



CoRe SoHO statement on hierarchy of guidelines concerning protection of SoHO donors, recipients, and offspring

As the trilogue meetings on the SoHO Regulation begins, *the Common Representation of Substances of Human Origin* (CoRe SoHO), the consortium of professional scientific associations in the field of SoHO, calls on the co-legislators to adopt a hierarchical framework for those standards, or elements of standards, that affect donor, recipient, and offspring protection for which no implementing act has been adopted (articles 56/4 and 59/4).

The European Commission's proposal lists the source of such guidelines, in this order: ECDC and EDQM guidelines, other guidelines of equivalent standard to the ECDC and EDQM guidelines, and accepted by competent authorities, and other technical methods. The European Parliament in its position on the SoHO Regulation clarifies that this list follows an order of priority. CoRe SoHO supports this approach.

A hierarchy of guidelines, as proposed, will ensure two important improvements to the current SoHO standards' system:

- 1) an increased harmonisation of standards and guidelines so as to facilitate the exchange of SoHO between Member States and hence optimise treatment options for all EU patients; and
- 2) safeguard all of the EU benefits from the expertise in the expert groups, whilst guaranteeing that the guidance is based on the latest scientific evidence.

As the impact assessment conducted by the European Commission states, the option to provide blood and tissue establishments with the freedom to make reference to a variety of national and international guidance may allow changes to standards to be implemented more quickly, but with a high level of variation across the EU and a high workload for small blood and tissue establishments. The European Commission rightly discarded this option in its proposal.

CoRe SoHO calls on co-legislators to confirm the hierarchy of the guidelines and not squander a historical opportunity to improve EU's SoHO system.

The CoRe SoHO consortium is composed of representatives from:

- European Association of Tissue and Cell Banks (EATCB)
- European Blood Alliance (EBA)
- European Eye Bank Association (EEBA)
- European Society for Blood and Marrow Transplantation (EBMT)

Although not a full partner of CoRe SoHO, the European Society of Human Reproduction and Embryology (ESHRE) supports this statement.

CoRe SoHO is a registrant on the EU Transparency Register as *Common representation of Substances of Human Origin* (SoHO), ref. number: 643638449840-70. Further information on the CoRe SoHO consortium and its partner associations can be found [here](#).