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NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee/Council
Subject: Regulation on standards of quality and safety for substances of human origin intended for human application
- Progress report

Delegations will find in Annex a progress report on the proposal mentioned in the subject above, to be presented at the EPSCO (Health) Council on 13 June 2023 with a view to inviting the Council to take note of it.

The present report has been drawn up under the responsibility of the Presidency and is without prejudice to particular points of interest or further contributions from individual delegations. It sets out the work done so far in the Council's preparatory bodies and gives an account of the state of play in the examination of the above-mentioned proposal.

Information from the Presidency on the progress achieved in the examination of the proposal for a Regulation on standards of quality and safety for substances of human origin intended for human application

Background

I. INTRODUCTION

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/EC¹, which was accompanied by an impact assessment. The proposal is based on Article 168(4)(a) of the Treaty on the Functioning of the European Union (TFEU). 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.
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 add more stringent measures.

¹ 11396/22.

3. On 27 October 2022, the European Economic and Social Committee adopted its positive opinion² on the proposal while the Committee of the Regions sent a letter of abstention on 6 December 2023.
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 October³, from Portugal on 10 October⁴ and from the Czech Republic on 13 October 2022⁵. An opinion was received from the European Data Protection Supervisor on 7 September 2022⁶. 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 2023⁷ and presented in ENVI on 2 March 2023. Further amendments were tabled in the Committee by 8 March 2023. The vote in the Committee is expected in late June and in plenary in September.

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. WORK WITHIN THE COUNCIL

6. Further to the progress achieved under the Czech Presidency⁸, the Swedish Presidency scheduled nine meetings of the Working Party on Public Health to take place before the EPSCO, and two further meetings afterwards. The objective of the Presidency is to complete the first examination of the proposal with a view to prepare Presidency compromise texts on several chapters. The first reading of the proposal was completed at the meeting of the Working Party on Public Health on 25 May. On the basis of the discussions at Working Party level, the Presidency continues to work on compromise texts for parts of the proposal, with a view to table these for technical discussions.
7. The meetings held so far focussed on the first examination of the proposal, starting from Chapter II (Competent Authorities). To facilitate the discussion and understanding of the implications of the proposal, articles were sometimes discussed in groups. For Chapters III to V, this included grouping corresponding articles of different chapters. This was done in particular to clarify the link between the SoHO supervisory activities outlined in Chapter III and the resulting general obligations on SoHO entities and SoHO establishments, outlined in Chapter IV and V respectively.
8. The discussions during the first reading of the text were to a large extent devoted to enhancing delegations' understanding of the provisions, the consequences of implementing them in practice and how that implementation would affect the existing structures in the Member States. In that context, requests were made for clarification of wordings in the proposal to the Commission and to the Council Legal Service, e.g. to better outline the distinct roles and tasks of the bodies and persons involved in the implementation.

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. As in the initial discussions on the proposal held under the Czech Presidency, most delegations continued to express support for the initiative to increase safety and quality standards for SoHOs but several questions were raised repeatedly, regarding the administrative burden and costs, the need for and added-value of creating new structures as provided for in the proposed provisions, the relation to other EU legislation (pharmaceuticals, medical devices and food) and how different products would be covered. Certain provisions were perceived as overly restrictive, resulting in requests for more flexibility (as regards e.g. required qualifications of personnel involved, format of inspections, and reporting deadlines). With an eye to ensuring a harmonised and cost-efficient implementation, delegations inquired about the possibility of financial and technical support from the Commission, possibilities for cooperation among Member States, and provision of templates and guidance to ensure correct understanding and implementation of measures once adopted. The relevance and need for implementing acts was also raised in this context.
10. Several delegations emphasised the importance of it being possible to take account of national measures as appropriate, to consider specific circumstances and exemptions from application (e.g. emergency/crisis situations, requirements of the military) and to keep in place existing systems that work well. Some delegations expressed concern that certain provisions would touch upon Member States' competences for the organisation and delivery of health services and medical care, as referred to in Article 168(7) TFEU. Furthermore, the appropriateness of combining two existing Directives into one Regulation and thereby grouping distinct types of SoHOs together was also questioned by several delegations. Concerns were raised regarding the enlargement of the scope (relative to the current Directives), the inclusion of certain SoHOs and the role of and requirements for SoHO entities versus establishments. Some delegations voiced concerns regarding certain derogations for SoHO for export.

11. In the context of the discussions, questions were put to the Council Legal Service which was asked to clarify the interaction between the proposal and Directive (EU) 2015/1535 and on the legal consequences of the wording used in the proposal when referring to external guidelines. These issues were addressed orally by the Council Legal Service and discussed during the meetings of the Working Party on Public Health.
12. Following the completion of the first examination, the Swedish Presidency has distributed one compromise text⁹, namely a revised text for Chapter II which is based on the discussions held at the meeting, written comments from delegations and clarifications from the Commission. This compromise text contains proposed adaptations to the proposal to improve its clarity, consistency, concision and to provide additional details where considered necessary. It also aims at a better alignment with national provisions.

Conclusions

13. The Council is invited to take note of the progress made so far in the negotiation of the proposal, confirm that the work carried out by the Presidency provides a good basis for future discussions and invite the incoming Presidency to build on that progress.

⁹ 9854/23