BRE-JBZ

From: Kaai, Geran
Sent: vrijdag 3 april 2015 16:00
To: Verweij, Ellen
Subject: FW: Thank you - Data Protection Regulation follow-up
Attachments: Healthcare Coalition on Data Protection - joint statement_ 29 January 2013.pdf; FINAL EFPIA position paper Data Protection 13 June 2012.pdf; Proposed Amendments to EC Proposed Regulation.doc

From: [redacted] [mailto[redacted]
Sent: vrijdag 22 februari 2013 13:55
To: Kaai, Geran
Subject: Thank you - Data Protection Regulation follow-up

Dear Mr Kaai,

I wanted to thank you again for taking your time to meet me and my colleague [redacted] It allowed us to explain our concerns on some articles of the proposed Regulation on Data Protection that may create unintended impacts on medical research. As discussed, attached you will find the digital version of EFPIA position paper and proposed amendments.

As always, should you have any more questions and/or comments, please do not hesitate in contacting me.

Kind regards,
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Working together for 2D-coding to fight counterfeit medicines

Joint Statement of the Healthcare Coalition on Data Protection

Benefits of data processing in healthcare and medical sciences while protecting patients' personal data

Representing leading actors of the healthcare sector in Europe, the Healthcare Coalition for Data Protection[1] would like to share their thoughts on the Commission's proposal for a General Data Protection Regulation. [2]
The Healthcare Coalition for Data Protection welcomes the Commission's effort to harmonise data protection requirements in the EU. The Coalition also welcomes the provisions supporting healthcare and health research. However, some areas must be improved to facilitate medical innovation, improvements in care delivery, and to support Europe's ground-breaking medical research for the benefits of society. Certain provisions might restrict the sharing of health data, delay innovation, create legal uncertainty and increase compliance costs if they remain unchanged.

The Healthcare Coalition on Data Protection proposes five key recommendations to improve the General Data Protection Regulation:

1. Maintain provisions for data processing for healthcare, research and ultimately patient safety.
2. Clarify definitions for data concerning health to allow a workable and effective data protection regime.
3. Consider the potential unwanted consequences of the Right to be Forgotten.
4. Avoid excessive administrative burden linked to impact assessment obligations.
5. Clarify rules and definitions around the concept of consent.

[1] *See last page for more explanation on the Healthcare Coalition on Data Protection*

[2] *http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf*

DETAILED BRIEFING

1. Maintain provisions for data processing for healthcare, research and ultimately patient safety

Today's modern information-based healthcare systems rely on data processing to deliver quality care. The availability of health data through the healthcare cycle is crucial for delivering quality care, clinical research, public health research, improving the quality of patient-centred healthcare services and reducing costs. ICT, electronic health records and mobile technologies are increasingly connecting all parts of the system delivering more personalised 'citizen-centric' healthcare, which is more targeted, effective and efficient.[3] Underpinning this emerging ecosystem is data. Not only is data crucial to responding to patient needs, but it also helps in defining public health policy development.

To capitalise on these benefits, it is vital that the EU strikes an appropriate balance between facilitating the secure use of health data for health purposes and patients' rights to privacy.

The Coalition recommends the provisions of article 81 and 83 are maintained and clarified as the Regulation moves through the legislative process.

2. Clarify definitions for data concerning health to allow a workable and effective data protection regime

Anonymised, and pseudonymised or key–coded data are used to conduct medical research, monitor the efficiency of treatments, monitor disease trends, support public health policies, etc.

The Coalition recommends:

- Amending Article 2 (material scope of the Regulation), to make explicit that the principles of data protection should not apply to data rendered anonymous (as recognised in Recital 23)
- Introducing a definition of anonymised data in Article 4(2) (b) and pseudonymised data in Article 4(2) (a).
- Adopting a proportionate approach to the use of pseudonymised data that recognises the context and the risk of re-identification to ensure a risk-based approach, as reflected in the opinion 4/2007 of the Article 29 Working Party Opinion[4]. In addition, the Regulation should create incentives for using pseudonymised data, by relieving certain restrictions.
- To ensure legal clarity, the regulation must ensure consistency with other EU legislation. For instance certain types of data (e.g. location data, online identifiers as defined in article 4(1), are already covered by the e-privacy Directive 2002/58EC, creating confusion.

