



27 November 2012

Proposed FEAM amendments to EC Proposal for a Regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data (COM(2012)0011)

Amendments to Article 4(20) (new), Article 6(1)(g) (new) and Article 9(2)(k) (new) should be included as a group.

Recital 23

Text from the Commission	Proposed Amendment
<p>The principles of protection should apply to any information concerning an identified or identifiable person. To determine whether a person is identifiable, account should be taken of all the means likely reasonably to be used either by the controller or by any other person to identify the individual. The principles of data protection should not apply to data rendered anonymous in such a way that the data subject is no longer identifiable.</p>	<p>The principles of protection should apply to any information concerning an identified or identifiable person. To determine whether a person is identifiable, account should be taken of all the means <u>reasonably likely</u> to be used either by the controller or by any other person to identify the individual. <u>Identification shall not be deemed “reasonably likely” in respect of data held for historical, statistical and scientific purposes, if information that enables the identification of a data subject is kept separately from the data that is the object of the historical, statistical and scientific purposes. Keeping separately can be achieved where appropriate safeguards are in place to prevent the risk of unnecessary identification and that any key enabling such identification is kept securely. A single data controller can achieve keeping separately for these purposes. The data controller need not engage a third party to hold any key if such appropriate safeguards are in place and the key is kept securely by that data controller.</u></p> <p>The principles of data protection should not apply to data rendered anonymous in such a way that the data subject is no longer identifiable. <u>Anonymisation is a valuable means of protecting data subjects that is promoted by this Regulation.</u></p>

Justification

Some forms of historical, statistical and scientific analysis require that data is attributable to an individual, without requiring the individual to be identifiable by the researchers. Pseudonymisation or key-coding is often used to enable such analysis while protecting the privacy of the research subjects. This amendment would clarify that key-coded data used for historical, statistical and scientific purposes are intended to be out of scope of the Regulation where appropriate safeguards are in place to protect the privacy of individuals, with reference to the approach used in Article 83. The amendment also clarifies that in specified circumstances a single data controller can hold key-coded data outside the scope of the Regulation and that this can be achieved without needing to send the key to a third party to hold. Further, separate parts of a single organisation should be able to process key-coded data in the same way as those outside the organisation.

Recital 26

Text from the Commission	Proposed Amendment
<p>Personal data relating to health should include in particular all data pertaining to the health status of a data subject; information about the registration of the individual for the provision of health services; information about payments or eligibility for healthcare with respect to the individual; a number, symbol or particular assigned to an individual to uniquely identify the individual for health purposes; any information about the individual collected in the course of the provision of health services to the individual; information derived from the testing or examination of a body part or bodily substance, including biological samples; identification of a person as provider of healthcare to the individual; or any information on e.g. a disease, disability, disease risk, medical history, clinical treatment, or the actual physiological or biomedical state of the data subject independent of its source, such as e.g. from a physician or other health professional, a hospital, a medical device, or an in vitro diagnostic test.</p>	<p>Personal data relating to health should include in particular all personal data pertaining to the health status of a data subject; information about the registration of the individual for the provision of health services; information about payments or eligibility for healthcare with respect to the individual; a number, symbol or particular assigned to an individual to uniquely identify the individual for health purposes; any information about the individual collected in the course of the provision of health services to the individual; information personal data derived from the testing or examination of a body part or, bodily substance, including or biological samples; identification of a person as provider of healthcare to the individual; or any information on e.g. a disease, disability, disease risk, medical history, clinical treatment, or the actual physiological or biomedical state of the data subject independent of its source, such as e.g. from a physician or other health professional, a hospital, a medical device, or an in vitro diagnostic test.</p>

Justification

Recital 26 must be consistent with definition of “data concerning health” in Article 4. This amendment would clarify that data concerning health includes personal data obtained from testing biological samples, rather than biological samples *per se*.

Recital 40

Text from the Commission	Proposed Amendment
<p>The processing of personal data for other purposes should be only allowed where the processing is compatible with those purposes for which the data have been initially collected, in particular where the processing is necessary for historical, statistical or scientific research purposes. Where the other purpose is not compatible with the initial one for which the data are collected, the controller should obtain the consent of the data subject for this other purpose or should base the processing on another legitimate ground for lawful processing, in particular where provided by Union law or the law of the Member State to which the controller is subject. In any case, the application of the principles set out by this Regulation and in particular the information of the data subject on those other purposes should be ensured.</p>	<p>The processing of personal data for other purposes should be only allowed where the processing is compatible with those purposes for which the data have been initially collected, in particular such as where the processing is necessary for historical, statistical or scientific research purposes. Where the other purpose is not compatible with the initial one for which the data are collected, the controller should obtain the consent of the data subject for this other purpose or should base the processing on another legitimate ground for lawful processing, in particular where provided by Union law or the law of the Member State to which the controller is subject. In any case, the application of the principles set out by this Regulation and in particular the information of the data subject on those other purposes should be ensured.</p>

