SOCIEDAD ESPAÑOLA DE EPIDEMIOLOGÍA

# REPORT by the SEE Working Group on Confidentiality and Data Protection on the Proposal for a European Data Protection Regulation and the Amendments presented

a) Comments on the proposal version under discussion at 26 February 2013
b) Specific examples of data processing in the field of public health research
c) Updated comments on 13 December 2013, after Parliament Approval

SEE Working Group on Confidentiality & Data Protection

# a) Comments on the proposal version under discussion at 26 February 2013[1]

## 1. General considerations

Concern over data protection in the European space has been a recurrent theme now for several decades. The protection of personal data, which seeks no more than the protection of the individual holder of the data and the defence of his rights, has been the subject of attention and regulation through Directive 95/46/EC of the European Parliament and 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 (DO L 281, of 23 November 1995), which sets out criteria of a general nature and of common application which must preside over the processing of personal information. The Directive also includes exceptions and precepts applicable to specific sectors which need, to reinforce the use of information without infringing the rights of the persons concerned, the detailing of general aspects of the rules for the processing carried out in particular sectors. In both the one case and the other, the European perspective, with excellent criteria, has tried to balance two elements apparently located at opposite extremes and therefore demanding a rational approach adjusted to law. In effect, the processing of personal information and the protection of the individual and his rights appear to be situated, in principle, in an irreconcilable position which runs the risk of overbalancing in favour of the use of data with few limitations, or else going for extreme guarantees to the individual, with limited possibilities in allowing the handling of personal information.

To ignore the advances that the processing of information, both manual and computerised, represents in today's society would be falling into a reactionary process. Computerised processing especially allows barriers of space and time to be overcome, and therefore makes personal information easily available, which results in improvements in the quality of life of the citizens in the sectors where it is applied. The advantages of technology seem to be unlimited, as it advances at a vertiginous pace. Now, together with the advantages recognised, it cannot be denied that there are risks and threats to individual rights. In fact, the use of personal data outside the principles and limits which submit it to legal rules can lead to a breach in the exercise of fundamental rights. To use the advantages given by the collection and processing of personal data and cancel or reduce the risks which this could involve, the rules on data protection seek to reconcile the two elements referred to: the processing of personal data and the protection of the rights of individuals. Directive 95/46/EC gave rise at that time to the preparation of rules on data protection in Member States which lacked them, and the adaptation of the existing rules in countries which had already legislated on the matter. With the passing of the years and continuous advances in integration, the Union has raised as a requirement the modernisation of the European framework of data protection and homogenization of the national

[1]Prepared by Mª Mercedes Serrano Pérez, Carmen Navarro Sánchez and Óscar Zurriaga Llorens.

regulations, this time through the preparation of a rule for direct application in the Member States, making subsequent national adaptation and interpretation unnecessary. The single market has also achieved personal data protection, seeking with this new regulation to eliminate the barriers and obstacles arising from the existence of different regulations in the Member States, in other words, to give uniformity to the processing of personal information within the Union. On the other hand, through these years, from the appearance of the Directive and up till now, the right to the protection of personal data has been raised to an independent right in art. 8 of the European Charter of Fundamental Rights of 7 December 2000, in art. 16 TFEU and in art. 8 ECHR, which revalidates its position in the European space and makes it, on the one hand, a key aspect in protection of the rights of individuals in current societies and, on the other, a material support for policies in the Union which need for their effectiveness the processing of personal information.

Thus, modernisation of the field of data protection from Europe is raised now, in 2012, through a Regulation (Proposal for a Regulation of the European Parliament and of the Council on the protection of the individual with regard to the processing of personal data and on the free movement of such data, 2012/001 (COD)), a legal instrument which after its approval by the Community institutions will become an applicable rule in all the Member States, according to art. 288 TFEU. This situation will alter the national regimes existing hitherto, which could have some divergence arising from the margins allowed by the 1995 Directive. With all this, it has to be said that the criteria set out in the Directive are still there in the new regulation in the fundamental aspects, which is evidence of the good state of data protection in Europe. This is no obstacle to accepting as necessary the incorporation of new elements and procedures which improve the protection of individuals and allow the continuing enjoyment of the benefits of handling the information, always within the general framework of finding a balance between these two elements.

