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From: General Secretariat of the Council

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Subject: Proposal for a regulation of the European Parliament and of the Council on
the protection of individuals with regard to the processing of personal data
and on the free movement of such data (General Data Protection
Regulation)

- Member States comments on Public sector and Chapter IX

Delegations will find below comments from delegations on Public sector and Chapter IX.

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IRELAND

Article 1

Ireland opposes inclusion of paragraph 2a (and the corresponding text in recital 8) because of the risk of fragmentation and the creation of obstacles to the free flow of personal data within the Union contrary to paragraph 3. An acceptable solution can be found instead in article 6 and article 21.

The old distinction between the public sector and private bodies has been eroded as a result of privatisation and outsourcing, and it no longer provides the basis for a sustainable differentiation between public and private spheres of activity.

Article 21

As regards article 21, Ireland can support removal of “important” in paragraph 1(c) (see footnote 98). The strict conditions set out in paragraph 2 are sufficient and the word “important” is superfluous.

In the context of courts acting in their judicial capacity, Ireland requests inclusion of the following sub-paragraph in paragraph 1 of article 21:

“(ca) the protection of judicial independence and the integrity of judicial proceedings;”

Articles 80 and 80a

Ireland supports the text of both articles.

Both articles use the verb “reconcile” in order to indicate that an appropriate balance between potentially competing rights must be established.

[the Collins English Dictionary includes the following definition: “... to make (two apparently conflicting things) compatible or consistent with each other”.]

Article 80b

In order to ensure consistency, replace “specific and suitable measures to safeguard the rights and freedoms of the data subject” with “appropriate safeguards for the rights and freedoms of the data subject”.

Article 81

We repeat our request to remove the reference to point (g) of Article 9.2 in the chapeau of paragraph 1.

We do not really understand the reference to “vocational rehabilitation” in paragraph 1(a). We think that “monitoring and alert purposes” may already be included under “the prevention or control of communicable diseases and other serious threats to health ...” in paragraph 1(b).

In paragraph 2, we think that “studies conducted in the public interest in the area of public health” is a form of scientific research which is already included under scientific purposes.

Article 81a

Paragraph 1 is too detailed and should be simplified; something on the following lines, for example:

Member States may determine the specific conditions for the processing of genetic data. Union law or Member State law shall provide for appropriate safeguards for the rights and freedoms of the data subject.

Article 82

In paragraph 2, delete “or for stricter rules ensuring a higher level of protection of the rights and freedoms in respect of” and insert “for”.

Article 82a

We agree with deletion of this Article.

Articles 83a, 83b, 83c and 83d

The text of these articles is both confusing and likely to result in unforeseen and unhelpful restrictions on data processing.

Recent DAPIX discussions have revealed a wish for a simpler approach. Consideration should, therefore, be given to the following simpler solution: delete all four articles and, following the logic of Directive 95/46, insert the following paragraph 3 in Article 21 –

3. Subject to appropriate safeguards for the rights and freedoms of the data subjects, Union or Member State law to which the data controller or processor is subject may restrict by way of a legislative measure the scope of the obligations and rights provided for in points (b) and (e) of Article 5.1, Article 6.3a and Articles 14a, 15, 16, 17, 17a, 18 and 19 when personal data are processed for historical, statistical or scientific purposes, or for the purpose of archiving in the public interest.

The end of this paragraph repeats the words already used at the end of recital 125.

SPAIN

Public sector

Art. 1.2a

The Spanish delegation can support the new paragraph added by the Presidency. However, we would like to react to some of the comments and proposals made by other delegations during the DAPIX meeting:

- Spain could accept the erasure of the first part of the new paragraph 2a: “For cases other than those referred to in Articles 81, 83a, 83c and 83d”. The deletion of this part of the provision would clarify that it is possible for the Member States to introduce a higher level of protection *also* in Articles 81, 83a, 83c and 83d, which is a possibility apparently banned according to the current wording.
- On the contrary, we would not support the substitution of the expression “higher level of protection” for “specific regime”. We have misgivings with the concept of “specific regime”: what is the scope of a specific regime? Does this mean that Member States are allowed to introduce a data protection regime different than the one envisaged in the Regulation? Can this “specific regime” establish different general principles and conditions for these specific processing operations? We believe that, with the current wording, it is possible to give a positive answer to the last two questions, especially when there is nothing similar to the expression “within the limits of this Regulation”. That is why we prefer the expression “higher level of protection”: although it is not extremely precise, at least it ensures that the provisions introduced by Member States as regards the processing of personal data by public authorities are subject to the general principles and conditions of the Regulation (as a minimum common protection in every Member State).

Art. 6.3

For similar reasons than those mentioned above, we would not accept the new proposal for paragraph 3 of article 6. With the new wording suggested by the Presidency, not only will Member State law be able to establish legal obligations or define a public interest, but also to specify the general conditions governing the lawfulness of data processing. Literally, the current version of article 6.3 envisages the possibility for member States to establish different conditions for a lawful processing than those provided by the Regulation. From our perspective, this will imply a general derogation of the Data Protection Regulation through Member State law.

As a compromise agreement, we would be able to accept the new wording if a provision was included so as to ensure that this “specification” of the general conditions is always “rooted” in the Regulation. For instance:

The purpose of the processing shall be determined in this legal basis or as regards the processing referred to in point (e) of paragraph 1, be necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller. **While ensuring an equal or higher level of protection of the rights and freedoms of the data subject, this legal basis may specify inter alia the general conditions governing the lawfulness of data processing the controller, the type of data which are subject to the processing, the data subjects concerned; the entities to, and the purposes for which the data may be disclosed; the purpose limitation; storage periods and** processing operations and processing procedures, including measures to ensure lawful and fair processing (...).

Chapter IX

Art. 80

The Spanish delegation considers that it is irrelevant whether the regulation establishes or not the necessity to “reconcile” the right to data protection and the right to freedom of expression: the national authorities will have to “reconcile” these two rights in any case, even if it is not envisaged in the Regulation. Taking this into consideration, Spain would support to keep this article as general and unspecific as possible. The current wording would be adequate, provided that the concept of “national law” referred to in article 80 does not only include laws in strict sense, but also sentences, decisions or rulings by national courts. This is of the utmost importance for Spain, because we do not have any laws “reconciling” the freedom of expression with other rights; on the contrary, it is the judiciary decisions that establish criteria to exercise that “reconciliation” of rights.

Art. 80b

We would suggest the following wording to ensure that article 80b does only refer to other identifiers of general application that have a similar nature than the national identification number (that is to say, we intend to exclude from this article other identifiers created by private companies):
(...) Member States may determine the **specific** conditions for the processing of a national identification number or any other identifier of general application. **The national identification number or any other identifier of similar nature of general application shall be used only under** specific and suitable measures to safeguard the rights and freedoms of the data subject.

Art. 81

As regards to art. 81.1.a, we cannot support the introduction of the concept “vocational rehabilitation” until we receive the feedback by the Ministry of Health. Basically, our issue with this concept is that we do not understand what it refers to.

Our objections are stronger, however, concerning paragraph (d) of article 81.1. In our opinion, this provision allows insurance companies to lawfully process personal data basing only on their private interest of rendering a service. This is by all means excessive. Furthermore, we believe it is unnecessary to include such a provision to ensure that insurance companies can develop their activities: currently, the '95 Directive does not envisage such a clause, and as far as we know, they have been rendering their services up to this moment with no particular difficulties. We propose to erase this paragraph.

Art. 81c

As we have already expressed, we are concerned with the scope of the expression “more specific rules”, especially since there is no reference to “within the limits of this Regulation” anymore.

Therefore, we would suggest erasing that expression from art. 81a.1.

