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[REDACTED]
CC: [REDACTED] SG DATA
PROTECTION OFFICER (EC) <DATA-PROTECTION-
OFFICER@ec.europa.eu>
Sent at: 24/08/15 10:56:20
Subject: Informal comments - Our ref. 2015-0629 D-1428

Dear Sir,

Please find attached a scanned version of a letter sent to you by regular mail today.

Best regards,



EDPS Secretariat

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European Data Protection Supervisor

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WOJCIECH RAFAŁ WIEWIÓROWSKI
ASSISTANT SUPERVISOR

Mr Ladislav MIKO
Acting Director-General
DG SANCO
European Commission
Rue Breydel 4
B-1049 Brussels

Brussels, 24 August 2015

[REDACTED] (2015) 1428 C 2015-0629

Please use edps@edps.europa.eu for all
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Subject: EDPS informal comments on 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 Miko,

I am writing in reply to a consultation of the EDPS on 30 July 2015, in connection with the inter-service consultation of the Commission services, concerning the above captioned draft Commission Decision.

We welcome the informal consultation of the EDPS at this stage of the procedure. You will find attached a note containing our preliminary comments.

These comments are without prejudice to any formal Opinion that may follow under Article 28(2) of Regulation (EC) No 45/2001. In that Opinion, also other relevant elements may be discussed.

Our services are at your disposal, should you need any clarification in relation with this letter.

Yours sincerely,

Wojciech Rafał WIEWIÓROWSKI

Cc: Mr John RYAN, Acting Director, DG SANCO

Contact person: [REDACTED]



EDPS informal comments 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 above captioned draft Commission implementing decision (the "draft Decision") regulates the procedures for the functioning of the early warning and response system ("EWRS") for notifying alerts in relation to serious cross-border threats to health. In doing so, it repeals Decision 2000/57/EC of a similar content.

The main body of provisions establishing and regulating the EWRS, however, is included in Decision 1082/2013/EC, which contains also provisions on the protection of personal data in the context of the EWRS operation and was the subject of a specific EDPS Opinion.¹

As the EWRS system involves the processing of sensitive data, such as health data, the provisions regulating its functioning have been previously notified to the EDPS pursuant to Article 27 of Regulation (EC) No 45/2001 (*prior checking*). Consequently, on 22 April 2010, the EDPS has issued a prior checking Opinion assessing the data protection implications of the EWRS system and formulating suggestions and recommendation aimed at enhancing the compliance of the system with data protection rules (the "Prior Checking Opinion").²

Without prejudice to the recommendations included in the two mentioned EDPS Opinions, which both remain valid and operative, in the following paragraphs, we address the data protection issues in connection with the draft Decision, in particular:

- As a general comment, we note that, unlike Decision 2000/57/EC, the draft Decision does not refer to the applicability of Regulation (EC) No 45/2001 and Directive 95/46/EC. We therefore recommend that the draft Decision should explicitly refer to the application of Regulation (EC) No 45/2001 and national rules implementing Directive 95/46/EC. This could perhaps be done in Article 5, or in a separate new Article.

Besides, as highlighted in the Prior Checking Opinion, we recommend that a recital clarifies that the data protection rules relevant for the identification of controllers and processors, or on data quality, on data retention, on access rights and information of the data subjects and on data security should each be appropriately applied in this context.

- We also recommend mentioning in the recitals to the draft Decision- where the succession of normative acts is reported- that the EDPS has been consulted and has given comments, not only on the Draft, but also on Decision 1082/2013/EC and on the functioning of the EWRS in general.

¹ EDPS Opinion of 28 March 2012 on the proposal for a decision of the European Parliament and of the Council on serious cross-border threats to health, available at https://secure.edps.europa.eu/EDPSWEB/webdav/shared/Documents/Consultation/Opinions/2012/12-03-28_Threats_health_EN.pdf.

² EDPS Opinion of 22 April 2010 (case 2009-0137), available at https://secure.edps.europa.eu/EDPSWEB/webdav/shared/Documents/Supervision/Priorchecks/Opinions/2010/10-04-26_EWRS_EN.pdf.

- Further, we understand that, pursuant to the draft Decision, the information sharing under the EWRS system will not only take place between EU Institutions and bodies (bound by Regulation (EC) No 45/2001) and EU Member States (bound by Directive 95/46/EC and its national implementing rules), but will also involve the World Health Organisation and, possibly, third countries. Therefore, we recommend that the draft Decision should make explicit reference to the application of Articles 7, 8 and 9 of Regulation (EC) No 45/2001³ and Articles 25 and 26 of Directive 95/46/EC.⁴
- Finally, we recommend that the qualification '*to authorised recipients on a need-to-know basis*' or similar be added to the end of the first sentence of Article 4(2) of the draft Decision, which provides for '*special arrangements of the EWRS informatics application*' to allow '*availability of the information communicated through the EWRS in another Union alert system*'.

Brussels, 24 August 2015

³ 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 L8, 12.1.2001, p. 1.

⁴ 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. 31–50.