The European Commission presented on 25 January 2012 the Draft of the Proposed General Regulation on Data Protection of the European Union, the definitive text of which is likely to take until 2014. Some critical comments have emerged on this proposal, but especially after publication of the amendments contained in the Report by LIBE (**Committee on Civil Liberties, Justice and Home Affairs** (2012/0011/(COD) which has presented the *Draft Report on the proposal for a regulation of the European Parliament and of the Council on the protection of the individual with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) (COM(2012)0011 – C7-0025/2012 – 2012/0011(COD).* Some amendments contained in the Report, if approved in the terms presented, would directly affect the processing of personal data in specific sectors. One of the sectors prejudiced by the changes announced in the European ambit is that of health, including scientific research in this space.

In fact, some of the amendments included in the report mean a substantial retrocession and with irreversible consequences in the field of health and scientific research in the same context, where the processing of

personal data relating to health becomes a fundamental instrument in carrying out the functions which society itself demands. This retrocession would cause a diminution in the rights of individuals, both from the individual viewpoint, valuing health as a subjective right of all individuals with regard to individualised treatment, and from the conception of health as a social asset, a value which belongs to all society and in which research processes are for the purpose of protecting that society and improving the quality of life. In this double consideration of health, the processing of personal data is necessary both for personal medical treatment and also, where applicable, for studies of a more general nature, from understanding the fact of health as a group asset which is directed to a higher objective: the protection of health as a public asset. Health is also an asset protected in art. 35 of the European Charter of Fundamental Rights. The precept sets out that "on defining and executing all the policies and actions of the Union a high level of protection of human health will be guaranteed". On the other hand, health associations are aware of the need to establish a harmonized and coherent framework which assists in the international transfer of data, a situation which, through the connection of these associations with their European counterparts, will encourage the carrying out of their activities in the fields of health and research and will improve the levels of health for all the citizens of the Union.

## 2. The general framework of the processing of data relating to health and scientific research contained in the Proposal for the Regulation and the amendments presented.

### *2.1. General framework of the processing of data relating to health.*

The processing of data relating to health and scientific research is inferred from the joint reading of arts. 6, 9, 81 and 83 of the Proposal for the Regulation and from some statements involved.

Thus, statement 31 establishes the **legality of processing in two situations**, either with the consent of the person concerned, which as a novelty in the Proposal must be explicit (art. 5.8), or on a legitimate basis established by law, whether in this Regulation or in legislative acts of the Member State or of the Union referring to this Regulation (basis or situation which legitimises the processing of data without the consent). Statement 37 brings in some circumstances in which there is a **legitimate basis for processing data without the need to obtain consent, that is,** when it is necessary to safeguard the essential interest of the life of the person concerned, an expression which is equivalent to a vital interest (situation which could arise in the health ambit). Statement 41 **prohibits the processing of sensitive data** which, due to the delicate nature of the information contained, can severely breach the rights of the person concerned. These data can only been processed if the person concerned has given his consent (again this has to be an explicit consent), although **exceptions to this possibility** must be authorised in relation to specific needs, also in explicit form. The exceptions which justify the processing of this kind of especially delicate data, without the need for consent to be given, and according to statement 42, must be established by a legislative act and with the appropriate

guarantees to protect fundamental rights and personal data. And among the reasons, the same statement provides for **grounds of public interest, including public health, social protection and the management of health care services, especially to guarantee the quality and efficacy of the procedures used to settle claims for benefits and for services in the regime of illness insurance or for purposes of scientific, historical or statistical research.** Finally, statement 122 says that the processing of personal data relating to health, as a special category of data requiring greater protection, can be justified, it is understood without the consent of the person concerned, on legitimate grounds for the benefit of the citizens and society as a whole, in particular when dealing with guaranteeing the continuity of cross-border health care. Therefore, the legitimate ground of the benefit of the citizens replaces in these cases the need to obtain consent.

