SoHO Coordination Board (SCB)

Information paper:

The SoHO regulation:

All you need to know to get started.

This information paper is intended for communication and awareness building activities at national and regional level and for targeted messages for professionals involved in the donation, procurement, testing, processing, storage, distribution, supply and clinical use of SoHO. It does not provide legal interpretation; in case of doubt, readers should refer to the Regulation's text and relevant guidance issued at Union and/or national level.

By supporting consistent messaging across Member States, this paper aims to facilitate timely understanding of the new requirements and promote readiness for implementation.

Information Paper

The SoHO regulation:

All you need to know to get started.

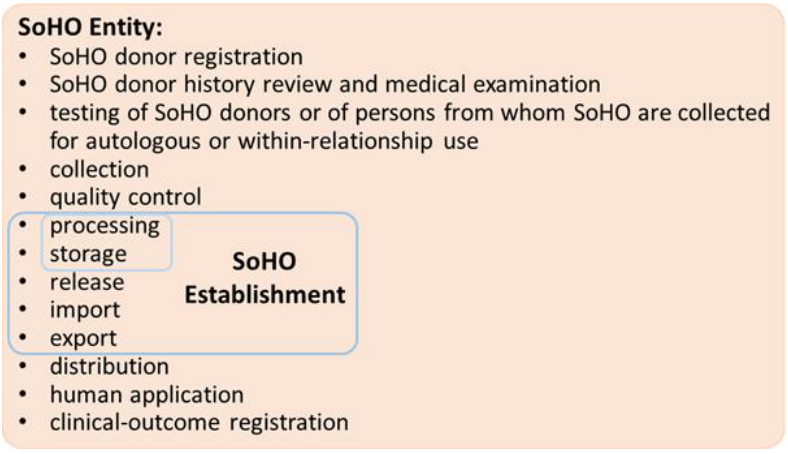
Introduction:

This paper aims to guide you through the essentials of Regulation (EU) 2024/1938 (hereinafter "SoHO Regulation") . It is designed to assist you in ensuring that your activities are compliant with the provisions of the SoHO Regulation by 7 August 2027, when the new Regulation will enter into application. For more details or clarifications, do not hesitate to reach out through the provided channels.

- ⇨ Are you involved in activities, as indicated in figure 1, concerning Substances of Human Origin (SoHO) [Article 3 (1)] intended for human applications?
- ⇨ Are you a facility where SoHO are applied to patients such as Clinics, Sport Clinics, Dentists, Gynaecologists, Ophthalmologists and any organisation using or processing SoHO?
- ⇨ Are you planning to commence SoHO-related activities?

If so, the new SoHO Regulation 2024/1938 shall apply to you as of 7 August 2027.

Figure 1: Activities [Article 2 1(c)] covered under this regulation include:



Important: Every SoHO establishment is a SoHO entity but not every SoHO entity is a SoHO establishment!

Scope:

The SoHO Regulation regulates Substances of Human Origin (SoHO) intended for human application. A SoHO is any substance derived from the human body, whether it contains cells or not and whether these cells are living or not, for example, and not limited to blood, tissues, cells, reproductive cells (oocytes, sperm cells), breastmilk and microbiota. SoHO includes processed substances intended for human application, such as f.e. fresh frozen plasma, cartilage, tendons and ligament, sperm suspension from testicular tissue for within relationship use, cryopreserved adipose tissue for autologous use, frozen fresh (raw) donor human milk. The SoHO Regulation encompasses activities involving SoHO donors, recipients, and offspring from medically assisted reproduction. It harmonises standards across the EU and extends protection to all types of SoHO ensuring uniform safety, quality and effectiveness and protection for donors, recipients and offspring from medically assisted reproduction.

In the case of SoHO collected for the purposes of manufacturing medical devices and medicinal products, the SOHO regulation covers donor registration, donor history review, medical examination, testing, collection and release. It also applies to storage, distribution, import and export of SOHO, carried out on SoHO up to and including their distribution to a manufacturer regulated by other Union legislation.