Additionally, we would propose simplifying the content of this article by erasing the examples of “genetic testing” included in paragraph 1. In our opinion, the examples provided after “in particular” do not clarify the content of the article. More specifically, we are opposed to any reference to the processing of genetic data in the area of insurance, because it will certainly unbalance the relation between the insurance services provider and the citizen (for example, it might increase the price of the insurance because the citizen might be genetically predisposed to suffer certain illnesses).

With our suggestions, the article would remain as follows:

Member States may provide for ~~more specific rules or for~~ stricter rules ensuring a higher level of protection of the rights and freedoms of the data subject on the processing of genetic data for genetic testing, in particular for medical purposes, in order to establish parentage, or in the area of insurance and worker protection, in accordance with point (h) of Article 9(2); this shall also apply to genetic data which are processed for genetic analyses carried out as part of genetic testing. Processing for scientific purposes shall be subject to the conditions and safeguards referred to in Article 83c. Member State law shall provide for specific and suitable measures to safeguard the rights and freedoms of the data subject.

Art. 83a, 83b, 83c: general comments

The Spanish delegation has repeatedly stated that these articles are too complex. From our perspective, these provisions should just establish the general principle of the further processing with scientific, statistic or historical purposes compatibility with the initial processing operation. The rest of the content of these articles could be provided by articles 6 and 21. Accordingly, we suggest following the '95 Directive in this particular aspect.

Art. 83a

As regards to paragraph 1, we propose to erase the first part of the sentence: “By derogation from points (b) and (e) of Article 5(1) and from Article 6(3a)”. The articles referred to by this provision (arts. 5.1.b and e and art. 6.3a) basically establish the general principle that personal data shall not be processed in an incompatible way. On the other hand, art. 83a.1 provides that further processing for archiving purposes shall not be considered incompatible with the initial purpose. Consequently, there is no “derogation” from either article 5(1)(b) and (e) or from Article 6(3a).

As for paragraph 1a, we consider it unnecessary. The objective of this article is to establish the compatibility of further processing for archiving purposes. The rest of the provisions of the Regulation (principles of data processing, conditions for lawfulness of the processing...) still apply to the further processing for archiving purposes. That is to say: the data processing operation for a further purpose of archive shall respect the principles of art. 5, have a legal base as envisaged in art. 6... Hence, the content of paragraph 1a of art. 83a is already provided in other parts of the Regulation.

Regarding paragraph 2, we have insisted that the derogations for the exercise of certain rights in case of further processing for archiving purposes are already included in other parts of the Regulation (for instance, in articles 14a.4.(e) and 17.3.d) or could be included in art. 21.

Nevertheless, if it is necessary to keep this article to achieve a compromise, we would not object.

But, in this case, we should clarify that our remark in footnote 69 does not reproduce accurately the Spanish position. Our issue with letter (b) is the fact that the only way to exercise the right to rectification is by the provision of a supplementary statement. We do not support such limitation.

The right to rectification should be exercised in the same terms as in normal data processing operations.

Our proposal for art. 83a is the following:

Processing of personal data for archiving purposes in the public interest

1. By derogation from points (b, final part) and (e) of Article 5(1) and from Article 6(3a), further processing of personal data for archiving purposes (...) carried out in the public interest pursuant to Union or Member State law shall not be considered incompatible with the purpose for which the data are initially collected and may be processed for those purposes for (...) longer (...) than necessary for the initial purpose.
 - 1a. ~~The controller shall implement appropriate safeguards for the rights and freedoms of the data subject, in particular to ensure that the data, without prejudice to paragraph 3, are not processed for any other purposes or used in support of measures or decisions affecting adversely any particular individual, and specifications on the conditions for access to the data.~~
2. Where personal data are processed for archiving purposes carried out by public authorities or bodies or private bodies in the public interest pursuant to Union or Member State law, Member State law may, subject to appropriate measures to safeguard the rights and freedoms of the data subject, provide for derogations from:
 - a) Article 14a(1) and (2) where and insofar as the provision of such information proves impossible or would involve a disproportionate effort or if recording or obtaining or disclosure is expressly laid down by Union law or Member State law;
 - b) Article 16 insofar to define the cases where rectification may be exercised exclusively by the provision of a supplementary statement;
 - c) Articles 17, 17a and 18 insofar as such derogation is necessary for the fulfilment for the archiving purposes.
3. Without prejudice to Article 80a, the controller shall take appropriate measures to ensure that personal data which are processed for the purposes referred to in paragraph 1 may be made accessible and used only for important reasons of public interest or for safeguarding the rights and freedoms of the data subject or overriding rights and freedoms of others according to Union or Member State law to which the controller is subject.

Art. 83b

Most of the remarks expressed for art. 83a are also applicable to art. 83b and c.

As for paragraph 1, additionally to the erasure of the first part of the sentence, we would suggest to include the term “further”, because from our perspective, the objective of this article is precisely to determine the compatibility of further processing for statistical purposes.

Paragraph 1a could be erased, for the same reasons as in art. 83a.

As regards to paragraph 2, from the current wording it is impossible to determine whether it applies to “initial” data processing for statistical purposes or to “further processing operations”. Anyway, we consider that the conditions and requirements provided by letters (a), (b) and (d) are already included in other parts of the Regulation. Therefore, we believe that it is not strictly necessary to keep these provisions.

Article 83b

Processing of personal data for statistical purposes

1. ~~By derogation from points (b) and (c) of Article 5(1) and from Article 6(3a) Further processing of personal data for statistical purposes carried out in the public interest pursuant to Union or Member State law shall not be considered incompatible with the purpose for which the data are initially collected and may be processed for those purposes for longer than necessary for the initial purpose.~~

1a. ~~The controller shall implement appropriate safeguards for the rights and freedoms of the data subject, in particular to ensure that the data are not processed for any other purposes or used in support of measures or decisions affecting adversely any particular individual, and specifications on the conditions for access to the data.~~

2. ~~(...) Personal data may be processed for statistical purposes (...) in the public interest pursuant to Union or Member State law (...) provided that:~~

(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;~~

~~(c) — (...); and~~

~~(d) — that the controller provides appropriate safeguards for the rights and freedoms of the data subject individual~~

3. **Where personal data are processed for statistical purposes carried out by public authorities or bodies or private bodies in the public interest pursuant to Union or Member State law, Member State law may, subject to appropriate measures to safeguard the rights and freedoms of the data subject, provide for derogations from:**

a) *Article 14a(1) and (2) where and insofar as the provision of such information proves impossible or would involve a disproportionate effort or if recording or obtaining or disclosure is expressly laid down by Union law or Member State law;*

d) **Article 16 insofar to define the cases where rectification may be exercised exclusively by the provision of a supplementary statement;**

b) *Articles 17, 17a and 18 insofar as such derogation is necessary for the fulfilment for the statistical purposes (...).*

Art. 83c

Regarding paragraph 2, we would propose to erase the expression “including for scientific research”. We do not imagine a scientific purpose that is different from a scientific research, so we do not see why should “scientific purposes” include “scientific research”. There are no scientific purposes other than scientific research.

As for paragraph 3a, we consider that the actual wording is very confusing. First, it must be clear that to publish or disclose personal data is a further processing, different than the processing of data for scientific purposes. Therefore, this new processing requires a legal base and to fulfil the rest of the requirements of the Regulation. That is to say, if the personal data that are going to be made public are non-sensitive, then article 6 should apply. On the contrary, if the personal data disclosed are sensitive, then article 9 is applicable. But the current wording of paragraph 3a mixes it up. It subjects a legal base for processing personal data that are sensitive (explicit consent) to a legal base for ordinary data processing (that the interests or rights of the data subject do not override the interests of the controller). If the data subject has given explicit consent, then, why is it necessary to balance their rights with the interests of the controller?

