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NOTE

From: General Secretariat of the Council
To: Council

Subject: 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
- Progress report

Delegations will find in Annex a progress report on the proposal mentioned in the subject above, due to be presented at the EPSCO (Health) Council on 9 December 2022, 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 of 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 and repealing Directives 2002/98/EC and 2004/23/EC

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/EC¹ (hereafter ‘the proposal’), 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) (QMV). 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, 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 substances of human origin (SoHOs) such as human breast milk and faecal microbiota transplants, which were previously unregulated at EU level. Moreover, the framework envisaged shall 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, the proposal aims to increase harmonisation to facilitate cross-border exchanges and access to SoHO therapies. However, Member States would still have the possibility 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. The Committee of the Regions was invited to deliver its opinion on the proposal on 22 July 2022 and announced that it would issue a renunciation letter by the end of the year.
4. Assessments by national parliaments were received from Spain on 5 October³, Portugal on 10 October⁴ and the Czech Republic on 13 October 2022⁵. An opinion from the European Data Protection Supervisor was received on 7 September 2022⁶. All assessments were positive and welcomed the initiative.
5. At the European Parliament, the proposal has been allocated to the Committee on Environment, Public Health and Food Safety (ENVI). The rapporteur is MEP Nathalie Colin-Oesterlé (EPP, FR). During an exchange of views between the Commission and ENVI on 8 September 2022⁷, MEP Colin-Oesterlé underlined the importance of the proposal for addressing safety issues and tackling the problem of shortages of SoHO supply. She underlined in particular the need for greater harmonisation of national measures to facilitate the exchange of material, the importance of respecting the principle of voluntary unpaid donation and the need for an alert system in case of shortages of essential SoHOs.

² 14428/22.

³ 13266/22.

⁴ 13409/22.

⁵ 13596/22.

⁶ 12524/22.

⁷ https://multimedia.europarl.europa.eu/en/webstreaming/committee-on-environment-public-health-and-food-safety_20220908-0900-COMMITTEE-ENVI

Progress in Council during the Czech Presidency

6. During the Czech Presidency and prior to the EPSCO (Health) Council, three meetings of the Working Party on Public Health (16 September, 7 October, 14 October 2022) and an informal virtual meeting of members of the Working Party on Public Health (8 November 2022) were dedicated to the proposal. Following a general presentation of the proposal and an exchange of views on the impact assessment, the focus of the debate has been on Article 3, containing 70 definitions. The rationale for this approach was to ensure a common understanding of the overall new approach to SoHOs and the technical concept of the proposal, with a view to facilitating the subsequent discussion and negotiations on the operative articles of the proposal.
7. The proposal was overall well received and most delegations expressed support for the initiative to increase the safety and quality standards of SoHOs. In the initial and subsequent discussions, concerns expressed by delegations focused mostly on the following items: the additional administrative burden, costs and the need to create the new structures provided for in the proposal, the delineation to other EU legislation (pharmaceuticals, medical devices and food) and on whether the proposed provisions would be appropriate to tackle shortages in the supply of SoHOs. Furthermore, the appropriateness of combining two existing directives into one regulation and thereby grouping different types of SoHOs was questioned by some delegations. Several delegations also emphasised the importance of being able to take national measures as appropriate and indicated that the proposed timeline for application of the proposal was too short.

8. Regarding the impact assessment, some delegations questioned the estimates regarding a reduction in workload for administrations and healthcare professionals, but no further requests were made for additional assessments and no national impact assessment was presented. Delegations mainly asked for more information on the key measures, including the possible extra workload these could bring for authorities and the need to reorganise authorities and oversight systems in the Member States. They also asked for the benefits for healthcare professionals to be highlighted. The Commission clarified that the proposal does not call for a reorganisation of the authorities but aims to strengthen them and to support healthcare professionals by improving legal certainty and supporting the use of digitalised methods which would facilitate cross-border exchange and collaboration in the field of SoHOs. The idea was to have one central national authority that would coordinate the oversight of bodies, strengthen competences within the authorities and communicate with other Member States and the Commission.
9. Regarding the discussion on definitions (Article 3), the Czech Presidency had grouped the definitions into nine substantive parts (general definitions, the SoHO concept, supervisory activities, supply, medically assisted reproduction, vigilance, clinical studies, storage and distribution, and blood plasma) which were initially discussed in the first three Working Party meetings. Each definition was presented by the Commission and discussed with delegations with the aim of reaching a common understanding and identifying the need for possible amendments.
10. Key points raised in the discussion included the following: several delegations argued in favour of deleting definitions where the substance is adequately addressed in the articles or which represent generally known terms, others were in favour of keeping definitions to improve the clarity of the Regulation and legal certainty in the field of SoHOs. Many aspects of the new SoHO concept and related terms were repeatedly discussed and are expected to be examined again at future Working Party meetings during the negotiation of the related articles. These include, for instance, the definitions of SoHO, SoHO entity and SoHO establishment, and definitions related to processes such as storage and processing and medically assisted reproduction.

11. Based on the interventions and comments of delegations, the Czech Presidency tabled a Presidency compromise text that was discussed at the informal virtual meeting of members of the Working Party on Public Health on 8 November 2022. This text contained suggestions on the way forward regarding the definitions as well as the proposed amendment to Recital 6. This later amendment was made to shift the focus from blood, tissues and cells to the concept of SoHO. Regarding Article 3, the Czech Presidency compromise text proposed the following: 1) keep certain definitions unchanged; 2) revise definitions based on the discussion at the Working Party on Public Health; 3) delete definitions which are not used in the operative provisions, represent generally known terms or where the content could be better presented or explained in the articles, including the scope (Article 2); 4) postpone the discussion on definitions where further discussion is considered necessary to reach a common agreement during the negotiation of relevant articles. The Czech Presidency stressed that all definitions would be reassessed when examining the related articles of the proposal.
12. In general, the Presidency compromise text was well received by delegations. However, several delegations emphasised that no final decision on the proposed compromise text could be taken at this stage of the negotiation, and in particular regarding the deletion of definitions, which could be put in square brackets for the time being. Following the informal virtual meeting of members of the Working Party on Public Health on 8 November 2022, the Czech Presidency is preparing a revised Presidency compromise text to be shared with delegations. The remaining articles of Chapter I will be discussed at the next Working Party on Public Health on 13 December 2022.
13. All delegations hold a scrutiny and/or parliamentary reservation on the proposal and are still analysing its provisions.

Conclusions

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