

EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
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To date, most of the Member States have adopted national limits for the use of gametes in their country. These limits are in general covering the distribution of gametes for maximum 12 families.

During the recent legislative procedure on the new Regulation on substances of human origin (SoHO)¹, the European Parliament and the Council did not agree to the introduction of an EU-wide limit.

However, as of 7 August 2027, the new SoHO Regulation will require Member States' authorities to enforce all national maximum limits for distribution by gamete banks. Hence these limits will apply even in cases of cross-border distribution to other Member States, and this marks a significant step forward in the control of cross-border distribution of sperm in the EU.

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 – see in particular its Article 58(10).