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BRE-JBZ

From: Kaai, Geran
Sent: vrijdag 3 april 2015 15:57
To: Verweij, Ellen
Subject: FW: Data Protection Regulation - brief NFU, NWO, VSNU en KNAW
Attachments: 14 1429 Europees Parlement implications Draft General Data Protection Re....pdf

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From: [redacted] [mailto:[redacted]]
Sent: donderdag 20 februari 2014 15:53
To: Vaes, Marianne; Verboom, Johan; Pieters, Davy; Buitink, Ricco; Kuiper, Elizabeth; Kaai, Geran
Subject: Data Protection Regulation - brief NFU, NWO, VSNU en KNAW

Beste collega's,

Graag wil ik jullie op de hoogte brengen van deze brief over de General Data Protection Regulation (GDPR) die gezamenlijk door NFU, NWO, VSNU en KNAW is opgesteld en verstuurd naar de rapporteur van de GDPR MEP Albrecht.

Hartelijke groet,

[redacted]

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Concerns Implications Draft General Data Protection Regulation
Date 14-2-2014

Our reference 14.1429/CB/GvE

Dear Mr. Albrecht,
Dear Members of the Civil Liberties, Justice and Home Affairs (LIBE) Committee,

We would like to inform you that we have serious concerns about the implications for medical, historical, social sciences and humanities research of the amendments of the European Parliament to the Draft General Data Protection Regulation as published in the report of November 22, 2013. We specifically aim at the amendments regarding articles 81 (1)(b), 81 (2a) and 83, which seem to jeopardise very valuable medical, historical, social sciences and studies in the field of humanities.

We would like to illustrate our concerns by giving some examples:

- Article 81 (2a): Taking medical research as an example, medical research about risks for disease implementing new [redacted] to carefully [redacted] cannot [redacted] carried out wi[redacted] consent. The effects of occupational or environmental risks requires that the data of all who were at risk are taken into account. Data need to be combined and working with fully anonymous data is impossible in this context. The amendment to Article 81 (2a) introduces a disproportionate threshold for the consent exemption. Currently in many Member States, consent is often not required to process pseudonymised (i.e. coded) data as there are multiple, successful governance mechanisms and technical standards in place to ensure data security and privacy, including research ethics committees, data access committees, codes of conduct, and encryption and key management to restrict data access. Requiring a '*high* public interest' for the processing of medical and health data implies an exceptional, emergency situation disproportionate to the risks and benefits of such processing. 'High' adds no value to the judgment that needs to be made about the use of data and will only create confusion and ideological or political bias as to which research is allowable. Such a bias is contrary to a free society. The only relevant questions are whether the research cannot be carried out otherwise, is methodologically correct, will be properly published to improve our knowledge and whether proper data safety is assured. In that case there is always a public interest in such data being used.
- Article 81 (1)(b): Relating to the use of data with consent, this article is ambiguous. The current phrasing seems to exclude broad consent for future 'health-related research' as approved by an ethics committee. If LIBE indeed intends that specific or multiple layered consent is necessary that would cause a major burden for and threat to genomic research and to large-scale studies and research infrastructures.
- Article 83: Also relating to the use of data with consent, worries exist about the term 'highest technical standards'. The EP should consider that the technical standards for the safe processing

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of data as prescribed in Chapter IV of the proposed GDPR, are sufficient for any kind of scientific research as well.

As this letter attempts to demonstrate, scientific research, most notably medical, historical, social sciences and humanities research, are of vital importance to the wellbeing of European citizens. The use of personal data, such as information on religious background, age, gender and medical issues provide valuable insights for scientific research. The LIBE report approved by the LIBE Committee will have a detrimental effect on the sustainability of current resources and hamper the leadership of Europe in scientific research.

In conclusion, we respectfully, but urgently ask that the LIBE report to be amended so as to respect the wishes of research participants and make possible common forms of broad consent in research. The undersigned parties are of the opinion that a right balance must be struck between data protection and scientific research, which is not the case at the moment. The implications of these amendments would be detrimental for innovation, European healthcare and the wellbeing of European citizens. We hope that before it is being voted in plenary in the European Parliament, our points of concern have duly been taken into consideration.

Yours sincerely,

[redacted]
NFU

[redacted]
NWO

[redacted]
VSNU

[redacted]
KNAW