3. Consider the potential unwanted consequences of the Right to be Forgotten

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[3] *eHealth Action Plan 2012-2020 – Innovative healthcare for the 21st century, COM (2012) 736 final*
[4] *http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2007/wp136_en.pdf*

Implementing the right to be forgotten and to erasure in the healthcare context requires careful consideration of the consequences:

- Deleting data from electronic health records may run counter to individual treatments and patient safety: healthcare providers will not have access to life-saving information on the patient when establishing a diagnosis, such as allergies, ongoing treatments, specific conditions (e.g. diabetes), blood type, medical history, organ donation, etc.
- Statistical analyses might be weakened, particularly in the case of orphan diseases or conditions with difficult inclusion and exclusion criteria, such as paediatrics.

We are concerned that whilst Article 17(3)(b) provides an exemption *'for reasons of public interest in the area of public health'*, it is not clear whether this exemption applies to healthcare provision.

The Coalition recommends that Article 17(3) (b) is clarified in order to exclude the possibility of erasing data concerning health.

4. Avoid excessive administrative burden linked to impact assessments obligations

A key objective of the reform is to make data controllers accountable for their processing of personal data, while avoiding excessive administrative burden. However a few provisions risk creating legal uncertainty and bureaucratic complexity:

- Article 33 requires that the processing of data concerning health is subject to the data protection impact assessment requirement, but the criteria for impact assessments are not defined and may be clarified by delegated act (Article 33 (6)).

- In addition, while Article 34 prohibits certain processing of personal data before approval by the supervisory authority, it does not specify the timelines for the approval process. Legal certainty concerning the approval process of supervisory authorities is crucial for stakeholders.

The Coalition recommends:

- Article 34 should mirror the principles outlined in recital 74: mandatory prior consultation should only be foreseen for:
    - Very limited processing activities, which could be privacy invasive and which differ significantly from existing processing activities
    - Risky processings which might obviously not be in compliance with the Regulation.
- Article 34 should set out a clear timeline for the approval of supervisory authorities

- A single data protection assessment should be permitted to cover similar processing activities and activities which present similar privacy risks.
- Impact assessments should not be "one-size-fits-all". Under a principle of accountability, organisations should be able to adopt impact assessments, appropriate to their type of organisation and processing activities, legal requirements and contractual obligations. The delegated and implementing acts (Article 34 (8-9)) should be deleted.

- Impact assessments should not constitute disproportionate and unsustainable administrative and financial burden to small and medium sized medical practices.

5. Clarify rules and definitions around the concept of consent

The Coalition warmly welcomes high visibility of consent in the draft Regulation, and endorses the philosophy that consent is the basis of trust. However the lack of clarity on the way in which consent is to be treated in the context of healthcare and research is a matter of some concern. In healthcare, data protection should strive for an appropriate balance between a data subject's rights, and innovative use of information to support research and greater patient empowerment for self management.
We believe current proposals for consent may lead to a burdensome notice and 'opt-in' regime for individuals, overwhelming patients with information and creating significant resource demand.

The Coalition recommends:

- In the context of healthcare provision it is noted that Article 7(4) specifies that "*consent shall not provide a legal basis for the processing when there is a significant imbalance between the data subject and the controller*". The current wording might result, in the patient invoking a "significant imbalance" between the physician and himself in order to declare the consent given void. Whilst it is understood that in certain cases, such as employment, it is important to have such safeguards, the Regulation should explicitly clarify that art. 7(4) does not apply to the health sector.

- A doctor cannot provide treatment without processing patients' personal data. The Regulation should clarify that the act of seeking and agreeing to treatment should be considered as equal to 'explicit consent' in these contexts, and as per Article 4(8) and Article 7(1). This clarification would also avoid red tape.

- In the case of medical research, it should be noted that specific consent is not compatible with the approach taken in many research studies, where a broad consent model is used. There are also cases where it is difficult or impossible to secure consent. Article 83 provides an alternative legal basis for processing for research under which consent for processing of appropriately-protected data will not be required. It is therefore particularly important that Article 83 and the associated rules are clear and maintained in all delegated legislation.