Article 83c

Processing of personal data for scientific purposes

1. **By derogation from points (b) and (e) of Article 5(1) and from Article 6(3a), Further processing of personal data for scientific (...) purposes under the conditions referred to in paragraph 2 shall not be considered incompatible with the purpose for which the data are initially collected and may be processed for those purposes for longer than necessary for the initial purpose.**

- ~~1a. The controller shall implement appropriate safeguards for the rights and freedoms of data subjects, in particular (...) that the data are not processed for any other purposes or used in support of measures or decisions affecting adversely any particular individual and by pseudonymisation of personal data.~~

2. **(...)Personal data may be processed for scientific (...) purposes, including for scientific (...) research, provided that (...) these purposes cannot reasonably be otherwise fulfilled than by processing personal data and (...) 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; (...)**

3. Where personal data are processed for scientific purposes, Member State law may, subject to appropriate measures to safeguard the rights and freedoms of the data subject, provide for derogations from:

- a) **Article 14a(1) and (2) where and insofar as the provision of such information proves impossible or would involve a disproportionate effort or if recording or obtaining or disclosure is expressly laid down by Union law or Member State law;**
- b) **Article 16 insofar to define the cases where rectification may be exercised exclusively by the provision of a supplementary statement;**
- c) **Articles 17, 17a, and 18 insofar as such derogation is necessary for the fulfilment for the scientific purposes.**

~~3a. Personal data processed for scientific (...) purposes may be published or otherwise publicly disclosed by the controller **provided that** the interests or the rights or freedoms of the data subject do not override these interests and when:~~

- ~~a. the data subject has given explicit consent; or~~
- ~~b. the data were made manifestly public by the data subject.;~~
- ~~c. the publication of personal data is necessary to present scientific findings.~~

Art. 83d

History is a science as much as Sociology, Economy or Law, so the data processing for historical research should not be included in a different article from the data processing for scientific research. We propose to erase art. 83d, so that historical research will be regulated by art. 83c.

FRANCE

Firstly, we reiterate that we would like the proposal for a Regulation to cover the processing of both personal data and public sector data, in accordance with the political agreement reached by the ministers. That said, we would like the proposal for a Regulation to include scope for flexibility as regards the processing of public sector data, and are willing to work along those lines. We can be satisfied with the inclusion of specific derogations in individual articles (cf. Articles 6, 9, 21, 25, 33, 34, 35, 42, 44, 51, 51a, 52, 53*, 61*, 75*, 79, 79a*, 79b*, Chapter IX, 91*¹) but, in the spirit of compromise and subject to the comments below, we could consider the idea of a general clause.

Article 1 – Subject matter and objectives

We wish to make the following comments on the new paragraph 2a added to Article 1:

We have doubts as to what is covered by the concept of a "a higher level of protection of the rights and freedoms of the data subject" (in conjunction with the proposed additions to recital 8). We would like the Council Legal Service to provide an analysis of that concept via a written opinion.

We would also highlight our three primary concerns regarding that provision:

¹ Articles marked with an asterisk are those which do not include specific derogations for the public sector but for which we would like such derogations to be discussed.

- the relationship between the addition and the specific rules set out in various articles of the Regulation is not clear and raises concerns about legal uncertainty surrounding public data processing. We stress that should a general derogation be inserted in Article 1 of the Regulation, it should not in any case make it possible to call into question specific derogations already provided for by the text, and it should be without prejudice to other requests (in particular in Articles 53, 61, 75, 79a, 79b, and 91). Furthermore, the fact that only some articles in Chapter IX are referred to at the start of the new paragraph 2a makes it all the more difficult to understand that relationship;
- in any case, we do not want the general clause to be able to pose an obstacle to the exchange of data between Member States;
- lastly, we have serious reservations about the obligation, at the end of paragraph 2a, on Member States to notify the European Commission of all their national measures. Such a procedure would increase the administrative burden on Member States and could lead to the European Commission checking the degree of protection provided to persons by the Member States in areas for which the European Union may not necessarily be competent. We are also concerned about the fact that the notification obligation presupposes that such measures may only be taken within a certain deadline.

For all the above reasons, should a general provision be added in Article 1 of the Regulation, we would prefer an alternative wording making it possible to introduce the flexibility required for data processing operations carried out in the context of public interest activities.

Article 2 – Material scope

Regarding the amendment to point (e) of paragraph 2 ("*safeguarding of public security*"), we reiterate that if consistency in the scope of the two "data protection" package tools is to be maintained, the matter of delimiting the scope of the proposal for a Directive must be agreed on in the context of working party meetings on that tool.

Article 6 – Lawfulness of processing

In contrast, regarding the corresponding recital 31, we would like the term "*legal obligation*" to be amended and **replaced** by "*legal basis*".

Chapter IX – Provisions relating to specific data processing situations

Article 80 – Processing of personal data and freedom of expression

Firstly, we would stress that this article should be discussed in conjunction with Article 17 on the right to be forgotten, insofar as paragraph 3 of the latter expressly refers to Article 80.

As regards substance, we reiterate our concerns about the relationship between the proposal for a Regulation and the rights to freedom of expression and to information.

We are drawing up proposals for alternative wordings and will send them separately.

Article 80a – Processing of personal data and public access to official documents

We recall the importance of the right to access administrative documents, which fully complies with Article 15 of the Treaty on the Functioning of the European Union.

We would also express our concerns regarding the relationship between the proposal for a Regulation and the national and European rules applicable to access to public documents, in particular in the context of the Directive on the re-use of public data (Directive 2013/37/EU of the European Parliament and of the Council of 26 June 2013 amending Directive 2003/98/EC on the re-use of public sector information (PSI Directive)). Serious consideration must be given to the matter.

We therefore enter a **reservation on this article** at this point.

Article 80b – Processing of national identification number

We would stress that the link between the first and second sentences of this article on national identification numbers could be clarified by **adding** the words "***In this case***" to the start of the second sentence.

Article 81 – Processing of personal data for health-related purposes

Regarding this article, we would like to thank the presidency in general for incorporating several French requests.

Nevertheless, we wish to make the following comments:

- we have **reservations** as regards the addition of a reference to "***vocational rehabilitation***" in point (a) of paragraph 1 and what that term covers. We feel that it would be preferable to refer to those activities in Article 82, which deals with data processing in the employment context;
- we object to the addition of a new point (d) to that paragraph to include **insurance activities** in Article 81. Apart from the fact that insurance and reinsurance activities should be governed by a contract, such activities, pertaining to the private sector, do not belong in an article focused on data processing.

Furthermore, we request that **a new paragraph be added** to this article to clarify the manner of implementing point (f) of Article 44(1) and to provide a framework for such transfers by restricting them to transfers to health care professionals only, after the pseudonymisation of the personal data transferred:

“1a. The personal health data transferred in application of the article 44. 1 (f) are transmitted only:

a. to the health professionals, as defined in the paragraph 1 (a) of the article 81, acting to protect the vital interests of the data subject or other persons, and

b. after the pseudonymisation of the personal data.”

Concerning the corresponding recital, recital 122, we reiterate the amendments we requested earlier:

122) The processing of personal data concerning health, as a special category of data which deserves higher protection, may often be justified by a number of legitimate reasons for the benefit of individuals and society as a whole, in particular in the context of ensuring continuity of cross-border healthcare **or a health alert or health security, or for historical, statistical** (...) or scientific purposes or studies **conducted in the public interest in the area of public health**. Therefore this Regulation should provide for harmonised conditions for the processing of personal data concerning health, subject to specific and suitable safeguards so as to protect the fundamental rights and the personal data of individuals. This includes the right for individuals to have access to their personal data concerning their health, for example the data in their medical records containing such information as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided.