Exceptions include:

- Organs intended for transplantation, as defined in Article 3, points (h) and (q), of Directive 2010/53/EU
- breast milk used for feeding one's own child without any processing carried out by a SoHO entity
- SoHO intended for autologous use neither processed nor stored before human application

Key Provisions:

Entities engaged in SoHO activities must comply with registration and authorization requirements:

- Register as a **SoHO entity** if involved in any SoHO activities [Article 2 1(c)]
- Obtain authorisation as a **SoHO establishment** if involved in processing and storage, release, import or export
- Obtain authorisation as a **SoHO importing establishment** if involved in importing SoHO or SoHO preparations
- Obtain authorisation for SoHO preparations [Article 3 (38)]

Figure 2: Registration

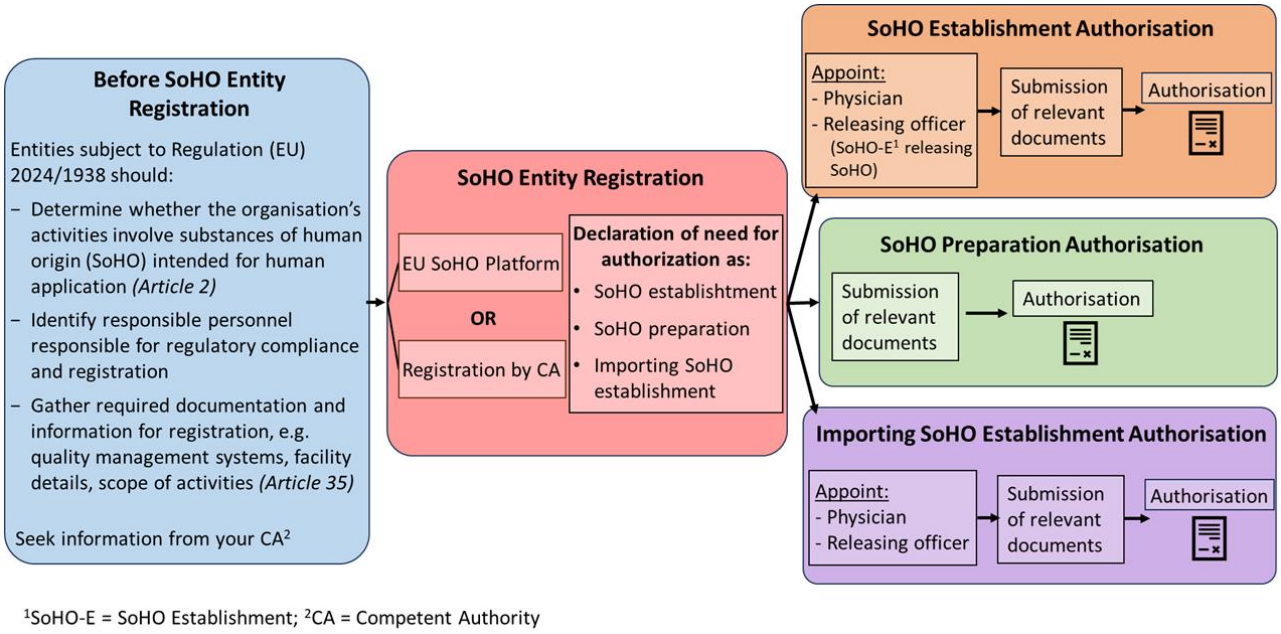


Figure 3: Overview of registration SOHO entities and documents for authorisations of SOHO establishments and SOHO importing establishments:

Overview

SoHO Entity	SoHO Establishment	SoHO Importing Establishment
Registration in the SoHO Platform	Registration in the SoHO Platform	Registration in the SoHO Platform
+	+	+
[Preparation Process Dossier (PPD)]	SoHO Establishment Dossier (SED)	SoHO Establishment Dossier (SED)
	+	+
	Preparation Process Dossier (PPD)	SoHO Importing Establishment Dossier (SIED)
		+
		Preparation Process Dossier (PPD)

Note: Additional information may be requested by the Competent Authorities (hereinafter 'CA').

