

EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
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The Substances of Human Origin (SoHO) Regulation¹ respects the principles recognised by the Charter of Fundamental Rights of the EU. The right for dignity and integrity of SoHO donors should always be considered, for example by ensuring that consent for donation is freely given and SoHO donors or their representatives are informed about the intended use of the donation.

While the SoHO Regulation does not apply to activities related to collection of SoHO not intended for human application or manufacturing (e.g., collection of blood samples for research), SoHO donations exclusively for research without any human application should also comply with voluntary and unpaid donation standards.

The European Health Data Space (EHDS) Regulation² aims to facilitate the reuse of health data for research, innovation and policy making. It will provide access to already available health data in an electronic format, collected for primary care and/or research. Member States remain responsible for the collection of this data at source. Therefore, the EHDS does not require the collection of new datasets from newborn babies.

EHDS introduces multiple safeguards to protect EU citizens' health data. This includes the analysis of anonymised or pseudonymised data, without patient identifiers, only inside a secure processing environment and by authorised users who hold a permit. All EU citizens will have the right to opt out from the reuse of their health data. Member States will decide whether the legal guardians will be able to opt out from the reuse of their babies' health data.

In addition, Article 4 of the SoHO Regulation as well as Article 51 of the EHDS Regulation allow Member States to introduce stricter measures and additional safeguards at national level.

¹ Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC OJ L, 2024/1938, 17.7.2024.

² Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 OJ L, 2025/327, 5.3.2025.