Council of the European Union

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'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Draft REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL 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 (**first reading**) - Adoption of the legislative act

1. On 14 July 2022 the Commission submitted its proposal[1], based on Article 168(4), point (a) TFEU, to the Council.

2. The European Data Protection Supervisor delivered its opinion on 7 September 2022[2].

3. The European Economic and Social Committee delivered its opinion on 27 October 2022[3].

4. The Committee of the Regions was consulted and decided not to issue an opinion.

[1] 11396/22 + ADD 1-6.
[2] OJ C 450, 28.11.2022, p. 7.
[3] OJ C 75, 28.2.2023, p. 154.

5. On 24 April 2024 the European Parliament adopted its position at first reading on the Commission proposal[4]. The outcome of voting in the European Parliament reflects the compromise agreement reached between the institutions and should, therefore, be acceptable to the Council.

6. The Permanent Representatives Committee is therefore asked to confirm its agreement and to suggest that the Council approve the European Parliament's position, as set out in PE-CONS 8/24, as an "A" item at a forthcoming meeting.

7. If the Council approves the European Parliament's position, the legislative act will be adopted.

   After being signed by the Presidents of the European Parliament and of the Council, the legislative act will be published in the *Official Journal of the European Union*.

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[4] 9239/24.