Analysing the articles of the regulation, we find in the first place a broad definition of data related with health, set out in art. 4.12, which would have to be completed with statement 26. According to the precept cited **"data relating to health"** means "any information referring to the physical or mental health of a person or the care provided by personal health services". And according to statement 26, data relating to health must include, "in particular all data relating to the health of the person concerned: information on the registration of the person for the provision of health services, information on payments or the admissibility for health care with respect to the person; a number, symbol or other datum assigned to a person identifying him unequivocally for health purposes; any information collected during the provision of health services to him; information derived form tests or examinations of a part of his body or body substance, including biological samples; identification of a person as provider of health care to him; or any information on, for example, all illness, disability, risk of illness, medical history, clinical treatment, or real physiological or biomedical state of the person concerned, independently of its source, such as for example, any doctor or other health professional, hospital, medical device or diagnostic test in vitro". As can be appreciated the concept of **data relating to health is extremely broad**, although perhaps thought should be given to the exclusion of **genetic data** from the concept of data relating to health referred to in the Proposal for the Regulation, and their inclusion be considered, taking account of their usage also for reasons of public health.
Art. 9 of the Proposal prohibits the processing of especially delicate or sensitive data, among them those data relating to health, save for the exceptions referred to in section 2, among which is the giving of consent for the processing of these data; or in section h), if the processing of data relating to health is necessary for the purposes of health and under the conditions of art. 81; or again, in the third place, letter i), if the processing is necessary for purposes of historical, scientific or statistical research, with observance of the conditions and guarantees of art. 83. However, the processing of personal data will be lawful if, according to art. 6, the person concerned consents to it or, without the need to obtain the consent, the data processing is necessary for historical, statistical and scientific research, again with the fulfilment of the guarantees of art. 83 (art. 6.2).

To summarise the state of the question:

**The processing of data relating to health,** which are especially sensitive, is prohibited as a general rule except:

-where the person concerned has consented to the processing (by explicit consent)

- that they are health data with purposes of health and in accordance with the conditions of art. 81, which are all health reasons and which we shall see later. The health purpose is the reason of public interest which shelters the processing of these data without consent (which does not prevent the person concerned from giving it, but on the other hand cannot prevent the processing).

On the other hand, data processing (all the data of art. 9, including data relating to health) for purposes of historical, statistical or scientific research is justified without consent, always under the conditions and guarantees of art. 83 (art. 9.2 i).

### *2.2. Amendments to art. 81 presented by the LIBE Report*

Art. 81 deals with the circumstances of the processing of data relating to health, in accordance with art. 9.2 h), which we have just studied, and therefore without the consent of the person concerned, provided that it is necessary (conditions of art. 81):

a) for the purposes of preventive medicine or occupational medicine, medical diagnosis, the provision of health care or treatment or the management of health care services, provided that such data are processed by a health professional subject to the obligation of professional secrecy or by another person also subject to an equivalent obligation of confidentiality in virtue of the legislation of the Member State or the regulations established by the competent national bodies; or

b) for reasons of public interest in the field of public health, such as protection against serious cross-border health risks, or to guarantee high levels of quality and safety in medicines or health material; or

c) for other reasons of public interest in fields such as social protection, especially in order to guarantee the quality and efficacy of the procedures used to settle claims for benefits and services in the regime of illness insurance.

2. The processing of personal data relating to health where necessary for purposes of historical, statistical or scientific research, such as the establishment of registers of patients in order to improve diagnosis, distinguish between similar types of diseases and prepare studies for therapies, will be subject to meeting the conditions and guarantees referred to in article 83.

3. The Commission will be empowered to adopt acts delegated, in accordance with article 87, in order to specify other reasons of public interest in the field of public health referred to in section 1, letter b), as well as the criteria and requirements of the guarantees over the processing of personal data for the purposes referred to in section 1.

The enumeration contained in the precept must be considered as restricted, save for the provision of section 3, in relation with the possibility of including by means of a delegated act other reasons of public interest to

allow the data processing, which could generate some legal uncertainty. Although it could also facilitate the adaptation of data processing in this terrain to the needs which are presented, through speeding up the procedure in order to incorporate new situations into the general regulation of the precept. Sensu contrario it has to be understood that the processing of data relating to health outside the cases of art. 81.1 will require the explicit consent of the person concerned, although the precept does not expressly say so.

The **Spanish Epidemiology Society (SEE) PROPOSES AN AMENDMENT** to section 1 b) of art. 81 to clarify the reasons of public interest in the field of public health which legitimise the data processing. According to the text of the Proposal for the Regulation the reasons of public interest seem to be circumscribed only to those expressly set out in the text. To avoid a literal interpretation (therefore excluding other reasons) the following text is proposed: "b) for reasons of public interests in the field of health, **among these**, protection against serious cross-border risks, or to guarantee high levels of quality and safety in medicines and health materials, or"