The Healthcare Coalition on Data Protection gathers:

CED:
The Council of European Dentists (CED) is the representative organisation of the dental profession in the European Union, representing over 340,000 practicing dentists from 32 national dental associations and dental chambers in 30 European countries. Established in 1961, the CED promotes high standards of oral healthcare and effective patient-safety centered professional practice across Europe and contributes to the safeguarding and the protection of public health.

HOPE:
HOPE, the European Hospital and Healthcare Federation, is an international non-profit organisation, created in 1966. HOPE represents national public and private hospital associations and hospital owners, either federations of local and regional authorities or national health services. HOPE mission is to promote improvements in the health of citizens throughout Europe, high standard of hospital care and to foster efficiency with humanity in the organisation and operation of hospital and healthcare services.

FEAM:
The Federation of European Academies of Medicine (FEAM) represents national academies in 14 EU member states. Its mission is to promote cooperation between the national Academies of Medicine and to extend to the political and administrative authorities of the European Union the advisory role that the Academies exercise in their own countries on matters concerning medicine and public health.

COCIR:
COCIR represents the Radiological, Electromedical and Healthcare IT industry in Europe. COCIR encourages the use of advanced technology to support healthcare delivery worldwide and promotes free worldwide trade of medical devices and maintaining the competitiveness of the European health sector.

EFPIA:
The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 37 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world. EFPIA supports a vision of modern and sustainable healthcare systems in Europe, where patients have equal and early access to the best and safest medicines, which supports innovation, empowers citizens to make informed decisions about their health and ensures the highest security of the medicines supply chain.

Continua Health Alliance:
Continua Health Alliance is a non-profit, open industry organization of healthcare and technology companies joining together in collaboration to improve the quality of personal healthcare. With more than 220 member companies around the world, Continua is dedicated to establishing a system of interoperable personal connected health solutions.

GSMA:
The GSMA represents the interests of mobile operators worldwide. Spanning more than 220 countries, the GSMA unites nearly 800 of the world's mobile operators with more than 230 companies in the broader mobile ecosystem, including handset makers, software companies, equipment providers and Internet companies, as well as organisations in industry sectors such as financial services, healthcare, media, transport

and utilities. The GSMA also produces industry-leading events such as the Mobile World Congress and Mobile Asia Expo.

mHealth is one of the focus areas of the GSMA's Connected Living programme, a market development initiative that is designed to help operators accelerate the delivery of new mobile connected devices and services. The purpose of the GSMA's mHealth initiative is to support cost-effective delivery of better healthcare for everyone.

For more information, please visit the GSMA corporate website at www.gsma.com or Mobile World Live, the online portal for the mobile communications industry, at www.mobileworldlive.com.

CPME:

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

We believe the best possible quality of health and access to healthcare should be a reality for everyone. To achieve this, CPME promotes the highest level of medical training and practice, the safe mobility of physicians and patients, lawful and supportive working conditions for physicians and the provision of evidence-based, ethical and equitable healthcare services. We offer support to those working towards these objectives whenever needed.

We see the patient-doctor relationship as fundamental in achieving these objectives and are committed to ensuring its trust and confidentiality are protected while the relationship evolves with healthcare systems. Patient safety and quality of care are central to our policies.

We strongly advocate a 'health in all policies' approach to encourage cross-sectorial awareness for and action on the determinants of health, to prevent disease and promote good health across society.

CPME's policies are shaped through the expertise provided by our membership of national medical associations, representing physicians across all medical specialties all over Europe and creating a dialogue between the national and European dimensions of health and healthcare.

efpia

European Federation of Pharmaceutical Industries and Associations

13 June 2012

EFPIA Position on Reform of the 1995 Data Protection Directive:
Biomedical Research Under the EC Proposed General Data Protection Regulation (COM(2012) 11 final)

EFPIA welcomes the Commission's efforts to further harmonise data protection requirements in the EU. The inconsistent application of privacy requirements impedes our industry's ability to conduct meaningful biomedical research that leads to the discovery of new medicines, and it creates particular challenges for the collection and reporting of safety data concerning medicines.

EFPIA also welcomes recognition that the public interest in advances in medical science warrants **special rules on the collection and use of personal data for medical research purposes** *(Art. 83)*, and **justifies collection and use of data for public health purposes** *(Art. 81(1))*. Both of these activities already take place under highly controlled and regulated conditions which are designed to protect patient privacy.

