

# The SoHO Regulation: all you need to know to get started

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## 1 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 below, 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.

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

- SoHO donor registration
- SoHO donor history review and medical examination
- Testing of SoHO donors or of persons from whom SoHO are collected for autologous or within-relationship use
- Collection
- Quality control
- Processing (Processing and storage = SoHO establishment)
- Storage (Processing and storage = SoHO establishment)
- Release (SoHO establishment)
- Import (SoHO establishment)
- Export (SoHO establishment)
- Distribution
- Human application
- Clinical-outcome registration

If you are engaged in both processing and storage, release, import/export of SoHO or SoHO preparations, you are required to register as a SoHO entity and obtain a SoHO establishment authorisation. For all other activities in the list above, you are required to register as a SoHO entity.

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

## 2 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 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

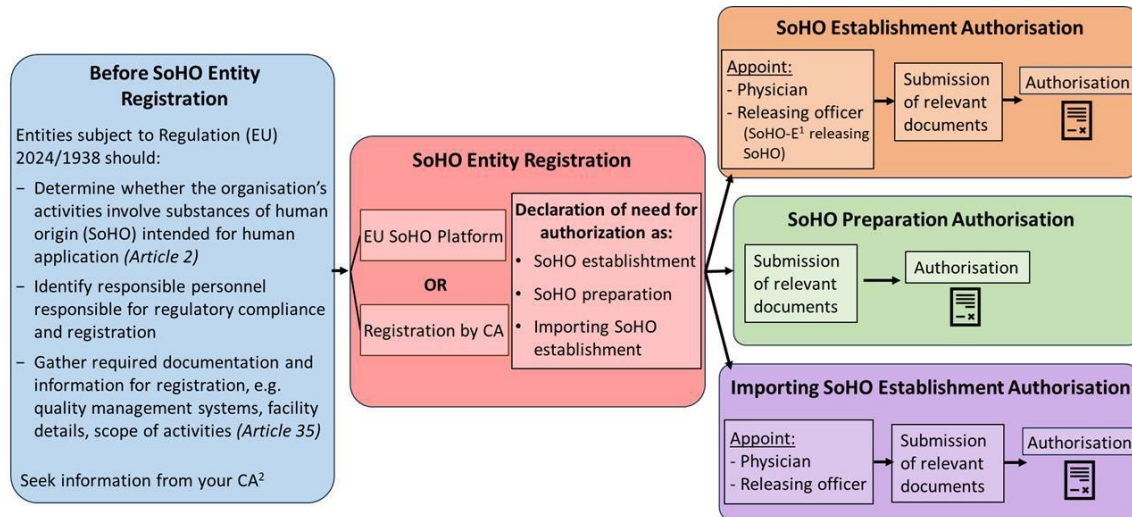
### Key provisions

Entities engaged in SoHO activities must comply with registration and authorisation 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 \(38\)](#)]

### 3 REGISTRATION

The following image shows the registration process and is explained in the steps below.



<sup>1</sup>SoHO-E = SoHO Establishment; <sup>2</sup>CA = Competent Authority

Figure 1 Overview of registration process

#### 3.1 Before SoHO entity registration

Prior to registration, entities should determine whether the organisation’s activities involve SoHO intended for human application.

If the answer is yes, you need to:

- Identify a responsible person (RP), who would be responsible for regulatory compliance and registration.
- Gather required documentation and information necessary for registration e.g. quality management systems, facility details, scope of activities (Article 35)

#### 3.2 SoHO Entity Registration and Relevant Authorisation(s)

Entities in Ireland are required to register directly on the EU SoHO platform. During the registration you will be requested to declare whether additional authorisation(s) are required for any of the following:

- If your organisation is involved in both processing and storage; release or import/export of any SoHO, then you are required to apply for a relevant **SoHO establishment authorisation**.
- If your organisation is involved in any processing of SoHO, then you are required to apply for a relevant **SoHO preparation authorisation**.

- If your organisation is involved in import of any SoHO, you are required to apply for a **SoHO importing establishment authorisation**.

As part of your application for a SoHO establishment authorisation or an importing SoHO establishment authorisation, you are required to nominate a physician and a releasing officer as well as the RP.

The HPRA will verify your details in the SoHO Platform and may contact you for more information as part of the registration process, before the authorisation is granted by the HPRA as the competent authority.

### 3.3 Overview of requirements

New to this regulation is also the term SoHO preparation (SP) [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.
- All establishments will need to prepare the relevant dossier(s) detailing their activities, as per the table below, for review by the HPRA. The HPRA will publish specific guidance in relation to these.

Type of establishment	Requirements
SoHO entity	<ul style="list-style-type: none"><li>- Registration in the SoHO platform</li></ul>
SoHO establishment	<ul style="list-style-type: none"><li>- Registration in the SoHO platform</li><li>- SoHO Establishment Dossier (SED)</li><li>- Preparation Process Dossier (PPD)</li></ul>
SoHO importing establishment	<ul style="list-style-type: none"><li>- Registration in the SoHO platform</li><li>- SoHO Establishment Dossier (SED)</li><li>- SoHO Importing Establishment Dossier (SIED)</li><li>- Preparation Process Dossier (PPD)</li></ul>

## 4 COMPLIANCE AND GUIDELINES

The registration as SoHO entity serves as the first requirement for compliance under the new SoHO framework and ensures that CAs 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](#)
- [Recommendations for non-hospital SoHO entities](#)

For further assistance, contact us at [compliance@hpra.ie](mailto:compliance@hpra.ie) or consult the [FAQ](#) page.

## 5 TIMELINE

The SoHO Regulation will take effect on 7 August 2027.

All SoHO entities will need to register on the EU SoHO Platform before this date. The HPRA will publish instructions on how entities can register on the platform soon. Please sign up to our website updates to ensure you are kept up to date on the implementation of the SoHO Regulation.

### Previously authorised tissue establishments

- Will be deemed authorised under the new Regulation. The HPRA may require additional information during verification
- Previous authorised tissue establishments that are part of the EU coding platform will be automatically transposed to the EU SoHO platform. The HPRA 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. The HPRA may require additional information during verification
- Might need to integrate the information on their registration and authorisation in the EU SoHO platform based on the instructions of the CA. The HPRA will be in contact with existing blood establishments to discuss this process.

### 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 an 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 HPRA 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 reviewed by the HPRA, 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 HPRA, 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 the HPRA. Relevant documentation will be published on the HPRA website in due course.

For any additional information, contact us at [compliance@hpra.ie](mailto:compliance@hpra.ie). Further details on registration on the EU SoHO platform will be published soon on the HPRA website.

## 6 SUPPORT AND RESOURCES

- [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](#)

Please ensure that you are signed up to our website alerts, to ensure you receive up to date information on the SoHO Regulation and its requirements.