Article 81a

We would ask for **this new article to be deleted**.

We are not in favour of certain types of data being the subject of specific articles, as this would run the risk of leading to a proliferation of such articles. The general philosophy of data protection legislation is to focus on the purposes of the data-processing operations carried out rather than on the data being processed.

Article 82

We have doubts as to the idea of a "*higher level of protection*", referred to in Article 82(1), and the notification procedure provided for under Article 82(2). What exactly would be covered by this notification requirement: only laws, or all other rules as well, including decrees and collective agreements?

We therefore place a **scrutiny reservation** on these two issues.

Article 82a

The French authorities would like **this specific article on social welfare activities to be reinstated**.

We would prefer to see an ad hoc article devoted to social welfare activities, along the same lines as appears in the European Parliament's mandate. The field of social welfare is much broader than just the activities that involve the processing of health-related data, concerning as it does family and retirement-related aspects as well, among other things.

Article 83a – Derogations for processing of personal data for archiving purposes in the public interest

We recall our concerns, which we have expressed consistently, regarding this article and data processing carried out for archiving purposes.

In particular, we would repeat our request for the deletion of paragraph 1a and recall our proposed amendments to the wording of this article (insertions in bold, italics and underlined) and of the corresponding recitals, 125 and 125a:

125) The processing of personal data for historical, statistical or scientific (...) purposes and for archiving purposes in the public interest should, in addition to the general principles and specific rules of this Regulation, in particular as regards the conditions for lawful processing, also comply with respect other relevant legislation such as on clinical trials. The processing of personal data for historical, statistical and scientific purposes and for archiving purposes in the public interest should (...) be considered **compatible** with the purposes for which the data are initially collected and **should** be processed for those purposes (...) for a longer period than necessary for that initial purpose.. Member States should **have the possibility** to provide (...), specifications and derogations **from certain rules of the regulation, in particular for the time limits erasure, for the right to information (...), the rights of rectification and erasure for processing of special categories of data, the right of access to public information, the right to be forgotten, the right to restriction,** the right to data portability, **the right of blocking of processing, the data protection by design and by default, the communication to the data of a breach of security of their personal data, the impact assessment on data security, codes of conduct, and the powers of the supervisory authority (...).**

125b) **Council Resolution of 6 may 2003 on archives in** the Member States stresses the importance of archives for the understanding of the history and culture of Europe” and “that well-kept and accessible archives contribute to the democratic function of our societies’ (...). Where personal data are processed for archiving purposes (...), this Regulation should also apply to that processing, bearing in mind that this Regulation should not apply to deceased persons (...).

Public authorities or public or private bodies that hold records of public interest should be services which, pursuant to Union or Member State law, have (...) a legal obligation or main mission to acquire, preserve, appraise, arrange, describe, communicate, promote, disseminate and provide access to records of enduring value for general public interest, for providing proof of the rights of individuals or for historical, scientific or statistical purposes. (...) In particular, (...) data processed for archiving purposes in the public interest may be further processed (...) for (...) public interest, such as providing specific information related to the political behaviour under former totalitarian state regimes, or for safeguarding the rights and freedoms of the data subject or overriding rights and freedoms of others according to Union or Member State law.

(...)

Codes of conduct may contribute to the proper application of this Regulation, when personal data are processed for archiving purposes in the public interest by further specifying appropriate safeguards for the rights and freedoms of the data subject. Such codes should be drafted by Member States' official archives or by the European Archives Group. Regarding international transfers of personal data included in archives, these must take place without prejudice of the applying European and national rules for the circulation of cultural goods and national treasures.

Article 83a

Processing of personal data for archiving purposes (...)

1. By derogation from points (b(...)), d and (e) of Article 5(1) and from Article 6(3a), (...) processing of personal data for archiving purposes (...) carried out in the public interest *inter alia to provide proof of the rights of individuals or for historical, statistical or scientific purposes pursuant to Union or Member State law* shall (...) be considered compatible with the purpose for which the data are initially collected and shall be processed for those purposes for (...) longer (...) than necessary for the initial purpose.

(...)

2. Where personal data are processed for archiving purposes carried out by public authorities or bodies or private bodies in the public interest *inter alia to provide proof of the rights of individuals or for historical, statistical or scientific purposes* pursuant to Union or Member State law, Member State law may (...) provide for derogations from:

- a) Article 14a(1) and (2) (...);
- b) Article 16 (...) ;
- c) Articles 17, 17a, 17b, (...) 18, 19, 23, 32, 33, 53 (1b) item d and e (...) ;

2a) *Specifications on the conditions for access to the data are determined for the data subject at article 15, insofar as the applications for access are made in a sufficiently precise manner, provided by national law, to enable identification of the processing for which the data are initially collected.*

3. Without prejudice to Article 80a, the controller shall take appropriate measures to ensure that personal data which are processed for the purposes referred to in paragraph 1 will (...) be made accessible (...) according to (...) Member State law to which the controller is subject.

Article 83b – Processing of personal data for statistical purposes

Regarding the new paragraph 1a of this article on the processing of personal data for statistical purposes, we would like to express the same reservations as for Article 83a(1a), concerning the appropriate safeguards provided for by this measure (are these the same safeguards as provided for in the proposal for a regulation, or other measures?). We therefore place a **reservation** on this provision, which is the source of ambiguity and legal uncertainty.

In the same paragraph, the words "*affecting adversely*" also pose problems in that some legal systems require administrations to send information, including statistics, at the request of the judicial authorities.

Moreover, in some cases there is also a requirement to communicate certain information to authorised third parties. We therefore repeat our request that this idea – which appears in Directive 95/46/EC – be included among the definitions in the proposal for a regulation.

The new paragraph 3b is difficult to understand in conjunction with recital 125. The wording could therefore be clarified.

Furthermore, we are concerned about the application of the proposal for a regulation to "Big Data" activities, which may be comparable with private statistics activities.

Specific rules could be necessary so as not to hinder the development of the digital services of the future, particularly "**Big Data**".

We recall, in this respect, that this sector is an integral part of the **new Commission's digital roadmap** and that it would appear necessary that the provisions of this regulation should **secure the legal conditions for Big Data to develop in Europe**.

Proposals are therefore currently being drawn up and will be sent by the French authorities in a separate note.

Article 83c – Processing of personal data for scientific and historical purposes

The French authorities recall their request for a reference to "**studies conducted in the public interest**" to be inserted in paragraph 2.

Concerning paragraph 3a, the French authorities would like point (c) to appear in the introductory text of the paragraph, so that it would apply in all cases to points (a) and (b):

*“3a. Personal data processed for scientific (...) purposes may be published or otherwise publicly disclosed by the controller **provided that the interests or the rights or freedoms of the data subject do not override these interests, and the publication of personal data is necessary to present scientific findings and when:***

- *the data subject has given explicit consent ; or*
- *the data were made manifestly public by the data subject;*
- *the publication of personal data is necessary to present scientific findings.”*

Article 84

The French authorities support this article, which is particularly necessary in order to take account of situations subject to obligations of secrecy.

CROATIA

Croatia considers that the proposed solution which provides three legal techniques is acceptable. According to the present proposal the member states could be able to adopt additional legal measures regarding data processing if they are not in contradiction with the provisions of the Regulation. The provisions of the regulation provide the minimum and the maximum level of protection which the member states can provide as well as the possibility for the member states to provide higher level in case the data is processed by public bodies. It also provides different situations of limitation of the data subject's rights when it's necessary and proportionate following the balance with other legitimate values. Regarding specific provisions for different fields, Croatia considers it is not possible to foresee specific legal regimes in all cases.

