EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels
SANTE.D.2/KB/eb/(2025) 2846059

By e-mail only

Subject: Nomination of representatives to the Regulatory Committee on standards of quality and safety for substances of human origin

Your Excellency,

Regulation (EU) 2024/1938 on standards of quality and safety for substances of human origin (SoHO) intended for human application ([1]) stipulates that the Commission shall adopt an implementing act on the EU SoHO platform, as referred to in Article 74 of the Regulation, at the latest by 7 August 2025, and the implementing acts as referred to in Articles 41, 42, 43 and 48 at the latest by the date of application of this Regulation.

The Regulation provides that the Commission shall be assisted by a Committee, within the meaning and with the tasks as laid down in Regulation (EU) No 182/2011 ([2]).

The members of the Regulatory Committee on standards of quality and safety for substances of human origin shall be composed of representatives of the Member States. Each Member State shall appoint their own representatives. In accordance with Regulation (EU) No 182/2011, the Commission shall chair and provide the Secretariat of the Committee. In accordance with Article 5(1) of the Standard rules of procedure for committees ([3]), each Member State shall decide on the composition of its delegation and inform the chair. With the chair's permission, the delegations may be accompanied by no more than two experts who are not part of the delegation.

In view of the aforesaid, you are kindly invited to designate your representatives to the Regulatory Committee on standards of quality and safety for substances of human origin.

([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. OJ L, 2024/1938, 17.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj

([2]) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers. OJ L 55, 28/02/2011, p. 13–18, ELI: http://data.europa.eu/eli/reg/2011/182/oj

([3]) Standard rules of procedure for committees.

To all Deputy Permanent Representatives of the EU Member States

Please communicate their contact details by sending an email to SANTE-SOHO@ec.europa.eu by **11 April 2025**.

As the Commission services use AGM application (A new Gateway for EU Meetings) for planning and organising meetings, the national authorities should also designate a specific contact point (correspondent) for the Regulatory Committee. This correspondent will receive the invitations to meetings and be responsible for the distribution of the invitation to nominated representatives as well as for informing the Commission about the participants for the meeting.

Please also find attached the draft Rules of Procedure of the Committee drawn up on the basis of Standard rules of procedure for committees to be adopted at the first meeting.

The first meeting of the Committee is planned to take place virtually in June 2025.

Yours faithfully,

Sandra GALLINA

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Enclosure: Draft Rules of Procedure for the Regulatory Committee on standards of quality and safety for substances of human origin

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