The LIBE Report adds a new section 1 to art. 81, through **Amendment 326,** which does not seem to make much sense, according to which: "When the purposes referred to in points a and c of section 1 can be achieved without the use of personal data that data must not be used for these purposes", which in our view would be achieved by application of the principles of the quality of the data. Specifically, section c of art. 5 which alludes to the data as "adequate, relevant and limited to the essential minimum in relation to the ends for which they are processed, will only be processed if and provided that these ends cannot be achieved by the processing of information which does not involve personal data". The amendment is repetitive with respect to a general principle of observance in personal data processing. **THE REJECTION OF THIS AMENDMENT IS PROPOSED.**

**Amendment 327**, presented by the LIBE Report in the second section of art. 81, has much more relevance, for what it means in terms of scientific research. Amendment 327 proposes that "the processing of personal data relating to health where necessary for purposes of scientific, statistical or historical research will only be allowed with the consent of the person concerned and under the conditions and guarantees of art. 83".

As we have already said, art. 83, interpreted in the light of art. 6 of the Proposal for the Regulation, legitimises the processing of data for historical, statistical and scientific ends without consent, in the limits of the precept itself, that is, if these ends cannot be achieved without identifying or allowing identification of the person concerned or if the data which attribute the information are preserved separately without this impeding the achievement of these ends. The amendment, therefore, substantially alters the conditions of data processing for the purposes of historical, scientific and statistical research on calling for consent which would be explicit, this being the general rule in the cases where it had to be given. The obligation of obtaining

explicit consent, a consent which cannot be deduced from any action by the subject (and therefore cannot be a tacit consent, as in the earlier European regulation on data protection), would reduce the possibility of scientific research in forming an added obstacle to research work. It must be remembered here that the benefits of the research activity in health matters redounds on society itself, since it enables advances in matters of public health from the viewpoint of its conception as a social asset and value which merits the maximum protection. **This does not mean that the right to data protection would be divested of every guarantee, but so extreme a condition of use in this field cannot be considered acceptable in a rational weighting of all the interests in play.** This taking into account, also, that the right to data protection is not an absolute right and like all others must admit limitations depending on the protection of other assets and rights worthy of protection. On the other hand, observance of the rest of the criteria and principles of the regulation is not excepted, so that the principles of quality of data, the obligations of the processing manager, especially secrecy and confidentiality and the rights of individuals continue to be of application. Therefore, this is not a question of defending a reduction of guarantees which must surround the processing of data with these ends, but of allowing their use in matters of research, without the reinforcement of a requirement which would condemn the research to ineffectiveness. The need to obtain explicit consent for the processing of this type of data cannot be defended. **THE REJECTION OF THIS AMENDMENT IS PROPOSED.**

The LIBE Report adds, through **Amendment 328,** section 2 a) (new) to art. 81, according to which "The law of the Member States must establish exceptions to the requirement of consent for the research referred to in section 2 in relation with research which serves an especially high public interest, if the research cannot be carried out in another way. The data in question will be made anonymous, or if this should not be possible for the purposes of the research, made pseudonymous under the highest technical standards, adapting the steps necessary to prevent the re-identification of the persons concerned. This processing will be subject to the authorisation of the competent supervisory authority, in accordance with art. 34 (1).

This amendment, which envisages that the law in the Member States shall establish exceptions to the giving of consent (explicit) for the processing of the data for historical, statistical and scientific ends, has to be seen in relation with the requirement of obtaining consent for that processing which has already been introduced through the alteration of art. 81 section a) by the earlier amendment (327). The rejection of the earlier amendment leads us also to rejection of the possibility of admitting exceptions to the giving of consent, a requirement on which we have already pronounced in matters of the processing of data with statistical, historical and scientific ends. **THE REJECTION OF THIS AMENDMENT IS PROPOSED**.

### *2.3. Amendments to art. 83 presented by the LIBE Report.*

Art. 83 of the Proposal for Regulation indicates that:

***Processing for purposes of historical, statistical or scientific research***

1. Within the limits of this Regulation, personal data can be processed for purposes of historical, statistical or scientific research only if:
a) these purposes cannot be achieved in another way by the processing of data which does not allow or does not permit the identification of the person concerned;
b) the data which enable the attribution of information to an identified or identifiable person concerned are preserved apart from the rest of the information, to the degree that these purposes can be achieved in this way.

2. The bodies which carry out historical, statistical or scientific research may publish or disclose personal data in another way only if:
a) the person concerned has given his consent in the conditions established in article 7;
b) the publication of personal data is necessary in order to present the results of research or to facilitate research, provided that the interests or fundamental rights and liberties of the person concerned do not prevail over such objectives; or
c) the person concerned has made the data public.

