


Novedades en el nuevo reglamento y su expresión en el ámbito de la salud

**Sociedad Española de Epidemiología
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Propuesta original de la Comisión (enero 2012):

- Art. 9. 1: The **processing of** personal data, revealing race or ethnic origin, political opinions, religion or beliefs, trade-union membership, and the processing of **genetic data or data concerning health** or sex life or criminal convictions or related security measures **shall be prohibited**.
- Art. 9.2: Paragraph 1 shall not apply where
 - (h) processing of data concerning health is necessary for health purposes and subject to the conditions and safeguards referred to in Article 81; or
 - (i) processing is necessary for historical, statistical or scientific research purposes subject to the conditions and safeguards referred to in Article 83;
- **Texto mantenido en Posición Común de PE**

Propuesta original de la Comisión (enero 2012):

- Art. 5 (b): Personal data must be: collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes (**no hay referencia a fines compatibles**)
- Art. 6.2: Processing of personal data which is necessary for the purposes of historical, **statistical or scientific research shall be lawful subject to the conditions and safeguards referred to in Article 83.**
- Art. 6.4: Where the purpose of further processing **is not compatible** with the one for which the personal data have been collected, the processing must have a legal basis at least in one of the grounds referred to in points (a) to (e) of paragraph 1. This shall in particular apply to any change of terms and general conditions of a contract.

Propuesta original de la Comisión (enero 2012):

Article 83

Processing for historical, statistical and scientific research purposes

1. 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.**

(...)

Posición común PE (marzo 2014):

- **Art. 5 (b):** collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes (purpose limitation).
- **Art. 6.2:** Processing of personal data which is necessary for the purposes of historical, **statistical or scientific research shall be lawful subject to the conditions and safeguards referred to in Article 83.**
- **Supresión de Art. 6.4** sobre posibilidad de tratar datos para finalidades no compatibles sobre cualquier base legal adicional distinta del interés legítimo

Versión Presidencia italiana (diciembre 2014):

- Art. 5 (b): Personal data must be: collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes; **further processing of data for historical, statistical in the public interest or scientific purposes shall not be considered as incompatible subject to the conditions and safeguards referred to in Article 83.**
- Art. 6.2: Processing of personal data which is necessary for archiving purposes in the public interest, or for historical, statistical or scientific purposes shall be lawful **subject also** to the conditions and safeguards referred to in Article 83.
- Art. 6.4: Where the purpose of further processing is incompatible with the one for which the personal data have been collected, the further processing must have a legal basis at least in one of the grounds referred to in points (a) to (e) of paragraph 1.

Versión Presidencia letona (JAI marzo 2015):

- Se mantiene 6.2 en versión Presidencia italiana
- Tratamientos para **finés compatibles no exigen nueva base legal** (aparentemente cuando se trata del mismo responsable)
- **Fines estadísticos o científicos siempre compatibles**
- Garantías adicionales en **nuevo Art. 83**, que no son tales, sino salvaguardas para los casos en que los EEMM derogan el régimen general de derechos y obligaciones
- Inconsistente: “Cons. 25: It is often not possible to fully identify the purpose of data processing for scientific purposes at the time of data collection. Therefore data subjects can give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research”

Versión Comisión (enero 2012):

Article 81

Processing of personal data concerning health

1. Within the limits of this Regulation and in accordance with point (h) of Article 9(2), **processing of personal data concerning health must be on the basis of Union law or Member State law** which shall provide for suitable and specific measures to safeguard the data subject's legitimate interests, and be necessary for:

(...) **(b) 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, inter alia for medicinal products or medical devices; or**

(...) 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.

Posición Común PE (marzo 2014):

1. In accordance with the rules set out in this Regulation, in particular with point (h) of Article 9(2), **processing of personal data concerning health must be on the basis of Union law or Member State law** which shall provide for suitable, consistent, and specific measures to safeguard the data subject's interests and fundamental rights, to the extent that these are necessary and proportionate, and of which the effects shall be foreseeable by the data subject, for:

(...) (b) **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, inter alia for medicinal products or medical devices, and if the processing is carried out by a person bound by a confidentiality obligation; or

(...)

.../....

Posición Común PE (marzo 2014):

1a. When the purposes referred to in points (a) to (c) of paragraph 1 can be achieved without the use of personal data, such data shall not be used for those purposes, unless based on the consent of the data subject or Member State law.

1b. Where the data subject's consent is required for the processing of medical data exclusively for public health purposes of scientific research, the consent may be given for one or more specific and similar researches. However, the data subject may withdraw the consent at any time.

(...) 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.

2a. MS law may provide for, **exceptions to the requirement of consent for research, as referred to in paragraph 2, with regard to research that serves a high public interest** 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 unwarranted re-identification of the data subjects. However, the data subject shall have the right to object at any time in accordance with Article 19.

Versión Presidencia letona (JAI marzo 2015):

- Art. 9.2. (hb): **Processing 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 health care and of medicinal products or medical devices, on the basis of Union law or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject data;
- Art. 9.2.i: (i) Processing is necessary for archiving purposes in the public interest or historical, **statistical or scientific (...) purposes and subject to the conditions and safeguards laid down in Union or Member State law**, including those referred to in Article 83.
- Cons. 41: In addition to the specific requirements for such processing, the **general principles and other rules of this Regulation should apply, in particular as regards the conditions for lawful processing**

**¡Gracias por su
atención!**

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