Changes made in the introductory paragraph 8) of the Regulation are positive in the sense that it provides for the possibility that MS in national legislation prescribe a higher level of protection for personal data than those provided for in this Regulation. In accordance with the introductory proposed paragraph 2a, in Article 1, Chapter I, represents an improvement over the initial proposal. HR believes that should be taken into consideration the possibility that each MS independently decides whether to prescribe more stringent standards of protection not only for the processing of data by public authorities, but also for data processing by private entities. DK proposal in the context of the legality of the processing of personal data, as specified in Article 6, paragraph 3, provides detailed explanations governing the subject matter.

Croatia welcomes the changes regarding the possibility to provide higher level of protection by the member states when the personal data are processed by public bodies (recital 8 and article 1. 2a).

However, Croatia thinks we may further consider the liberty of the member states to provide higher level of protection when the data are processed by non-public bodies. We mention it especially taking into consideration that in 10 or 15 years the member state could have the necessity to provide higher level of protection taking into consideration the technological development.

When providing higher level of protection the member states should never adopt provision which could in any way jeopardise the data flow within the EU.

RECITAL 8

Regarding the processing of personal data Member States should be allowed to maintain or introduce national provisions ensuring a higher level of protection than that provided for in this Regulation, except for those cases where this Regulation lays down specific regimes of data protection.

ARTICLE 1.2a

For cases other than those referred to in Articles 80, 80a, 81, 83a, 83b, 83c and 83d, Member States may maintain or introduce national provisions ensuring a higher level of protection of the rights and freedoms of the data subject, than those provided for in this Regulation.

Regarding RECITAL 122 we propose to reword the first part of the sentence since according the actual formulation there are special categories of data which deserve higher protection when actually there are two types of data, „ordinary“ personal data and special categories of personal data.

LUXEMBOURG

These comments are complementary to previously made comments and do not preclude any further comments in subsequent discussions.

General comments

Luxembourg thanks the Italian Presidency to raise this issue in the context of the negotiations on the data protection framework which is crucial for several delegations.

For Luxembourg, it is fundamental that the proposed Regulation continues to apply a level of maximum harmonisation as the 1995/46 Directive has done so far. As the Presidency mentions in their cover note, the EUCJ has held this interpretation of the 1995/46 Directive which does not make a distinction between public and private sectors. The fact that the EU Charter of fundamental rights is now part of the EU legal system is reinforcing this and questions the possibility for sectorial minimum harmonisation. Going below the levels of the 1995 Directive in terms of fragmentation and consistent level of protection for data subjects is unacceptable for Luxembourg, and, most probably, also for the European Parliament.

Luxembourg understands that several Member States have concerns with regard to their national legislations in the public sector which they wish to be able to maintain, particularly if a higher level of protection seems to be given. For Luxembourg, this is legitimate and could be acceptable if clearly framed.

It should be remembered that a number of accommodations have already been made in the text so far: aside from numerous references to national law in various articles (eg. article 4, article 9, article 20, article 26, article 35, etc), Member States have the possibility for further national law provisions based on Article 6 and on Article 21. The entire chapter IX also allows the national legislator to derogate and/or specify in various fields. In order to meet the concerns from Member States, Chapter IX has been substantially extended to cover a large variety of domains. Article 21 also allows a certain flexibility to the national legislator when restricting obligations on controllers or rights of data subjects. In view of Luxembourg, these are already three different angles which accommodate the need for more flexibility for the public sector. Luxembourg is ready to work on these (article 6, article 21 and chapter IX) and to find the right balance to meet Member States' concerns.

Introducing – on top of those three possibilities for flexibility mentioned above – in Article 1 the possibility for Member States to maintain or introduce additional provisions for a higher level of protection in Article 1 of the Regulation needs to be analysed carefully. The subject matter and the objectives as outlined in Article 1 are set by Article 16 TFEU and should not be nuanced in secondary legislation in this way. Questions can be raised as to who assesses according to what criteria whether national provisions are indeed providing for a 'higher' level of protection. Furthermore, the cover note of the Presidency also talks about 'more specific laws' which is not the same (and possibly even more difficult to determine) as 'higher'.

There seems to be a misunderstanding as far as the role of the public sector in the internal market is concerned. The Treaty applies to public administrations (or other entities vested with public authority) and a large body of secondary legislation aims precisely at framing/regulating the behavior of public administrations within the internal market, e.g. to make sure that measures taken by authorities are non-discriminatory, justified and proportionate, that information provided to citizens and businesses is transparent, that applications, complaints etc. are dealt with in a fair manner². Furthermore, a series of internal market legislation specifically mandates the flow of data between public authorities and refers to issues of data protection (through references to the existing EU data protection framework)³.

² See for example the Services Directive, the public procurement package, the directive on actions for damages related to infringements of competition law.

³ See for example the provisions on administrative cooperation in the Services Directive and in the revised directive on the recognition of professional qualifications, the IMI regulation, standardisation legislation and technical harmonisation legislation.

On a more practical side, Luxembourg would like to flag the difficulty there may be to make a clear-cut distinction between what is public and what is private. The public character of an entity may depend on the activities it fulfills: for instance a certification body could be set up as a private entity while fulfilling certain specific activities on behalf of the State at the same time. How would such a body implement the different sets of rules? Why would personal data be treated differently whether it is processed by a public or a private entity? And why would the Regulation apply again as soon as the data are deemed to cross a border?

In any solution found, Luxembourg wishes to avoid as much as possible a legislation that will have different scopes in each Member State (because the public sector is defined differently in each Member State), thereby undermining the objective of ensuring a consistent and high level of protection across the EU, and taking a step back from the 1995 Directive. The result is lack of transparency, clarity and legal certainty for the data subject.

Luxembourg also supports maintaining references to the Regulation as an introductory phrase in the relevant articles in Chapter IX: this sets a clear frame that the general principles set out in this Regulation remain valid in the national laws. Finally, any reference to Member State law should always be complemented by a reference to “or Union law”.

35a) This Regulation provides for general rules on data protection. However in specific cases provided for in the Regulation Member States are also empowered to lay down national rules on data protection. Within the limits of this Regulation Member States are not excluded from defining in law the circumstances of specific processing situation, including determining more precisely the conditions under which processing of personal data is lawful.

121) Member States law should reconcile the rules governing freedom of expression, including journalistic, artistic and or literary expression with the right to the protection of personal data pursuant to this Regulation, in particular as regards the general principles, the rights of the data subject, controller and processor obligations, the transfer of data to third countries or international organisations, the independent supervisory authorities and co-operation and consistency. In order to take account of the importance of the right to freedom of expression in every democratic society, it is necessary to interpret notions relating to that freedom, such as journalism, broadly. (...) **Therefore, Member States should classify activities as "journalistic" for the purpose of the exemptions and derogations to be laid down under this Regulation if the object of these activities is the disclosure to the public of information, opinions or ideas, irrespective of the medium which is used to transmit them. They should not be limited to media undertakings and may be undertaken for profit-making or for non-profit making purposes.**

124) [DELETION]

125a) For the purposes of this Regulation, processing of personal data for statistical purposes should be limited to the processing carried out by public authorities or bodies performing tasks of official statistics in the public interest pursuant to Union or Member State law.

(...) The confidential information which the Union and national statistical authorities collect for the production of official European and official national statistics should be protected. European statistics should be developed, produced and disseminated in conformity with the statistical principles as set out in Article 338(2) of the Treaty of the Functioning of the European Union, while national statistics should also comply with national law. Union law or national law should, , determine statistical content, **rules** of access, specifications for the processing of personal data for statistical purposes and appropriate measures to safeguard the rights and freedoms of the data subject and for guaranteeing statistical confidentiality. Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics and repealing Regulation (EC, Euratom) No 1101/2008 of the European Parliament and of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No 322/97 on Community Statistics, and Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programmes of the European Communities⁴ provides further specifications on statistical confidentiality for European statistics.