3. The Commission will be empowered to adopt acts delegated, in accordance with article 86, in order to specify the criteria and requirements for the processing of personal data for the purposes mentioned in sections 1 and 2, as well as the necessary limitations on the rights of information and of access by the person concerned, and to detail the conditions and guarantees of the rights of the person concerned in such circumstances.

The LIBE Report proposes **Amendment 334** to art. 83.1 in the following terms: "Within the limits of this Regulation personal data can be processed for purposes of historical, statistical and scientific research where not included in the categories of data referred to in arts. 8 and 9 only if"

The Amendment has to be understood in a joint reading of Amendments 336 and 337 which "introduce as new sections 1a) and 1b) which require the obtaining of explicit consent from the person concerned for the processing of the data of arts. 8 and 9 (remembering that art. 8 refers to processing the data of children and 9 is on the processing of sensitive data), which serve important public interests and which are made anonymous or pseudonymous. We have already justified the processing of data for historical, scientific and statistical ends without the need to obtain consent, as set forth in the proposal for the Regulation in art. 9.2 h), within the guarantees of 83. Therefore we reject the amendment and we defend the draft text as set out in the Proposal. **THE REJECTION OF THIS AMENDMENT IS PROPOSED.**

The LIBE Report proposes in **Amendment 335** an alternative text for art. 83.1.b): "the data which allow the attribution of information to an identified or identifiable person concerned shall be preserved separately from the rest of the information", a text which omits the last part of the proposal for the Regulation and therefore does not admit the possibility of the contrary (that is, of maintaining data which give information associated to a person), in attention to achieving the ends of historical, statistical or scientific research. In the field of scientific research for public health ends, working with personal data which identify the person is a requirement arising from its proper purpose. In health matters and in scientific research, the processing of anonymous or disassociated data, which therefore only give information, without allowing the identification of the person concerned in them, absolutely blocks the purpose of registers, studies and other research instruments which need, in addition to obtaining the objective information, to attribute it to the subject who is suffering the illness or at risk of suffering it, in order not to reduce the health protection from an individual viewpoint but also from a group perspective. **THE REJECTION OF THIS AMENDMENT IS PROPOSED.**

The LIBE Report proposes a new section 1 a) in art. 83, in **Amendment 336,** with the following text: "Without prejudice to the exceptions of section 1 b) the data included in the categories of data referred to in arts. 8 and 9 could be processed for purposes of historical, scientific and statistical research only with the consent of the person concerned". For the reasons already set out, **THE REJECTION OF THIS AMENDMENT IS PROPOSED.**

The LIBE Report proposes a new section b) in art. 83.1, in **Amendment 337,** with the following text: "The law of the Member States must establish exceptions to the requirement of consent already referred to in section 1 a) in accordance with research which serves an especially high public interest, if the research cannot be carried out in another way. The data in question must be made anonymous, or if this should not be possible for the purposes of the research, made pseudonymous under the highest technical standards, adapting the steps necessary to prevent the re-identification of the persons concerned. This processing will be subject to the authorisation of the competent supervisory authority, in accordance with art. 34 (1)".

This amendment must be interpreted in accordance with the amendment introduced through section 1 a) which requires the giving of consent for the processing of the data of art. 9 for historical, scientific and statistical ends. This new amendment envisages the possibility of making an exception to the general rule of the giving of consent (also subject to a legal concept absolutely undefined "which serves exceptionally the important interests of the State"). The rejection of the previous amendment also justifies the rejection of this one. **THE REJECTION OF THIS AMENDMENT IS PROPOSED.**

The Report LIBE proposes the deletion of section b) of art. 83.2, in **Amendment 339,** and although it is highly improbable that research data could be published allowing the identification of the person concerned, the maintenance of art. 83.2 b) in the terms of the proposal for the Regulation is defended, since the rights and fundamental liberties of the person concerned remain sufficiently guaranteed. **THE DELETION OF THIS AMENDMENT IS PROPOSED.**

## b) Specific examples of data processing in the field of public health research[2].

Two specific examples are attached, of registers of diseases (System of Information on Rare Diseases in the Valencia Community) and on research projects (Prospective European Study on Diet, Cancer and Health, EPIC), the work of which would be seriously threatened if not stopped altogether, if the new Community regulation does not regulate the exception to the giving of explicit consent for the purposes of public health and research

### Example 1: System of Information on Rare Diseases in the Valencian Community

The System of Information on Rare Diseases in the Valencian Community (SIER-CV) established in Order 4/2012 of 7 March, of the Ministry of Health (DOCV No. 6748 of 4 April 2012) is for the purpose of covering needs of epidemiological information on rare diseases (ER), including congenital anomalies, in the field of the Valencian Community, supplying information of checked validity on their incidence and prevalence, assisting the analysis of associated factors, supplying indicators which make possible a comparison with other territories and delivery the information necessary to direct the preparation and evaluation of preventive activities.

