*. The EDPS considers that **the role of the ECDC pursuant to the EUDPR needs to be further ascertained**, in particular in the light of its role in the definition of the functional requirements of the EWRS and the contract tracing applications. In this regard, we recall that pursuant to the EUDPR “controller” means the Union institution or body [...] which, alone or jointly with others, determines the purposes and means of the processing of personal data. As highlighted in the EDPS **Guidelines on the concepts of controller, processor and joint controllership under Regulation (EU) 2018/1725**<sup>22</sup>, the determination of the means particularly refers to the technical and organisational measures that are put in place when carrying out a specific operation. In this context, the role of “controller” involves deciding on the “essential elements of the means” (e.g. the type(s) of data to be processed, the period for which they would be retained, from which data subjects would the data be collected, who will have access to data and who will be recipient, etc.), whereas the “processor” may determine the so-called “non-essential elements of the means” (e.g. the hardware or software to be used or the technical security measures)<sup>23</sup>. Therefore, **the EDPS recommends deleting the reference to the ECDC as “processor”** in Article 8(5) of the Proposal, as this qualification does not appear to be fully in line with the role of the ECDC as set out in the Proposal.

<sup>19</sup> Article 5.2(f) of the Proposal

<sup>20</sup> Article 5.2(f) of the Proposal

<sup>21</sup> [https://edps.europa.eu/sites/edp/files/publication/20-11-17\\_preliminary\\_opinion\\_european\\_health\\_data\\_space\\_en.pdf](https://edps.europa.eu/sites/edp/files/publication/20-11-17_preliminary_opinion_european_health_data_space_en.pdf)

<sup>22</sup> [https://edps.europa.eu/sites/default/files/publication/19-11-07\\_edps\\_guidelines\\_on\\_controller\\_processor\\_and\\_jc\\_reg\\_2018\\_1725\\_en.pdf](https://edps.europa.eu/sites/default/files/publication/19-11-07_edps_guidelines_on_controller_processor_and_jc_reg_2018_1725_en.pdf)

<sup>23</sup> See in particular, Section 3.1.3 “Purposes and means” of the EDPS Guidelines on the concepts of controller, processor and joint controllership under Regulation (EU) 2018/1725

- **Another new task entrusted to the ECDC by the Proposal** consists in the **development of solutions to access relevant health data** made available or exchanged through digital infrastructures, in accordance with data protection rules, and to provide and facilitate controlled access to health data to support public health research<sup>24</sup>. In this regard, the EDPS draws attention to its Guidelines on the protection of personal data in IT governance and IT management of EU institutions<sup>25</sup>, which provide a good insight into data protection requirements in the IT system development life cycle.

### 2.2.3 The ECDC tasks with regard to coordination of data at Union Level and work with international organisations

- The EDPS notes that the Proposal entrusts the ECDC with the role of coordinator for data collection, validation, analysis and dissemination of data at Union level<sup>26</sup>. For these purposes, the ECDC shall develop appropriate procedures to facilitate data transmission and access, together with the Member States and the Commission. Moreover, the ECDC shall work in close cooperation health authorities from the Union, third countries, the WHO, and other international organisations<sup>27</sup>. The Proposal provides for the establishment of disease-specific and disease-group-specific networks that shall be tasked with the transmission of national surveillance data to the ECDC<sup>28</sup>.
- In this regard, **the EDPS recalls that transfers of personal data to third countries or international organisations must comply with EUDPR**, including Chapter V (Articles 46 and following).
- In the context of the ECDC's network coordination tasks in case of cross-border health threats posed by communicable diseases, and in particular, in relation to the ECDC's task of establishing and operating a network of national blood and transplant services and their authorities (recital 12, Article 5.4(b) and Article 8b(1)), the EDPS encourages the development of a **Code of Conduct** for processing of personal data in accordance with Article 40 GDPR, as it could be an effective enabler of cross-border exchange of such data that would bring further clarity and trust into the new system.

Brussels, 08 March 2021

Wojciech Rafał WIEWIÓROWSKI

*[e-signed]*

<sup>24</sup> Article 11.2(d) of the Proposal.

<sup>25</sup> [https://edps.europa.eu/sites/edp/files/publication/it\\_governance\\_management\\_en.pdf](https://edps.europa.eu/sites/edp/files/publication/it_governance_management_en.pdf).

<sup>26</sup> Article 11(1) of the Proposal.

<sup>27</sup> Article 11(2)(c) of the Proposal.

<sup>28</sup> Article 5(5) of the Proposal.