Justification

This amendment clarifies that historical, statistical and scientific purposes are intended to be deemed ‘not incompatible’ purposes. While this appears to have been the intention of the original draft in order to be consistent with the 1995 Data Protection Directive, the use of “in particular” is ambiguous. This amendment is supported by the proposal to introduce a new paragraph 2 in Article 83.

There are a range of scientific activities, such as audit, that support research, but are not research *per se*. This proposal would also provide greater clarity by removing the word “research” to indicate that all such scientific activities are included in the scope of Article 83. [Note: this amendment is consistent with the Council Presidency’s proposed changes in the version dated 22 June 2012.]

**Article 4 – Paragraph 10
Definitions**

Text from the Commission	Proposed Amendment
(10) 'genetic data' means all data, of whatever type, concerning the characteristics of an individual which are inherited or acquired during early prenatal development;	(10) 'genetic data' means <u>information on the hereditary characteristics, or alteration thereof, of an identified or identifiable person, obtained through nucleic acid analysis.</u>

Justification

Not all “genetic data” contain sufficient information to identify an individual. The proposed definition of “genetic data” should therefore be clarified to ensure that it only relates to “personal data”. The definition should also be amended to relate specifically to information obtained by the analysis of nucleic acids to make it consistent with other widely used definitions. [Note: this amendment is consistent with the Council Presidency’s proposed changes released on 22 June 2012.]

**Article 4 – Paragraph 12
Definitions**

Text from the Commission	Proposed Amendment
(12) 'data concerning health' means any information which relates to the physical or mental health of an individual, or to the provision of health services to the individual;	(12) 'data concerning health' means <u>any information personal data</u> which relates to the physical or mental health of an individual, or to the provision of health services to the individual;

Justification

The proposed definition of “data concerning health” should be clarified to ensure that it only relates to “personal data”.

**Article 4 – Paragraph 20 (new)
Definitions**

Text from the Commission	Proposed Amendment
	<u>(20) 'Anonymisation' means processing personal data in such a manner that it can subsequently no longer be considered identifiable.</u>

Justification

Anonymous data falls outside of the scope of the Regulation and anonymisation is an important means to protect the privacy of data subjects. However, the act of removing identifiers to ensure that data are no longer personal – anonymisation – is an act of processing and must comply with the Regulation. This amendment establishes a definition of anonymisation to support the clarification of the legal basis for anonymisation in the amendments to Articles 6(1) and 9(2) below.

**Article 5 – Paragraph 10
Principles relating to personal data processing**

Text from the Commission	Proposed Amendment
Personal data must be: (e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the data will be processed solely for historical, statistical or scientific research purposes in accordance with the rules and conditions of Article 83 and if a periodic review is carried out to assess the necessity to continue the storage;	Personal data must be: (e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the data will be processed solely for historical, statistical or scientific research purposes in accordance with the rules and conditions of Article 83 and if a periodic review is carried out to assess the necessity to continue the storage until it becomes <u>apparent that continued storage is no longer necessary;</u>

Justification

This amendment would replace the proposal for periodic review of data stored solely for historical, statistical or scientific purposes with requirement more suited to the nature of these activities. For example, it is a characteristic of research that certain data may not be used for a long time until they become significant in the future. The future uses of data for research are also difficult to predict.

**Article 6 – Paragraph 1(g) (new)
Lawfulness of processing**

Text from the Commission	Proposed Amendment
	<u>(g) Processing is conducted for the purpose of anonymisation.</u>

Justification

Anonymous data falls outside of the scope of the Regulation and anonymisation is an important means to protect the privacy of individuals. However, the act of removing identifiers to ensure that data are no longer personal – anonymisation – is an act of processing. This amendment provides a legal basis for anonymisation of personal data in its own right, to clarify that this can be achieved without consent of the data subject. This amendment is complementary to the amendment in Article 9(2) below and also requires a definition of “anonymisation” to be included in Article 4.