To be able to achieve this objective it is necessary to establish how many people in the population are affected by ER. Given the peculiarities of ER, it is necessary to be able to search for those affected through multiple sources and in doing this the first step is to identify which sources have information on patients diagnosed with ER. In this sense the corporate sources of the health system which have diagnostic information and personal identification are basic (hospital registers, primary health care, pharmacy), but it is necessary also to resort to other types of sources not part of the health sources (such as the system of care for dependence, and educational systems) in which the diagnosis is also present but the personal identification is made by different means from those of the health sources. For this reason it is necessary to have the personal data available to make it possible to cross-reference these sources and identify the people reliably to avoid duplications and inconsistencies when trying to establish, for purposes of population vigilance, how many people are affected by ER. This task of crossed information with the purpose of identifying cases is vital, being arduous work in which advances have been made in recent times, thanks, precisely, to the existence of identifiers shared between the various sources of health origin.

The request for specific consent to do this becomes very difficult or impracticable, since each of the sources from which we start has a different hierarchy, specific management and, when it does accede to the information for it to be used in SIER-CV, time has passed since the information was collected and it is very difficult and costly to contact every one of the people included in these sources to ask for their consent.
The fact of dealing with diseases of very low frequency means that the search for cases must be very exhaustive, since the loss of identification in a single case hampers the analysis and interpretation of the data in the majority of the diseases considered, making it more difficult to orientate and evaluate the activities of prevention (one of the objects of the SIER-CV).

The application for consent for collection and use for the purposes of population vigilance of SIER-CV would mean, almost certainly, the impossibility of having this information available in an effective way, making the task enormously more difficult, delaying it in time and making it costly to the point of not being viable.

The SIER-CV has established, in the creation Order mentioned above, an article on confidentiality and data protection, in which it is stipulated that the confidentiality of the information is guaranteed, giving an assurance also that its use will be strictly for health in accordance with the General Health Act 14/1986, in article 10.3, and in the Constitutional Act 15/1999, on Personal Data Protection, in articles 7 to 11.

[2] Prepared by Mª Mercedes Serrano Pérez, Carmen Navarro Sánchez and Óscar Zurriaga Llorens.

## Example 2:European Prospective Investigation into Cancer and Nutrition (EPIC)

### What EPIC is and its contribution to improving the health of the population

EPIC (European Prospective Investigation into Cancer and Nutrition) (http://epic.iarc.fr/) is a large-scale study of more than 500,000 men and women in ten European countries (Denmark, France, Germany, Greece, Italy, the Netherlands, Norway, Spain, Sweden and the United Kingdom), which was promoted by the International Agency for Research on Cancer (IARC/WHO) and initially financed by the Europe Against Cancer Programme and the European Commission and the governments and national research agencies of the participating countries. Its objective is to research the relationship between diet, nutritional condition, lifestyle and genetic and environmental factors and the incidence of cancer and other chronic illnesses.

The results of the research by EPIC have been published in the leading medical magazines at world level - more than 300 articles in the last decade - and have appeared in various international communication media such as Le Monde, Le Figaro, El País, The Guardian, The Telegraph, The Daily Mail, Corriere della Sera, la Repubblica, New York Times, BBC News, CNN, USA Today.

The contributions by EPIC on which are factors of risk or of protection in the diet, physical activity and other lifestyles which are related with the risk of suffering cancer have been a point of reference for the preparation of recommendations on the prevention of cancer and other chronic illnesses by the World Health Organization, the World Cancer Research Fund (WCRF) and national and regional governments.

