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Committee on Civil Liberties and Home Affairs

## Excerpts from draft report 17.12.2012 on the proposed Data Protection Act

Amendment 27

Proposal for a regulation

Recital 42

Text proposed by the Commission (42) Derogating from the prohibition on processing sensitive categories of data should also be allowed if done by a law, and subject to suitable safeguards, so as to protect personal data and other fundamental rights, where grounds of public interest so justify and in particular for health purposes, including public health and social protection and the management of health-care services, especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system, *or for historical, statistical and scientific research purposes.*

Proposed change: delete the text in italics

Justification

Processing of sensitive data for historical, statistical and scientific research purposes is not as urgent or compelling as public health or social protection. Consequently, there is no need to introduce an exception which would put them on the same level as the other listed justifications.

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Amendment 327

Proposal for a regulation

Article 81 - paragraph 2

Text proposed by the Commission

2. Processing of personal data concerning health which is necessary for historical, statistical or scientific research purposes, such as patient registries set up for improving diagnoses and differentiating between similar types of diseases and preparing studies for therapies, is subject to the conditions and safeguards referred to in Article 83.

Amendment

2. Processing of personal data concerning health which is necessary for historical, statistical or scientific research purposes, *shall be permitted only with the consent of the data subject*, and shall be subject to the conditions and safeguards referred to in Article 83.

Justification

Clarification that the principle of minimisation of the processing of personal data also applies in case it is regulated by Member State law. Health data is extremely sensitive and deserves utmost protection.

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#### Amendment

2a. Member States law may provide for exceptions to the requirement of consent for research, as referred to in paragraph 2, with regard to research that serves an exceptionally high public interests, if that research cannot possibly be carried out otherwise. The data in question shall be anonymised, or if that is not possible for the research purposes, pseudonymised under the highest technical standards, and all necessary measures shall be taken to prevent re-identification of the data subjects. Such processing shall be subject to prior authorisation of the competent supervisory authority, in accordance with Article 34(1).

#### Justification

The amendments to paragraphs 2 and 2a ensure that health data, which is extremely sensitive, may only be used without the consent of the data subject if it serves an exceptionally high public interest and in this case must be anonymised or at least pseudonymised using the highest technical standards. See Council of Europe Recommendation R(97)5 on the protection of medical data, paragraph 9.

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#### Amendment 334

Proposal for a regulation

Article 83 – paragraph 1

Text proposed by the Commission

1. Within the limits of this Regulation, personal data may be processed for historical, statistical or scientific research only if:

(b) data enabling the attribution of information to an identified or identifiable data subject is kept separately from the other information *as long as these purposes can be fulfilled in this manner.*

#### Amendment

1. Within the limits of this Regulation, personal data not falling within the categories of data covered by Articles 8 and 9 may be processed for historical, statistical or scientific research purposes only if:

(b) data enabling the attribution of information to an identified or identifiable data subject is kept separately from the other information.

1b. Member States law may provide for exceptions to the requirement of consent for research, as referred to in paragraph

Article 83 – paragraph 1 a (new)

1a, with regard to research that serves an exceptionally high public interests, if that research cannot possibly be carried out otherwise. The data in question shall be anonymised, or if that is not possible for the research purposes, pseudonymised under the highest technical standards, and all necessary measures shall be taken

to prevent re-identification of the data subjects. Such processing shall be subject to prior authorisation of the competent supervisory authority, in accordance with Article 34(1).

#### Justification

In cases where the data subject has not given consent, sensitive data and data about children should only be used for research purposes if based on law and serving exceptionally high public interest. Otherwise, any "research", no matter if academic or corporate and including e.g. market research, could be used as an excuse to override all protections provided for in the other parts of this Regulation, such as in Article 6 on legal grounds etc. The wording is identical to the proposed provisions in Article 81.

#### Article 83 – paragraph 2

Text proposed by the commission

2. Bodies conducting historical, statistical or scientific research may publish or otherwise publicly disclose personal data only if:

(a) the data subject has given consent, subject to the conditions laid down in Article 7; or

*(b) the publication of personal data is necessary to present research findings or to facilitate research insofar as the interests or the fundamental rights or freedoms of the data subject do not override these interests; or*

(c) the data subject has made the data public.

#### Amendment

2. Bodies conducting historical, statistical or scientific research may publish or otherwise publicly disclose personal data only if:

(a) the data subject has given consent, subject to the conditions laid down in Article 7; or

*(old b) deleted*

(b) the data subject has made the data public.

#### Justification

Research purposes should not override the interest of the data subject in not having his or her personal data published See related Article 17(2).