**Article 9 – Paragraph 2(k) (new)
Processing of special categories of personal data**

Text from the Commission	Proposed Amendment
	<u>(k) Processing is conducted for the purpose of anonymisation.</u>

Justification

Anonymous data falls outside of the scope of the Regulation and anonymisation is an important means to protect the privacy of data subjects. However, the act of removing identifiers to ensure that data are no longer personal – anonymisation – is an act of processing. This amendment provides a legal basis for anonymisation of sensitive categories of personal data in its own right, to clarify that this can be achieved without consent of the data subject. This amendment is complementary to the amendment in Article 6(1) above and also requires a definition of “anonymisation” to be included in Article 4.

**Article 14 – Paragraph 5 – point (e) (new)
Right of the data subject to information**

Text from the Commission	Proposed Amendment
Paragraphs 1 to 4 shall not apply, where: a) the data subject has already the information referred to in paragraphs 1, 2 and 3; or (b) the data are not collected from the data subject and the provision of such information proves impossible or would involve a disproportionate effort; or (c) the data are not collected from the data subject and recording or disclosure is expressly laid down by law; or or (d) the data are not collected from the data subject and the provision of such information will impair the rights and freedoms of others, as defined in Union law or Member State law in accordance with Article 21.	Paragraphs 1 to 4 shall not apply, where: (a) the data subject has already the information referred to in paragraphs 1, 2 and 3; or (b) the data are not collected from the data subject and the provision of such information proves impossible or would involve a disproportionate effort; or (c) the data are not collected from the data subject and recording or disclosure is expressly laid down by law; or or (d) the data are not collected from the data subject and the provision of such information will impair the rights and freedoms of others, as defined in Union law or Member State law in accordance with Article 21; <u>or (e) the data are processed for historical, statistical or scientific purposes subject to the conditions and safeguards referred to in Article 83 and the provision of such information proves impossible or would involve a disproportionate effort.</u>

Justification

The right of the data subject to information could be problematic for research in situations where notifying participants would create a disproportionate burden that could prevent the research from proceeding. The Regulation includes a 'disproportionate effort' provision where the data are not collected from the data subject. However, in research studies where data are collected from the data subject, it may not always be possible or may be prohibitively burdensome for researchers to provide information to data subjects.

**Article 83 – Paragraph 1
Processing for historical, statistical and scientific research purposes**

Text from the Commission	Proposed Amendment
Within the limits of this Regulation, personal data may be processed for historical, statistical or scientific research purposes only if:	Within the limits of this Regulation, personal data may be processed for historical, statistical or scientific research purposes <u>under paragraph 2 of Article 6 and point (i) of Article 9(2)</u> only if:

Justification

Article 83 establishes an independent legal basis for the processing of personal data for historical, statistical and scientific purposes, provided the criteria in Article 83(1) (a) and (b) are met. This proposed amendment clarifies that data controllers may rely on an alternative legal basis, such as consent of the data subject, for processing of personal data for historical, statistical and scientific purposes rather than relying on paragraph 1 of Article 83.

**Article 83 – Paragraph 1 (a) and (b)
Processing for historical, statistical and scientific research purposes**

Text from the Commission	Proposed Amendment
Within the limits of this Regulation, personal data may be processed for historical, statistical or scientific research purposes only if: (a) these purposes cannot be otherwise fulfilled by processing data which does not permit or not any longer permit the identification of the data subject; (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.	Within the limits of this Regulation, personal data may be processed for historical, statistical or scientific research purposes only if: (a) these purposes cannot be otherwise fulfilled <u>reasonably be achieved</u> by processing data which does not permit or not any longer permit the identification of the data subject; and (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.

Justification

This amendment retains the safeguard that anonymised data should be used in place of personal data wherever possible. However, this amendment provides for a test based on what can reasonably be achieved, rather than the very strict test in the current draft that may prove prohibitive to research. This amendment also provides a conjunction between points (a) and (b) for clarity.

**Article 83 – Paragraph 2 (new)
Processing for historical, statistical and scientific research purposes**

Text from the Commission	Proposed Amendment
	<u>2. Further processing of data for historical, statistical or scientific purposes shall not be considered as incompatible under point (b) of Article 5(1) provided that the processing:</u> <u>(a) is subject to the conditions and safeguards of this Article; and</u> <u>(b) complies with all other relevant legislation.</u>

Justification

This amendment clarifies that historical, statistical and scientific research purposes are intended to be not incompatible purposes, by relating Article 5(1)(b) to Article 83. The proposal would ensure that the Regulation is

consistent with the previous 1995 Data Protection Directive, which states that “Further processing of data for historical, statistical or scientific purposes shall not be considered as incompatible provided that Member States provide appropriate safeguards.” (Art. 6(1)(b)). [Note: this amendment is consistent with the Council Presidency’s proposed changes in the version dated 22 June 2012.]

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