We can give an example on colorectal cancer. The hypothesis that a diet rich in fibre reduces the risk of colorectal cancer while one rich in red meat and charcuterie increases it was definitively confirmed by results from EPIC. These results were published in scientific magazines of great standing and have been applied in the latest recommendations by the WCRF Guides on dietetic strategies and healthy lifestyles for the prevention of cancer, which are a worldwide reference.
(http://www.dietandcancerreport.org/expert_report/recommendations/index.php)

### Why access to personal data is necessary in EPIC

Studies of large numbers, such as EPIC, collect information on diet, habits of life, medical histories, anthropometrical measurements, blood samples, etc., from healthy people taking part at the start of the study. Later the researchers must identify those who develop cancer, diabetes and other illnesses during the many years of follow-up in order to analyse if any of the factors are associated with the risk of developing the disease. To do this it is necessary to have their personal data available in order to make an effective cross-reference and identify reliably the participants in the large-scale numbers who appear in the registers of these diseases, such as cancer, which in turn depend on access to other medical records (clinical histories, health cards, radiotherapy, etc.) and also need to be cross-referenced to various data sources.

EPIC has been possible in Spain in compliance with the Community Directive on Data Protection 95/46/EC and the Constitutional Act 15/1999 of 13 December on Personal Data Protection (LOPD). The new Community legislation must continue making possible epidemiological research projects, such as the EPIC study, which need to use the links between registers with personal data to make them feasible and at a reasonable cost.

## c) Updated comments on 13 December 2013, after Parliament Approval (Annex I)[3]

This annex contains the view that the Working Group on Data Protection took on the Report from the Committee on Civil Liberties, Justice and Home Affairs (LIBE) of the European Parliament released on 21 November 2013.

**The Spanish Epidemiology Society (SEE) PROPOSES AN AMENDMENT** to section 1 b) of art. 81 to clarify the reasons of public interest in the field of public health which legitimise the data processing. According to the text of the Proposal for the Regulation the reasons of public interest seem to be circumscribed only to those expressly set out in the text. To avoid a literal interpretation (therefore excluding other reasons) the following text is proposed: "b) for reasons of public interests in the field of health, **among these**, protection against serious cross-border risks, or to guarantee high levels of quality and safety in medicines and health materials, or"

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**Amendment 326**
**Proposal for a regulation**
**Article 81– paragraph 1 a (new)**
***Text proposed by the Commission***

*Amendment*
***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.***

*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.*

SEE position: Section c of art. 5 alludes to the data as "adequate, relevant and limited to the essential minimum in relation to the ends for which they are processed, will only be processed if and provided that these ends cannot be achieved by the processing of information which does not involve personal data". The amendment is repetitive with respect to a general principle of observance in personal data processing. **THE REJECTION OF THIS AMENDMENT IS PROPOSED.**

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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.

[3] Prepared by Fernando García López, Beatriz Pérez Gómez and Rafael Fernández-Cuenca

*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.*

**SEE position**: art. 83, interpreted in the light of art. 6 of the Proposal for the Regulation, legitimises the processing of data for historical, statistical and scientific ends without consent, in the limits of the precept itself, that is, if these ends cannot be achieved without identifying or allowing identification of the person concerned or if the data which attribute the information are preserved separately without this impeding the achievement of these ends. The amendment, therefore, substantially alters the conditions of data processing for the purposes of historical, scientific and statistical research on calling for consent which would be explicit, this being the general rule in the cases where it had to be given. The obligation of obtaining explicit consent, a consent which cannot be deduced from any action by the subject (and therefore cannot be a tacit consent, as in the earlier European regulation on data protection), would reduce the possibility of scientific research in forming an added obstacle to research work. It must be remembered here that the benefits of the research activity in health matters redounds on society itself, since it enables advances in matters of public health from the viewpoint of its conception as a social asset and value which merits the maximum protection. **This does not mean that the right to data protection would be divested of every guarantee, but so extreme a condition of use in this field cannot be considered acceptable in a rational weighting of all the interests in play.** This taking into account, also, that the right to data protection is not an absolute right and like all others must admit limitations depending on the protection of other assets and rights worthy of protection. On the other hand, observance of the rest of the criteria and principles of the regulation is not excepted, so that the principles of quality of data, the obligations of the processing manager, especially secrecy and confidentiality and the rights of individuals continue to be of application. Therefore, this is not a question of defending a reduction of guarantees which must surround the processing of data with these ends, but of allowing their use in matters of research, without the reinforcement of a requirement which would condemn the research to ineffectiveness. The need to obtain explicit consent for the processing of this type of data cannot be defended. **THE REJECTION OF THIS AMENDMENT IS PROPOSED.**