- 126) Where personal data are processed for scientific (...) purposes, this Regulation should also apply to that processing. For the purposes of this Regulation, processing of personal data for scientific purposes should include fundamental research, applied research, **including** privately funded research, carried out in the public interest and in addition should take into account the Union's objective under Article 179(1) of the Treaty on the Functioning of the European Union of achieving a European Research Area. Scientific purposes should also include studies conducted in the public interest in the area of public health. (...)

⁴ OJ L 87, 31.3.2009, p. 164–173.

To meet the specificities of processing personal data for scientific purposes (...) specific conditions should apply in particular as regards the publication or otherwise disclosure of personal data in the context of scientific (...) purposes. Member States should have the possibility to provide for derogations from certain rules of the Regulation. (...). If the result of scientific research in particular in the health context gives reason for further measures in the interest of the data subject, the general rules of this Regulation should apply in view of those measures⁵.

Article 1

Subject matter and objectives

1. This Regulation lays down rules relating to the protection of individuals with regard to the processing of personal data and rules relating to the free movement of personal data⁶.
2. This Regulation protects (...) fundamental rights and freedoms of natural persons and in particular their right to the protection of personal data.
- 2a. *[This should be included in the recital only, the similar wording is already included in the recital 8]***
3. The free movement of personal data within the Union shall neither be restricted nor prohibited for reasons connected with the protection of individuals with regard to the processing of personal data.^{7 8}

⁵ CZ, DK, FI, FR, HU, MT, NL, PT, RO, SE, SI and UK scrutiny reservation. PL suggested to add the following text somewhere in the recital " When data are being processed for historical or archival purposes, the data subject shall have the right to obtain completion of incomplete or out of date personal data by means of providing a supplementary statement."

⁶ DE scrutiny reservation: DE thought that it was difficult to determine the applicability of EU data protection rules to the public sector according to internal market implications of the data processing operations.

⁷ DK, FR, NL, SI scrutiny reservation. FR thought that this paragraph, which was copied from the 1995 Data Protection Directive (1995 Directive 95/46), did not make sense in the context of a Regulation as this was directly applicable.

⁸ EE, FI, SE, and SI thought that the relation to other fundamental rights, such as the freedom of the press, or the right to information or access to public documents should be explicitly safeguarded by the operative part of the text of the Regulation. This is now regulated in Articles 80 and 80a of the draft Regulation.

CHAPTER IX
PROVISIONS RELATING TO SPECIFIC DATA PROCESSING
SITUATIONS

Article 80

Processing of personal data and freedom of expression⁹

1. *Member States shall provide for exemptions or derogations from the provisions of this Regulation in order to reconcile the right to the protection of personal data pursuant to this Regulation with the right to freedom of expression, including the processing of personal data for journalistic purposes and the purposes of artistic or literary expression.*

2. (...)

⁹ Reservation by BE and IT; scrutiny reservation by DE, EE and SI. BE and UK thought that the balance between competing fundamental rights should be struck by the judiciary and not by the legislature. SE thought that it was important to keep a broad margin of appreciation for Member States. DE thought that in the light of phenomena such as social media and the 'blogosphere', the relationship between data protection and freedom of speech had become much more important since 1995. Any analogous application to new forms of journalism should be provided for in a separate sentence. DE found it difficult to see how one right could be regulated at EU level and other fundamental right at Member State level. DE also stated that regarding the relationship of the Regulation to freedom of expression and to the right of public access to official documents, it should be clearly stated which articles may be derogated from. DE is of the opinion that private communication should be completely excluded from the scope of the Regulation. If necessary, the Regulation itself should provide for exceptions to protect freedom of expression. At least a reference to press law would need to be added. EE thought article 80 needed to be reworded along the lines of Article 80a.

*Article 80b*¹⁰

Processing of national identification number

DELETION

Article 81

Processing of personal data for health -related purposes¹¹

1. (...) ¹² In accordance with point[s (g) ¹³ and]-(h) of Article 9(2), (...) personal data referred to in Article 9(1) may be processed **on the basis of Union law or Member State law which (...) provides for suitable and specific measures to safeguard the data subject's legitimate interests (...)** when necessary for:
 - (a) the purposes of preventive or occupational medicine, medical diagnosis, the provision of care or treatment ¹⁴ or the management of health-care systems and ¹⁵ services, and where those data are processed by a health professional subject to the obligation of professional secrecy under Union or Member State law or rules established by national competent bodies to the obligation of professional secrecy ¹⁶, or by another person also subject to an equivalent obligation of secrecy under Member State law or rules established by national competent bodies; or

¹⁰ DK, NL, SK and SI scrutiny reservation.

¹¹ NL, LV, SK and SE scrutiny reservation.

¹² Deleted further to DK, DE, FR and IT suggestion.

¹³ According to DE it is not possible to evaluate whether extending the reference to include point (g) is appropriate until there has been thorough clarification of the relationship between Article 81 and the justifications listed in Article 9(2). Only then will it be possible to safely assess whether the reference to point (g) of Article 9(2) potentially weakens or undermines the requirements of point (h). IE doubted the need to refer to point (g). NL thought that any exceptions to Article 9 should be regulated there.

¹⁴ DE suggestion.

¹⁵ IE suggestion.

¹⁶ See clarification of the term professional secrecy in recital 122. PL would have preferred to refer to legal obligations, but some of the may not be laid down in (statutory) law. RO on the contrary thought it sufficient to refer to ' rules established by national competent bodies in the field of professional secrecy'.

- (b) reasons of public interest in the area of public health¹⁷, such as processing data for health security, monitoring and alert purposes¹⁸, the prevention or control of communicable diseases and other¹⁹ serious (...) ²⁰ threats to health or ensuring high standards of quality and safety of health care and services and²¹ of medicinal products or medical devices(c) (...)
- c) other reasons of public interest in areas such as social protection in order to ensure that Member States can perform tasks in these areas as provided for in their respective national law²²;
- [d) ²³].

2. Processing of personal data concerning health which is necessary for historical, statistical or scientific (...) purposes or for studies conducted in the public interest in the area of public health²⁴ is subject to the conditions and safeguards referred to in Articles 83a to 83d.
3. **The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying reasons of public interest in the area of public health as referred to in point (b) and (c) of paragraph 1, as well as criteria and requirements for the safeguards for the processing of personal data for the purposes referred to in paragraph 1. (...) ²⁵.**

[DELETION]

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- ¹⁷ Moved from the chapeau at the suggestion of BE.
- ¹⁸ FR suggestion.
- ¹⁹ DE suggestion
- ²⁰ Deleted in view of the remarks by DE that the limitation from Article 168(1)(2) did not apply here.
- ²¹ CZ proposal.
- ²² DE proposal.
- ²³ DE proposal linked to an amendment to Article 9(2)(h).
- ²⁴ FR suggestion. At the suggestion of DE and FR the examples were deleted here, as this risks give rise to a too limited interpretation of this paragraph.
- ²⁵ Deleted further to DE, ES, IE, NL, LV and RO reservation.
- ²⁶ Further to DE proposal. See also changes in Article 9(2)(h) and (k).

(...) [DELETION]

Article 83b

Processing of personal data for statistical purposes

1. By derogation from points (b) and (e) of Article 5(1) and from Article 6(3a) processing of personal data for statistical purposes carried out in the public interest pursuant to Union or Member State law shall not be considered incompatible with the purpose for which the data are initially collected and may be processed for those purposes for longer²⁷ than necessary for the initial purpose.
 - 1a. The controller shall implement appropriate safeguards for the rights and freedoms of the data subject, in particular to ensure that the data are not processed for any other purposes or used in support **of any measures that may affect any particular individual**, and specifications on the conditions for access to the data.
2. (...) Personal data may be processed for statistical purposes (...) in the public interest pursuant to Union or Member State law (...) provided that:
 - (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;
 - (c) (...); and

²⁷ ES and DE indicated that no time limits should be set out for archives. PT said that it did not matter how long data were kept.

