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<Commission>{PETI}Committee on Petitions</Commission>

<Date>{15/03/2019}15.3.2019</Date>

<TitreType>NOTICE TO MEMBERS</TitreType>

Subject: <TITRE>Petition No 0733/2018 by J.B. (Portuguese) on improving the protection of genetic data related to European Union citizens</TITRE>

**1. Summary of petition**

<TEXTE>After indicating how the General Data Protection Regulation (GDPR) defines genetic data and presenting a series of examples of companies that could have the commercialisation of these data as part of their objectives, the petitioner requests a clear legislative response from the European Parliament to the emerging market of genetic data, taking into account the fundamental rights to privacy, data protection and non-discrimination based on genetic characteristics, as established in the Charter of Fundamental Rights of the European Union. The petitioner requests that, with a view to taking into account the ethical component that this market of genetic data entails for humanity, the databases should be limited to those who have obtained permission for their use by the subjects, or that were chains of blocks with permission, or with participants in the same who have reached clear agreements on responsibility and security with regard to processing and other technical and organisational activities that protect the subjects.</TEXTE>

**2. Admissibility**

Declared admissible on 26 November 2018. Information requested from Commission under Rule 216(6).

**3. Commission reply**, received on 15 March 2019

The Charter of Fundamental Rights of the European Union guarantees in Article 8 explicitly that everyone has the right to the protection of personal data concerning him or her. The European Union adopted on 27 April 2016 the General Data Protection Regulation (‘GDPR’)[[1]](#footnote-1), which is directly applicable since 25 May 2018 and repealed Directive 95/46/EC. The principles and rules set out by the Regulation apply directly to companies and organisations in the private sector as well as to authorities and public bodies in the public sector that process personal data of individuals in the EU.

The principles of the Regulation provide among others that personal data must be processed fairly and lawfully, for specified and legitimate purposes, and must not be further processed in a manner incompatible with those purposes. Personal data must be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed (Article 5 GDPR).

A processing of personal data may only take place on the basis of one of the six grounds provided by Article 6 of the GDPR, namely: consent of the individual; performance of a contract with the person concerned; a legal obligation to which the data controller is subject; protection of the vital interests of the data subject or another natural person; performance of a task in the public interest; legitimate interests pursued by the data controller or by a third party except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject.

Genetic data is defined in Article 4(13) GDPR as personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question. The processing of genetic data is prohibited unless one of the exemptions and conditions provided for in Article 9(2) GDPR is fulfilled. Amongst others, the processing of genetic data may be allowed where individuals have given explicit consent to the processing of those personal data for one or more specified purpose, except where Union or Member State law excludes this possibility[[2]](#footnote-2). Processing of genetic data may also be allowed where processing is necessary to fulfil a substantial public interest on the basis of EU or national law which provides for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject, or, where processing is necessary for specific health-related or scientific purposes, including in the area of public health, under strict conditions and safeguards[[3]](#footnote-3).

Any processing on a large scale of genetic data creates specific risks to the privacy and data protection of individuals and would require the data controller to perform a data protection impact assessment prior to implementing the processing (Article 35 GDPR). The data protection impact assessment is a means to assist the data controller in putting in place the appropriate measures to address the risks, including safeguards, security measures and mechanisms to ensure the protection of personal data. In case of residual risks, the data controller must also consult the data protection authority.

Pursuant to Article 9(4) GDPR, Member States may provide further conditions or limitations concerning the processing of genetic, biometric or health-related data. Such limitations or conditions may consist in a prohibition to process genetic data for specific purposes or an obligation of prior consultation of the national data protection authority before processing such data.

Conclusion

The GDPR provides for all the necessary safeguards to protect the personal data, including genetic data, of individuals in the EU. Organisations processing personal data are responsible for complying with the GDPR and must implement appropriate technical and organisational measures to meet the requirements of the Regulation and protect the rights of individuals.

Without prejudice to the powers of the Commission as guardian of the Treaties, the monitoring and enforcement of the application of the data protection legislation falls primarily under the competence of national authorities, in particular data protection authorities and courts. Failure to comply with the Regulation may be sanctioned by data protection authorities with an administrative fine of up to EUR 20 million or 4% of the total worldwide annual turnover of the company.

1. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, p. 1–88. [↑](#footnote-ref-1)
2. See Article 9(2)(a) of Regulation (EU) 2016/679. [↑](#footnote-ref-2)
3. See in particular Article 9(2)(g), (h), (i) and (j) of Regulation (EU) 2016/679. [↑](#footnote-ref-3)