However, **EFPIA believes that there are still some limited changes needed to avoid unintended impacts on medical research:**

- **Application of certain requirements to key-coded data:** patient identities are disguised before clinical trial data are reported by study sites to pharmaceutical companies. "Key-coded data" can be directly re-identified only through access to a key held securely by each study site.
  - **Key-coding should be added as a recognized means for appropriately safeguarding personal data prior to transferring it to a third country** *(Art. 42)*. A transfer of key-coded data for scientific research purposes should not require any further authorisation or consultation where the recipient does not reasonably have access to the key and contractual or legal restrictions prohibit re-identification of the data subjects.
  - **Key-coded data should not be subject to the Regulation's mandated breach notification requirements that apply to data that directly identifies a natural person, provided the key is not compromised** *(Art. 31)*. Key-coded data is not readily identifiable without a parallel breach of the key.
  - **Scientific research conducted in accordance with Art. 83 should be expressly considered a legal and compatible basis to further process personal data**. Although the existing text implies this interpretation, a more express statement is needed for the avoidance of doubt. An affirmative statement to this effect would be consistent with Art. 6(1)(b) of the 1995 Data Protection Directive, which provides that "Further processing of data for historical, statistical or scientific purposes shall not be considered as incompatible provided that Member States provide appropriate safeguards." It also reflects the objective under Article 179(1) of the Treaty on the Functioning of the European Union of achieving a European Research Area.

- **A single data protection impact assessment should be permitted to cover processing of personal data that is of a similar nature and presents the same privacy risks** (Art. 33). A requirement to conduct multiple, duplicative assessments for similar data processing activities would add administrative burden without substantively increasing data protection.
  - A single assessment should be sufficient to identify potential risks and risk mitigation strategies related to similar uses of key-coded data for scientific research purposes. The same applies to the collection and reporting of information on drug adverse events.

- The **proposed definition of "genetic data" is overly broad** and would turn inherited characteristics such as eye and hair colour into sensitive data requiring heightened protections *(Art. 4(10))*.
  - A **more targeted definition based on existing international standards** would be: Information on the hereditary characteristics, or alteration thereof, of an identified or identifiable person, obtained through nucleic acid analysis.

- **Measures will need to be adopted to implement the regulation. The process for adoption of such implementing measures should include consultation with relevant stakeholders**.
  - For example, researchers should be consulted on the application of Art. 17(3) (retention of personal data necessary for public health or scientific research purposes) and Art. 83(3) (limitations on the rights of notice and access where necessary for scientific research purposes).

13 June 2012

Further Information

For further information, please contact:

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The **European Federation of Pharmaceutical Industries and Associations (EFPIA)** represents the pharmaceutical industry operating in Europe. Through its direct membership of 31 national associations and 35 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 2,000 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world.

This Position Paper is also supported by:

- **EuropaBio -** the European Association for Bioindustries. EuropaBio was created in 1996 to provide a voice for the biotech industry in Europe. Its mission is to promote an innovative and dynamic biotechnology-based industry in Europe. EuropaBio represents 62 corporate and 7 associate members operating worldwide, 2 Bioregions and 18 national biotechnology associations who in turn represent some 1800 small and medium sized biotech companies in Europe. Further information is available at http://www.europabio.org.

- The **International Pharmaceutical Privacy Consortium** (IPPC). The IPPC promotes responsible privacy and data protection practices in the research-based, global pharmaceutical industry. The IPPC seeks to increase awareness of privacy and data protection issues and to engage government in a dialogue about the need for data to support cutting edge biomedical research and public health activities. Further information is available at http://www.pharmaprivacy.org.

- The **Association of Clinical Research Organizations** (ACRO). ACRO represents the world's leading clinical research organizations. ACRO members provide specialized services that are integral to the development of drugs, biologics and medical devices. Each year, ACRO's members conduct thousands of clinical trials and provide related drug development services in more than 115 countries while ensuring the safety of nearly 2 million research participants. Further information is available at http://www.acrohealth.org.

10 December 2012

Proposed Amendments to EC Proposal for a General Data Protection Regulation (COM(2012)0011)

Article 4 – Paragraph 10

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

Justification

The proposed definition of "genetic data" in the Proposed Regulation should be brought in line with definitions used elsewhere, such as the definition of "human genetic data" used in the United Nations International Declaration on Human Genetic Data.