3. Where personal data are processed for statistical purposes carried out by public authorities or bodies or private bodies in the public interest²⁸ pursuant to Union or Member State law, Member State law may, subject to appropriate measures to safeguard the rights and freedoms of the data subject, provide for derogations from:
- a) Article 14a(1) and (2) where and insofar as the provision of such information proves impossible or would involve a disproportionate effort or if recording or obtaining or disclosure is expressly laid down by Union law or Member State law;
 - b) **Article 15 and 16 shall not apply where and insofar as granting access to or rectification of the personal data proves impossible or would involve a disproportionate effort**
 - c) Articles 17, 17a and 18 insofar as such derogation is necessary for the fulfilment for the statistical purposes (...).
4. (...).
5. (...).

²⁸ DE, ES and NL asked for a definition of *public interest*, and SI expressed scepticism to define *public interest*. NL, PT and FR found that the *public interest* was too narrow. NL indicated that that archives for taxation purposes was probably not considered as public interest but could be legitimate interest and PT thought that archives were useful *per se*. DE and ES found it necessary to decide the interest of protection (DE referred to archives of Google and Facebook and ES to data kept by *e.g.* the hunting club). COM added that the archives regime would not mean that the general rules should not be complied with., but that the archive rules kicked in when the original purpose was fulfilled or no longer applicable. The justification for the archiving rules were the public interest and archiving was not a purpose in itself for COM. UK said that it would like to see a reference to private bodies since the household exemption would not cover such archives. ES and UK doubted the need for a separate article;. UK queried whether Articles 6.3 and 20 would not suffice and ES indicated that Article 21 was enough to decide if personal data were processed for public interests and if derogations could be set out. BE also asked whether it would not be enough to refer to Articles 6.3 and 21. FI wanted to know if the cultural heritage was covered by the Article on archiving and suggested to clarify it in a recital. SK wanted that archives both from the public sector as well as from the private sector be covered.

Processing of personal data for scientific and for historical purposes²⁹

1. By derogation from points (b) and (e) of Article 5(1) and from Article 6(3a), processing of personal data for scientific **and for historical** (...) purposes under the conditions referred to in paragraph 2 shall not be considered incompatible with the purpose for which the data are initially collected and may be processed for those purposes for longer than necessary for the initial purpose.
 - 1a. The controller shall implement appropriate safeguards for the rights and freedoms of data subjects, in particular (...) that the data are not processed for any other purposes or used in support of measures or decisions affecting adversely any particular individual³⁰ and, **where appropriate**, by pseudonymisation of personal data³¹.

²⁹ CZ, DK, FI, FR, MT, NL, PT, RO, SE, SI and UK scrutiny reservation. ES was sceptical and did not know if the Article was needed since there were general rules applicable. ES thought that Article 83c was not complete without include private archives UK gave the example of a historical biography of a living person and asked whether Article 80 or 83c was applicable and how these Articles were interlinked. DK suggested to add in Article 6 and 9 research as long as the conditions in Article 83c were fulfilled. BE, IE, RO, SE and UK thought that addressing both scientific and historical purposes in one Article was a bad idea. The dividing line between scientific and historical purposes and e.g. political science purpose was not clear. They use different methods; for example in scientific research the names were not important whereas the name of the person in historic research is crucial. HU thought that the title should be changed into "Purpose of documentation".

³⁰ DE meant that decisions should be allowed in favour of individuals since many uses of archives currently explicitly permitted by law and intended to address past injustices would no longer be permissible including examining the Stasi Records Act, security checks and criminal investigations. DK objected to the underlying principle in this context because of the links to clinical research and treatment.

³¹ BE stated that in the 1995 Directive further processing fell under the general regime and suggested that this be the case here as well. NL supported DK and the need for research in the area of health for example to use personal data, NL was opposed to any restriction for such use.

2. (...) ³² Personal data may be processed for scientific (...) purposes, including for scientific (...) research, provided that (...) these purposes cannot reasonably be otherwise fulfilled than by processing personal data and (...) 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 manner³³; (...)
3. Where personal data are processed for scientific ***and for historical*** purposes, Member State law may, subject to appropriate measures to safeguard the rights and freedoms of the data subject, provide for derogations from:
- a) Article 14a(1) and (2) where and insofar as the provision of such information proves impossible or would involve a disproportionate effort³⁴ or if recording or obtaining or disclosure is expressly laid down by Union law or Member State law³⁵;
 - b) ³⁶;
 - c) Articles **16**, 17, 17a, and 18³⁷ insofar as such derogation is necessary for the fulfilment for the scientific ***or for the historical*** purposes³⁸.
- 3a. Personal data processed for scientific ***and historical*** (...) purposes may be published or otherwise publicly disclosed by the controller provided that the interests or the rights or freedoms of the data subject do not override these interests and when:

³² DK wanted to delete "In accordance with".

³³ DK thought that keeping data anonymous could represent administrative burden.

³⁴ BE suggested to add "or seriously impair the achievement of the research" giving as an example that patients should not no if they were given *real* medicine or placebo medication.

³⁵ BE suggested to add "or seriously impair the achievement of the research" giving as an example that patients should not no if they were given *real* medicine or placebo medication.

³⁶ ES wanted to add more flexibility to the paragraph. NL meant that the purpose of scientific research was to publish and it should always be possible to publish albeit under certain conditions, it therefore supported the ES suggestion.

³⁷ DE proposed adding Article 19.

³⁸ BE was sceptical to this paragraph and meant that instead of harmonising the rules MS should be entitled to adopt rules.

- a. the data subject has given explicit consent³⁹; or
 - b. the data were made manifestly public by the data subject.⁴⁰;
 - c. the publication of personal data is necessary to present scientific ***or historical*** findings⁴¹.
4. (...)

Article 84

Obligations of secrecy⁴²

1. (...), Member States may adopt specific rules to set out the (...) ⁴³ powers by the supervisory authorities laid down in Article 53(...) in relation to controllers or processors that are subjects under national law or rules established by national competent bodies to an obligation of professional secrecy or other equivalent obligations of secrecy, where this is necessary and proportionate to reconcile the right of the protection of personal data with the obligation of secrecy. These rules shall only apply with regard to personal data which the controller or processor has received from or has obtained in an activity covered by this obligation of secrecy⁴⁴.
2. Each Member State shall notify to the Commission the rules adopted pursuant to paragraph 1, by the date specified in Article 91(2) at the latest and, without delay, any subsequent amendment affecting them⁴⁵.

³⁹ DE wanted that consent should not be required for research on health aspects and the use of bio-banks. Support from DK that said that there are health legislation and ethics in science and consent from the relevant authorities should be enough. DK said that studies from the US showed that it was impossible to receive the consent of a large number of persons in order to do research, for deceases like cancer and infectious deceases it was important to use personal data. Support from SE and UK on consent.

⁴⁰ BE said that paragraph 2 could not be used for historical purposes.

⁴¹ HU requested the reinsertion of paragraph (c) on publication or public disclosure. DE queried whether the publication of personal data in the form of individual statistics if the data subject gives consent is possible under Article 83c(2) or not at all.

⁴² DE, ES, IT, NL and UK scrutiny reservation.

⁴³ BE and DE suggestion to cover all powers set out in Article 53.

⁴⁴ BE suggested adding a new paragraph: "The supervisory authority will consult the relevant independent professional body prior to taking a decision on data flows".

⁴⁵ CZ reservation. RO remarked that a uniform approach should be established for this type of provision, which might need to be moved to Chapter XI on final provisions.

