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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. Cion doc.:	11396/22 + ADD 1 - ADD 6
Subject:	Proposal for a Regulation 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 *- Mandate for negotiation with the European Parliament*

I. BACKGROUND

1. On 14 July 2022, the Commission submitted the proposal for a Regulation 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[1]. The proposal is based on Article 168(4)(a) of the Treaty on the Functioning of the European Union (TFEU). The ordinary legislative procedure is applicable. The proposal was accompanied by an impact assessment on which an exchange of view was held under the Czech Presidency. The proposal takes the form of a Regulation repealing two existing Directives, thereby combining provisions on blood, tissues and cells in a broader legal framework covering all substances of human origin (hereafter SoHO), except organs.

[1] 11396/22.

2. The proposal aims to strengthen the existing legal framework on blood, tissues and cells by reinforcing the rules and extending them to other SoHOs such as human breast milk and faecal microbiota transplants, which were previously unregulated at EU level. Moreover, the framework envisaged will allow for more flexible updating of provisions in line with scientific and technical development to render the legislation future-proof and to allow for better protection of donors, recipients, and offspring from medically assisted reproduction. Finally, an increased harmonisation is provided for to facilitate cross-border exchanges and access to SoHO therapies. However, Member States would still be able to adopt more stringent measures.

3. On 27 October 2022, the European Economic and Social Committee adopted its positive opinion[2] on the proposal while the Committee of the Regions sent a letter of abstention on 6 December 2022.

4. Member States' National Parliaments were consulted on the compliance of the proposed provisions with the principle of subsidiarity and proportionality. Assessments by national parliaments were received from Spain on 5 October[3], from Portugal on 10 October[4] and from the Czech Republic on 13 October 2022[5]. An opinion was received from the European Data Protection Supervisor on 7 September 2022[6]. All the assessments were positive and welcomed the initiative.

5. At the European Parliament, the proposal has been assigned to the Committee on Environment, Public Health and Food Safety (ENVI). The rapporteur is MEP Nathalie Colin-Oesterlé (EPP, FR). A draft report was issued on 18 January 2023[7] and presented in ENVI on 2 March 2023. Further amendments were tabled in the Committee by 8 March 2023. The vote in the Committee took place on 18 June 2023 and in plenary on 12 September 2023.

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2 14428/22.
3 13266/22.
4 13409/22.
5 13596/22.
6 12524/22.
7 https://www.europarl.europa.eu/doceo/document/ENVI-PR-738661_EN.html

II. STATE OF PLAY

6. The technical assessment of the proposal in Council started under the Czech Presidency[8] and continued under the Swedish Presidency[9]. Following the examination of the impact assessment and the development of compromise text on Article 3 (definitions) under the Czech Presidency, the Swedish Presidency proposed compromise text on Chapters I and II. The Spanish Presidency scheduled eleven meetings of the Working Party on Public Health during which the Presidency presented compromise texts on different sections of the proposal in two consecutive rounds. Overall, 26 meetings of the Working Party of Public Health were devoted to the examination of the proposal.

7. Revised versions of compromise text were discussed in five meetings of the Working Party (between 27 September and 10 October), with the aim to address all the issues raised by delegations during the examination of the original proposal at technical level and following the presentation of the first versions of Presidency compromise text. These include the following: clarification on the scope, application and relevant exemptions/derogations (e.g. military/security and emergency/crisis situations/specific situations such as the private context for using breast milk, the autologous use or the use in the surgical field), the assessment of borderline products with other regulatory frameworks (pharma, medical devices), the reference to and role of guidelines, provisions on supply monitoring and supply sufficiency, provisions on voluntary and unpaid nature of donations, the definition of roles and obligations of various actors (SoHO entities vs SoHO establishments and involved personnel, SoHO Coordination Board), the reporting system/SoHO platform, the impact on national systems and subsidiarity questions in relation to Member States' competences for the organisation and delivery of health services and medical care, as referred to in Article 168(7) TFEU.

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8 The progress was reported to the Council in 14769/22, dated 1 December 2022. A Presidency compromise text on Article 3 (Definitions) was tabled for discussion (14066/22) and an adapted version was distributed (14066 REV1/22).

9 9120/23 + COR1

8. The latest Presidency compromise text[10] focused on addressing several outstanding issues and clarification of wording: further strengthening the cooperation between different regulatory framework, address supply sufficiency of critical SoHO and emergency plans while respecting national competencies, application of provisions in specific situations (e.g. breastmilk for own child, autologous and within-couple use, bedside applications), acceptable and limited compensation for donation, provisions for clinical outcome monitoring, traceability and data collection, and the reference to guidelines. The text was examined by the WP at the meeting on 19 October 2023 and received broad support from delegations. A number of changes were made during the meeting with a view to addressing some remaining concerns from delegations, while others could not be included due to lack of support from most delegations.

The Presidency concluded the meeting by noting that there was broad support for the latest Presidency compromise text as revised during the meeting. It further indicated that the Permanent Representatives Committee would be invited to examine this text on 25 October 2023 with a view to reach an agreement and to mandate the Presidency to enter into negotiations with the European Parliament.

III. CONCLUSION

9. In the light of the above, the Permanent Representatives Committee is invited to:

– examine the overall compromise text, as set out in document 13802/23 and indicate its agreement on it;

– mandate[11] the Presidency to enter into negotiations with the European Parliament on the basis of this text in view to reach an agreement at first reading on the proposal for a Regulation 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.

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10 14094/23

11 In accordance with the approach on legislative transparency endorsed by the Permanent Representatives Committee on 14 July 2020 (doc. 9493/20), and in full consistency with Regulation (EC) No 1049/2001 and the Council's Rules of Procedure, the agreed mandate will be made public.