Article 31 – Paragraph 1

Text from the Commission	**Proposed Amendment**
1. In the case of a personal data breach, the controller shall without undue delay and, where feasible, not later than 24 hours after having become aware of it, notify the personal data breach to the supervisory authority. The notification to the supervisory authority shall be accompanied by a reasoned justification in cases where it is not made within 24 hours.	1. In the case of a personal data breach, **when the breach is likely to adversely affect the protection of the personal data or privacy of the data subject,** the controller shall without undue delay and, where feasible, not later than 24 hours after having become aware of it, notify the personal data breach to the supervisory authority. The notification to the supervisory authority shall be accompanied by a reasoned justification in cases where it is not made within 24 hours.

Justification

The introduction of a risk-based approach to breach notification reflects the request of Data protection authorities for a more focused duty to notify supervisory authorities of data breaches, to avoid authorities from being distracted by and overburdened with processing of notifications of minor data breaches which are unlikely to adversely affect the rights of data subjects. (See Article 29 Working Party Opinion 01/2012 on the Data Protection Reform Proposals at p.16.)

Article 33 – Paragraph 1

Text from the Commission	**Proposed Amendment**
1. Where processing operations present specific risks to the rights and freedoms of data subjects by virtue of their nature, their scope or their purposes, the controller or the processor acting on the controller's behalf shall carry out an assessment of the impact of the envisaged processing operations on the protection of personal data.	1. Where processing operations present specific risks to the rights and freedoms of data subjects by virtue of their nature, their scope or their purposes, the controller or the processor acting on the controller's behalf shall carry out an assessment of the impact of the envisaged processing operations on the protection of personal data. **A single assessment shall be sufficient to address a set of processing operations that present similar risks.**

Justification

A new privacy impact assessment should be required only where a process or project poses substantially new or different privacy risks from what has been analyzed in the past. Where a similar process or project has undergone a privacy impact analysis in the past, only those aspects of the process or project that are new or different should be required to be analyzed anew.

Article 42 – Paragraph 2 – point e (new)

Text from the Commission	Proposed Amendments
2. The appropriate safeguards referred to in paragraph 1 shall be provided for, in particular, by: (a) binding corporate rules in accordance with Article 43; or (b) standard data protection clauses adopted by the Commission. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2); or (c) standard data protection clauses adopted by a supervisory authority in accordance with the consistency mechanism referred to in Article 57 when declared generally valid by the Commission pursuant to point (b) of Article 62(1); or (d) contractual clauses between the controller or processor and the recipient of the data authorised by a supervisory authority in accordance with paragraph 4.	2. The appropriate safeguards referred to in paragraph 1 shall be provided for, in particular, by: (a) binding corporate rules in accordance with Article 43; or (b) standard data protection clauses adopted by the Commission. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2); or (c) standard data protection clauses adopted by a supervisory authority in accordance with the consistency mechanism referred to in Article 57 when declared generally valid by the Commission pursuant to point (b) of Article 62(1); ~~or~~ (d) contractual clauses between the controller or processor and the recipient of the data authorised by a supervisory authority in accordance with paragraph 4~~.~~**; or** **(e) for historical, statistical or scientific purposes, the measures referred to in Article 83(4).**

Justification

To be consistent with Article 83(4) (new).

Article 42 – Paragraph 3

Text from the Commission	Proposed Amendment
(3) A transfer based on standard data protection clauses or binding corporate rules as referred to in points (a), (b) or (c) of paragraph 2 shall not require any further authorisation.	3. A transfer based on ~~**standard data protection clauses or binding corporate rules as referred to in**~~ points (a), (b), (c), or **(e)** of paragraph 2 shall not require any further authorisation.

Justification

A transfer for research purposes of key-coded data that cannot and will not be re-identified by recipients located in third countries should be permitted without further administrative burdens.

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

Text from the Commission	**Proposed Amendment**
1.Within the limits of this Regulation, personal data may be processed for historical, statistical or scientific research purposes only if: (a) these purposes cannot be otherwise fulfilled by processing data which does not permit or not any longer permit the identification of the data subject; (b) data enabling the attribution of information to an identified or identifiable data subject is kept separately from the other information as long as these purposes can be fulfilled in this manner.	1.Within the limits of this Regulation, personal data may be processed for historical, statistical or scientific ~~research~~ purposes **under paragraph 2 of Article 6 and point (i) of Article 9(2)** only if: (a) these purposes cannot be otherwise fulfilled by processing data which does not permit or not any longer permit the identification of the data subject; (b) data enabling the attribution of information to an identified or identifiable data subject is kept separately from the other information as long as these purposes can be fulfilled in this manner.