FINLAND

We proposed that the first sentence in para 3 would be deleted. As for the public interest, we proposed that it would be opened up in the recitals. Drafting proposal for the recital:

“Statistical work carried out by the labour market organizations to survey salaries and income level and their developments in order to follow the increase of purchasing powers and costs in different sectors can be considered public interest in the meaning of Article 83(b).”

And deletion of first sentence in para 3.

Article 83b Processing of personal data for statistical purposes

1. By derogation from points (b) and (e) of Article 5(1) and from Article 6(3a) processing of personal data for statistical purposes carried out in the public interest pursuant to Union or Member State law shall not be considered incompatible with the purpose for which the data are initially collected and may be processed for those purposes for longer than necessary for the initial purpose.

1a. The controller shall implement appropriate safeguards for the rights and freedoms of the data subject, in particular to ensure that the data are not processed for any other purposes or used in support of measures or decisions affecting adversely any particular individual, and specifications on the conditions for access to the data.

2. (...) Personal data may be processed for statistical purposes (...) in the public interest pursuant to Union or Member State law (...) provided that:

- (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;
 - (c) (...);
- and
- (d) that the controller provides appropriate safeguards for the rights and freedoms of the data subject individual

3. ~~Where personal data are processed for statistical purposes carried out by public authorities or bodies or private bodies in the public interest pursuant to Union or Member State law, Member State law may, subject to appropriate measures to safeguard the rights and freedoms of the data subject, provide for derogations from:~~

- a) Article 14a(1) and (2) where and insofar as the provision of such information proves impossible or would involve a disproportionate effort or if recording or obtaining or disclosure is expressly laid down by Union law or Member State law;
- b) Article 16 insofar as rectification may be exercised exclusively by the provision of a supplementary statement;
- c) Articles 17, 17a and 18 insofar as such derogation is necessary for the fulfilment for the archiving purposes.

3. Without prejudice to Article 80a, the controller shall take appropriate measures to ensure that personal data which are processed for the purposes referred to in paragraph 1 may be made accessible and used only for important reasons of public interest or for safeguarding the rights and freedoms of the data subject or overriding rights and freedoms of others according to Union or Member State law to which the controller is subject.

UNITED KINGDOM

The UK's overall position on Chapter IX is to ensure that critical processing for research, scientific and medical health purposes is not undermined and that additional barriers, which are contrary to existing practice, are not erected.

We are concerned that the Chapter is becoming unwieldy and unnecessarily complex. In particular, the partitioning of Article 83 into four parts could give rise to confusion.

We believe that the really important and valuable paragraph in Article 83a-83d is the first paragraph, which makes clear the applicable derogations and explicitly states that processing for these additional purposes shall not be incompatible with the original purpose of the data collection. This is important but we believe that all of the four first paragraphs in those articles could instead be captured as one overriding article.

The subsequent paragraphs for each of these articles impose additional requirements which must be satisfied before the processing can go ahead. We recognise the need for appropriate safeguards where processing creates real risks. However we must be careful not to impose unnecessary or unduly onerous restrictions. Much of the processing when done for many of the purposes in Chapter IX will generally be valuable and explicitly be in the public interest.

With a view to avoiding such restrictions we have made some drafting suggestions below in order to make any restrictions imposed more consistent with a properly risk-based approach and which avoid deterring processing that is truly in the public interest. We do not believe that this processing for the public good should be subject to potentially stricter controls than other types of processing; so it is not clear why the general provisions in articles 5, 6 and 9 are not sufficient to regulate the processing. However, since this text is still quite fluid, we will have ongoing consultation with relevant stakeholders as this Chapter develops.

Recital:

Page 12: 122: We are not clear what the different levels of confidentiality (new text supplemented by fn 6) might cover and think reference to layers of confidentiality could be confusing and unhelpful; **and would like “which may cover different types of confidentiality” to be deleted.** We would also prefer the text to use ‘confidentiality’ instead of ‘secrecy’ in this context – this applies also to Article 81 1(a).

Page 15: 125b: We do not think that the last part of the last sentence is helpful. The current legislation does not apply to deceased persons (which we believe is correct and proportionate). We think that the addition of ‘unless information on deceased persons impinges the interest of data subjects’ leads to a lack of clarity. How will “*impinges*” be defined? And what purpose is served by this clause? **We would prefer the end of the sentence to be deleted.**

Articles:

We would like the old Article 6 2 to be reinstated to give clarity that research has a separate legal basis rather than having to rely on the interpretation of Art 6 1 (f).

Page 18: Article 1 2a: Mention of Article 81 & 83. We are not clear on the reasoning/logic behind this? We do not understand why Member States should not be allowed to introduce a higher level of protection to data used for health purposes? The mention here seems incongruous with the rest of the text, and almost draws too much attention to the health and research articles. Why make such a statement about these two articles?

Page 24: Article 81 (1) – The previous mention of Member State and Union law in the first paragraph was reassuring in that it gave a clear legal basis for processing in national law. **We would prefer it if “*in accordance with Union law or Member State law*” was reinstated as per previous versions of the text.**

Page 24: Article 81.1.a – We would **prefer the word ‘Confidentiality’ to replace ‘secrecy’** as set out re: recital 122 above.

In addition, the UK relies on individuals such as managers, administrators, charitable sector workers, healthcare support workers etc. who are not in regulated professions. We are concerned that the requirement to be under an ‘equivalent obligation’ [to a health professional] might not capture those in the healthcare sector who are not in a regulated profession but are nonetheless bound by an obligation of confidentiality placed on them through their legal contract. **We recommend the removal of the word ‘equivalent’**. The legal principle of confidentiality is important, not the fact that the individual comes from a regulated profession.

Page 25: Article 81 (d): We have a scrutiny reservation on this paragraph. This is new: we need to gather views from both the insurance and health sectors as well as other UK Government Departments that may have an interest before reaching a conclusion.

Page 26: Article 81a 1: **seventh line, after ‘safeguards’ insert: ‘and derogations’**.

Page 31: Article 83(b): We wish to ensure that valuable statistical research (which doesn't harm the individual or require the disclosure of personal information) is given the same positive treatment in the new regulations as statistics. Research for statistical purposes (statistical research) should be subject to 83b and not 83c and it is currently unclear if the current draft achieves clarity on this.

We would therefore welcome an explicit reference to Statistical Research on the face of the regulation (maybe **by including the words ‘and statistical research’ in the title of 83b**) which ensured there was no ambiguity about where statistical research fell.

We are concerned that, contrary to the risk-based approach, some of the wording in Arts 83b and 83c potentially imposes additional burdens regardless of time and cost considerations. The following suggestions are aimed at softening this approach to allow an assessment of reasonableness.

83b 2.(a) **insert ‘reasonably’ between ‘cannot’ and ‘be’ in the first line.**

83b 2.(b) **insert ‘so far as reasonably practicable’ between ‘is’ and ‘kept’ in the second line.**

Page 33: Article 83c 1a. The wording of this article should allow the feedback of health-related findings to individuals where the potential benefits outweigh the harms so **‘for any other purposes or used’ should be deleted from the second line.**

It is not always possible (or desirable) for data being processed for research purposes to always remain pseudonymised. In a large scale public health study for example, it may be necessary to link data between two current data sets (both pseudonymised) and to do so would require a brief period where the data was not pseudonymised while the linkage took place (to be pseudonymised again immediately thereafter). **We would therefore like, either to delete the sentence after ‘particular individual’ or to insert the following after ‘data’ in the last line: ‘as long as these purposes can be fulfilled in this manner’.**

Page 34: Article 83c 2. As for 83b 2., **insert ‘so far as reasonably practicable’ between ‘is’ and kept’ in the fourth line.**