New to this regulation is also the term SoHO preparation [Article 3 (37)] and the need for SoHO preparation authorisation [Article 3 (38)]. A SoHO-preparation means a type of SoHO that:

- Has been subjected to processing and, where relevant, one or more other SoHO activities

- Has a specific clinical indication
- Is intended for human application to a SoHO recipient or is intended for distribution.

Compliance and Guidelines:

The registration as SoHO entity serves as the first requirement for compliance under the new SoHO framework and ensures that CA have an accurate overview of all actors involved in the field, in accordance with Article 35 of the SoHO Regulation.

To ensure further compliance, all entities must have a quality management system, a responsible person and know how to notify serious adverse events and reactions and provide some data on annual activity levels. Detailed guidelines are available here:

- Recommendations for hospital SoHO entities [link];
- Recommendations for non-hospital SoHO entities [link].

For further assistance, contact us [*add link to CA mailbox*] or consult the FAQ page.

Timeline:

The SoHO Regulation will take effect on 7 August 2027.

All SoHO entities will need to register. (*Please include instructions by CA based on individual MS situation*)

Previously authorised Tissue establishments:

- Will be deemed authorised under the new Regulation
- Previous authorised Tissue establishments that are part of the EU coding platform will be automatically transposed to the EU SoHO platform. The CA (*add name*) will verify the information in the platform and will inform you if your status as establishment would have changed.

Previous authorised Blood establishments:

- Will be deemed authorised under the new Regulation
- Might need to integrate the information on their registration, authorisation in the EU SoHO platform based on the instructions of the CA (*Please include instructions by CA based on individual MS situation*).

SoHO not addressed explicitly in Directive 2002/98/EC or 2004/23/EC (e.g. Human breast milk and Faecal microbiota (hereinafter "FMT"):

- For entities that perform certain SoHO activities with SoHO not addressed explicitly in Directive 2002/98/EC or 2004/23/EC (e.g. Human breast milk and FMT) before 7 August 2027 will be able to continue these activities without applying the SoHO Regulation until 8 August 2028. However, they will need to register as entity and comply with the provisions

on SoHO donor protection [Chapter VI] and protection of SoHO recipients and offspring from medically assisted reproduction [Chapter VII] as of 7 August 2027 and need to apply for authorisation as SoHO establishment and SoHO importing establishment (when applicable) as well as for any SoHO preparation authorisations by 8 November 2027.

SoHO preparations:

- SoHO preparations [Article 3 (37)] previously authorised by the CA in your MS before 7 August 2027 will be deemed authorised. Establishments should include comprehensive details about these preparations in the new SoHO Preparation Compendium of the SoHO Platform. The information provided by the SoHO Entities responsible for the processing and/or distribution (in the case of importing SoHO Establishments) of SP, will be later revised by the Competent Authorities, in a second step. The information required by the Competent Authorities to assess if the SP can be deemed authorised (as defined in Articles 82 and 83) and published, shall consider the previous evaluations of the SP by the Competent Authority, and be proportional to the level of novelty and their alignment with the EDQM SOHO Monographs.
- You might be asked to provide additional information to your CA, please follow the instructions of your CA (*CA to provide additional instructions based on the individual MS situation*)

For any additional information, contact us [*link to CA***].** *Further details on registration through the national register or EU SOHO platform can be added by CA***.**

Support and Resources

Entities are encouraged to consult the registration process with the CA of the MS.

- 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
- Recommendations and Guidance Documents for the Management of Substances of Human Origin in Hospitals
- Recommendations and Guidance documents for the management of Substances of Human Origin in Non-Hospital entities
- Frequently Asked Questions