Justification

Article 83 establishes an independent legal basis for the processing of personal data for scientific purposes, provided the criteria therein are met, as referenced in Art. 6(2) and Art. 9(2)(i). This proposed amendment makes clear that the other legal bases for processing of personal data in Articles 6 and 9 (e.g., the consent of the data subject) remain unaffected and researchers may rely on those provisions to process personal data in lieu of reliance on paragraph 1 of Article 83.

Article 83 – Paragraph 2 (new)

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

Justification

Historical, statistical and scientific activities are recognised under the regulation as uses of data that are in the public interest. Specific safeguards which allow the use of data for these purpose are detailed in Article 83. This amendment clarifies the relationship of Article 5(1)(b) to Article 83. The proposal is consistent with the previous legislation. Art. 6(1)(b) of the 1995 Data Protection Directive provides that "Further processing of data for historical, statistical or scientific purposes shall not be considered as incompatible provided that Member States provide appropriate safeguards." The failure to carry forward this language into the Proposed Regulation appears to have been an oversight. [Further, this amendment is consistent with the Council Presidency's 22 June 2012 proposed amendments to Article 5(1)(b).]

Article 83 – Paragraph 3

Text from the Commission	**Proposed Amendment**
2. Bodies conducting historical, statistical or scientific research may publish or otherwise publicly disclose personal data only if: (a) the data subject has given consent, subject to the conditions laid down in Article 7; (b) the publication of personal data is necessary to present research findings or to facilitate research insofar as the interests or the fundamental rights or freedoms of the data subject do not override these interests; or (c) the data subject has made the data public.	3. Bodies conducting historical, statistical or scientific research may publish or otherwise publicly disclose personal data only if: (a) the data subject has given consent, subject to the conditions laid down in Article 7; (b) the publication of personal data is necessary to present research findings or to facilitate research insofar as the interests or the fundamental rights or freedoms of the data subject do not override these interests; or (c) the data subject has made the data public.

Article 83 – Paragraph 4 (new)

Text from the Commission	Proposed Amendment
	4. A controller or processor may transfer personal data to a third country or an international organisation for historical, statistical or scientific purposes if: **(a) these purposes cannot be otherwise fulfilled by processing data which does not permit or not any longer permit the identification of the data subject;** **(b) the recipient does not reasonably have access to data enabling the attribution of information to an identified or identifiable data subject; and** **(c) contractual clauses between the controller or processor and the recipient of the data prohibit re-identification of the data subject and limit processing in accordance with the conditions and safeguards laid down in this Article.**

Justification

A recipient of key-coded data, transferred for scientific research purposes has no means to re-identify subjects, and under this amendment, does not have access to the key and is contractually precluded from re-identifying data subjects. In such cases, the data is no longer "identifiable" in the hands of the recipient. This amendment would formalize a process for reasonably ensuring that key-coded data cannot and will not be re-identified by recipients located in third countries, allowing for the transfer of such data without further administrative burdens.

Article 83 - Paragraph 5

Text from the Commission	Proposed Amendment
(3)The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements for the processing of personal data for the purposes referred to in paragraph 1 and 2 as well as any necessary	**(5)**The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements for the processing of personal data for the purposes referred to in paragraph 1 and 2 as well as any necessary

limitations on the rights of information to and access by the data subject and detailing the conditions and safeguards for the rights of the data subject under these circumstances.	limitations on the rights of information to and access by the data subject and detailing the conditions and safeguards for the rights of the data subject under these circumstances.

Article 83 – Paragraph 6 (new)

Text from the Commission	**Proposed Amendment**
	6. In adopting the acts referenced in paragraph 5, the Commission [or other relevant body] shall consult with relevant stakeholders.

Justification

The operative text of the Proposed Regulation should state more expressly that the Commission's adoption of delegated acts [or the adoption of implementing measures by other bodies such as the European Data Protection Board] requires consultation with relevant stakeholders, as is already encouraged in Recital 129.