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**Amendment 328**
**Proposal for a regulation**
**Article 81 - paragraph 2 a (new)**

***Text proposed by the Commission*** *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, pseudoanonymised 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 pseudynomised using the highest technical standards. See Council of Europe Recommendation R(97)5 on the protection of medical data, paragraph 9.*

**SEE position**: This amendment, which envisages that the law in the Member States shall establish exceptions to the giving of consent (explicit) for the processing of the data for historical, statistical and scientific ends, has to be seen in relation with the requirement of obtaining consent for that processing which has already been introduced through the alteration of art. 81 section a) by the earlier amendment (327). The rejection of the earlier amendment leads us also to rejection of the possibility of admitting exceptions to the giving of consent, a requirement on which we have already pronounced in matters of the processing of data with statistical, historical and scientific ends. **THE REJECTION OF THIS AMENDMENT IS PROPOSED**.

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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 purposes only if:

*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:

*Justification*
*Data about children and sensitive data can only be used for research under the conditions in the new paragraphs 1a and 1b. It 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 pseudoanonymised using the highest technical standards.*

**SEE position**: The Amendment has to be understood in a joint reading of Amendments 336 and 337 which "introduce as new sections 1a) and 1b) which require the obtaining of explicit consent from the person concerned for the processing of the data of arts. 8 and 9 (remembering that art. 8 refers to processing the data of children and 9 is on the processing of sensitive data), which serve important public interests and which are made anonymous or pseudonymous. We have already justified the processing of data for historical, scientific and statistical ends without the need to obtain consent, as set forth in the proposal for the Regulation in art. 9.2 h), within the guarantees of 83. Therefore we reject the amendment and we defend the draft text as set out in the Proposal. **THE REJECTION OF THIS AMENDMENT IS PROPOSED.**

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**Amendment 335**
**Proposal for a regulation**
**Article 83 – paragraph 1 - point b)**
***Text proposed by the Commission***

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

**SEE position**: the amendment omits the last part of the proposal for the Regulation and therefore does not admit the possibility of the contrary (that is, of maintaining data which give information associated to a person), in attention to achieving the ends of historical, statistical or scientific research. In the field of scientific research for public health ends, working with personal data which identify the person is a requirement arising from its proper purpose. In health matters and in scientific research, the processing of anonymous or disassociated data, which therefore only give information, without allowing the identification of the person concerned in them, absolutely blocks the purpose of registers, studies and other research instruments which need, in addition to obtaining the objective information, to attribute it to the subject who is suffering the illness or at risk of suffering it, in order not to reduce the health protection from an individual viewpoint but also from a group perspective. **THE REJECTION OF THIS AMENDMENT IS PROPOSED.**

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**Amendment 336**
**Proposal for a regulation**
**Article 83 – paragraph 1 a (new)**
***Text proposed by the Commission***

*Amendment*
***1a. Subject to the exception in paragraph 1b, data falling within the categories of data covered by Articles 8 and 9 may be processed for historical, statistical or scientific research only with the consent of the data subjects.***

*Justification*
*Data about children and sensitive data can, as a rule, only be used for research with the consent of the data subject.*

**SEE position**: For the reasons already set out, **THE REJECTION OF THIS AMENDMENT IS PROPOSED.**

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**Amendment 337**
**Proposal for a regulation**
**Article 83 – paragraph 1 b (new)**
***Text proposed by the Commission***

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

**SEE position**: This amendment must be interpreted in accordance with the amendment introduced through section 1 a) which requires the giving of consent for the processing of the data of art. 9 for historical, scientific and statistical ends. This new amendment envisages the possibility of making an exception to the general rule of the giving of consent (also subject to a legal concept absolutely undefined "which serves exceptionally the important interests of the State"). The rejection of the previous amendment also justifies the rejection of this one. **THE REJECTION OF THIS AMENDMENT IS PROPOSED.**

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**Amendment 339**
**Proposal for a regulation**
**Article 83 – paragraph 2 - point b)**
***Text proposed by the Commission***
***(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***

*Amendment*
***deleted***

*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).*

**SEE position**: although it is highly improbable that research data could be published allowing the identification of the person concerned, the maintenance of art. 83.2 b) in the terms of the proposal for the Regulation is defended, since the rights and fundamental liberties of the person concerned remain sufficiently guaranteed. **THE DELETION OF THIS AMENDMENT IS PROPOSED.**

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