



Brussels,
SANTE D2/KB/eb/(2024)9962963

Your Excellency,

Subject: Request for the nomination of members of the SoHO Coordination Board (SCB)

I am writing to you regarding the nomination of members and alternates to the newly established SoHO Coordination Board (SCB) following the adoption of Regulation (EU) 2024/1938 on standards of quality and safety for substances of human origin (SoHO) intended for human application.

The role of the SCB is to promote and support coordination between Member States concerning the implementation of the SoHO Regulation, as well as to facilitate cooperation with stakeholders in that regard. The tasks of the SCB include documenting best practices on the implementation of SoHO supervisory activities and conditions for compensation, providing advice on whether the SoHO Regulation applies and providing opinions on the regulatory status for inclusion in the SoHO Compendium, setting indicative criteria for 'critical SoHO' and for 'critical SoHO entities', providing support for joint oversight activities related to inspections and to the assessment of SoHO preparation processes, supporting the Commission on the specifications for the SoHO platform and supporting the coordination during emergencies.

Art 68(2) of the SoHO Regulation specifies that each Member State shall appoint two permanent members and two alternates representing the SoHO national authority and, where the Member State chooses so, the Ministry of Health or other relevant authorities. The SoHO national authority may nominate members from other SoHO competent authorities. Appointed members shall nevertheless ensure that the views and suggestions they express are endorsed by the SoHO national authority.

I herewith invite your Member State to submit, in accordance with Art 68(3) of the SoHO Regulation, the names and affiliation of your nominated members and alternates, together with their corresponding declaration of interests. To this end, a form for the declaration of interests is Annexed to this letter. Member States shall nominate only members and alternates who do not have such conflicts. Please note that the Commission will make publicly available, on the EU SoHO Platform, the membership list, including the name, the institution of origin and the declaration of interests.

To all Deputy Permanent Representatives of the EU Member States

The SCB will start its activities in early 2025 and will gradually take over the activities related to blood, cells and tissues currently performed by the Competent Authorities on Substances of Human Origin Expert Group (BTCO), including the activities performed by its sub-groups on vigilance (VES), inspections in blood, cells and tissues (IES), and coding of tissues and cells (CES). Therefore, the SCB could be composed, for example, of members with a profile similar to the members of the Expert Group BTCO.

The members of the SCB will actively contribute to the above-mentioned tasks and should therefore be selected for their competence and experience in the field of SoHO. The composition of the SCB should be balanced to allow discussions of technical, policy and legal nature, in order to contribute to the work of the SCB and its sub-groups. It should be noted that members of the SCB will have the responsibility to disseminate information and documentation shared with the SCB members to other relevant competent authorities within their Member State.

The Commission will also set-up sub-groups of the SCB on inspections (replacing IES), vigilance and traceability (replacing VES and CES), authorisation and assessment of SoHO preparations, regulatory questions, supply of critical SoHO; and registration of entities and authorisation of establishments. Member States will be invited to nominate members for these sub-groups once these have been established (expected later in the course of 2025). Nominees for the sub-groups can be the same or different from the SCB nominees.

Please note that the existing Expert Group BTCO will be maintained but will be convened for meetings on organs only. Regarding the adoption of implementing acts under the SoHO Regulation, a dedicated (regulatory) Committee will need to be set up, in accordance with Art 79 of the SoHO Regulation.

The first meeting of the SCB will take place virtually via Webex on **Friday 24 January 2025**. During this meeting, the rules of procedure, as specified in Art 68 (8) of the SoHO Regulation, will be presented for approval. Candidates for co-chairing the SCB are invited to express their interest by Friday 31 January 2025. The second meeting of the SCB will take place physically at the Commission premises in Brussels in the week of 10 February 2025. At this meeting, the co-chair of the SCB will be elected.

In order to keep the above-mentioned timeframe, the European Commission would be very grateful if you could provide the requested information, i.e. the names and affiliation of your nominated members and alternates together with the corresponding declaration of interests for any member and alternate, **by 8 January 2025 at the latest**.

Should you need any additional information, you may contact Stefaan Van Der Spiegel, Team Leader SoHO/ SANTE D2 (email: Stefaan.VAN-DER-SPIEGEL@ec.europa.eu, office number: +32 229 55406) and Katleen Baert, Policy Officer SoHO/ SANTE D2, (email: katleen.BAERT@ec.europa.eu, office number +32 229 55981).

Yours sincerely,

Sandra GALLINA

Annex: Form to declare interests
Privacy statement

Copy: Health attachés,

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