

SoHO Coordination Board (SCB)

Position paper

for the activities related with the repurposing of organs as SoHO

The aim of this document is to guide professionals on how to find appropriate technical guidance to **manage and organise the activities related with organs donated under Directive 2010/53/EU ('Organs Directive'¹) when they transition to Regulation (EU) 2024/1938 ('SoHO Regulation')²**. Examples include when hearts and pancreas donated as organs for transplantation are sent to SoHO Establishments to be processed as SoHO Preparations (as heart valves and pancreatic islets respectively)³.

These activities do not refer to:

- **Donation and collection of Substances of Human Origin (SoHO) as regulated by the SoHO Regulation, within SoHO Entities;**
- **SoHO donated and collected as starting material for the manufacturing of MP, investigational MP, ATMPs or MDs, as defined in Article 2 (6) of the SoHO Regulation.**

The present document was drafted by the SoHO Preparation Assessment and Authorisation (SPA) Working Group (WG) of the SoHO Coordination Board (SCB).

¹ Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14).

² 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

³ Other specific activities related to repurposing organs, particularly from living donors, should be covered in national guidance and recommendations issued by the Competent Authorities.

Cross-Regulatory aspects of the activities related with the **repurposing** of organs collected under the Organs Directive (Directive 2010/53/EU) as SoHO Preparations⁴:

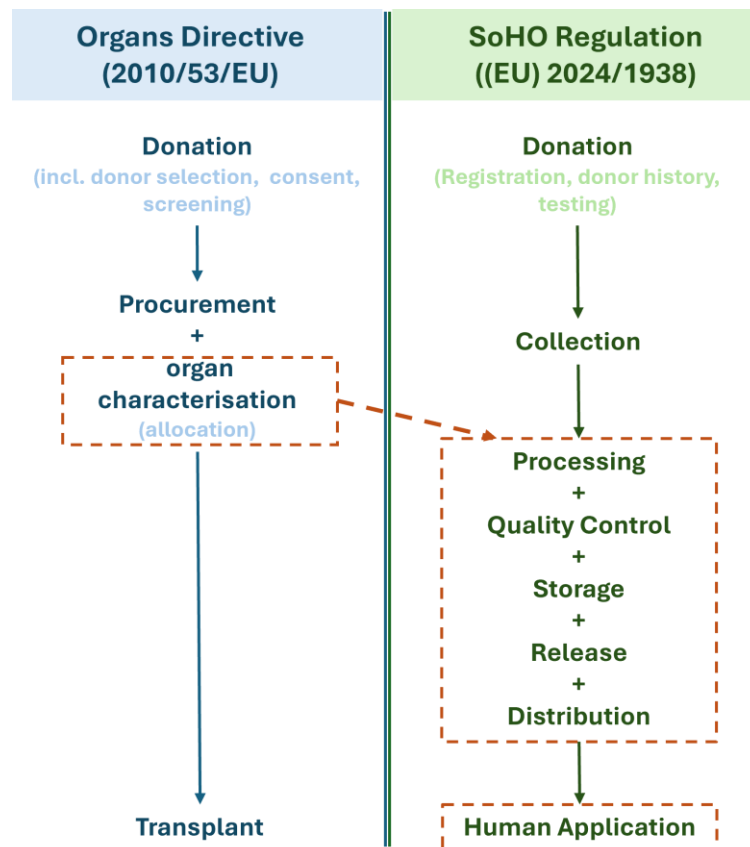


Fig.1 - Representation of activities conducted under the **organ** and **SoHO** legal frameworks. The repurposing of organs as SoHO is indicated in orange (-----)

The repurposing of organs donated and procured under the national laws implementing the ‘Organs Directive’ into SoHO Preparations can be considered as a secondary use for donated organs for transplant.

This activity should not be viewed as a regular procedure⁵. Rather, it shall be seen as a secondary and exceptional use for donated organs to prevent them from being unused when organ transplantation is not feasible following donation and procurement.

Consent:

⁴ The references to technical guidance associated to ‘**SoHO originally donated, collected, and processed under the SoHO framework transitions to Medical Devices (MD) or Medicinal Products (MP) framework to manufacture MP**’ are not included in the current document.

⁵ Regular collection/procurement of organs as SoHO (performed repeatedly), shall be seen as SoHO activity under the Regulation (EU) 2024/1938 and comply with the technical requirements defined in this regulation.

Consent for organ donation is taken under national law in the respective implementation of the requirements set out by the Organs Directive requirements⁶.

In Member States that use opt-in systems requiring explicit consent for organ donation, organ procurement organisations where the possibility for repurposing organs is feasible, should include in their informed consent for organ donation, an indication that the donated organs may be further processed as SoHO preparations for human application, or repurposed, falling under different regulatory frameworks, as appropriate.

SoHO entities, through the cooperation with donation centers, shall provide prospective SoHO donors, their relatives or any persons granting authorisation on their behalf, in accordance with national legislation, with all appropriate information relating to the donation and collection process in accordance with national legislation, including a general description of the potential uses and benefits of the donation (cf. also Art. 55(1) and (4)).

Consent for repurposing of organs shall be aligned with the national regulations and procedures defined by the relevant Competent Authorities.

The following table summarizes the references which are relevant for these requirements at EU level:

Source	Reference
Organs Directive	Article 4, Article 14
SoHO Regulation	Article 53, Article 55
EDQM Organ Guide (9th Edition)⁷	Family approach and consent/authorisation for post mortem organ donation (Chapter 4)
EDQM Tissue and Cells Guide⁸ (6th Edition)	Recruitment of potential donors, identification and consent (Chapter 5)

Donation and Procurement/Collection:

The activities performed by organ procurement organisations (i.e. Donation organisations which are not SoHO Entities, i.e. do not perform regular SoHO activities) can be registered under the SoHO Entity activities in the SoHO Platform (as *Ad hoc* collection sites, under the details of additional 'Activity Address'⁹). Registration in the SoHO Platform should not be regarded as a prerequisite for accepting organs for repurposing as SoHO, but rather as an optional mechanism to clarify the relevant activities and activity addresses, where necessary.

It is recommended to register as Donor Registries (SoHO entities) those organisations allocating SoHO from repurposed organs at national level or in more than one Member State or Third Countries (i.e. European Organ Exchange Organisations).

⁶ Directive 2010/53/EU, Art. 14: The procurement of organs shall be carried out only after all requirements relating to consent, authorisation or absence of any objection in force in the Member State concerned have been met.

⁷ Guide to the quality and safety of organs for transplantation

⁸ Guide to the quality and safety of tissues and cells for human application

⁹ Details for registration in the EU SoHO Platform to be included in future editions of the 'Technical Guidance for the Registration of SoHO Entities'

Whenever possible, Service Level Agreements (SLA) should be in place between organ procurement organisations and SoHO Entity, where organs not suitable for transplantation will be processed as SoHO preparations.

Repurposing of organs shall be aligned with the coordination, allocation, and traceability, vigilance systems/ procedures defined by the Organs and SoHO Competent Authorities.

The following table summarizes the references which are relevant for these requirements at EU level:

Source	Reference
Organs Directive	Article 6, Article 7
SoHO Regulation	Recital 26
EDQM Organ Guide (9th Edition)	Specific organ characterisation, assessment and selection criteria (Chapter 7 - Tissue- and cell-specific selection criteria 7.2.8) Organ procurement, preservation and transportation (Chapter 11) Biovigilance (Chapter 16) Principles and good practice in allocating organs from deceased donors (Chapter 17)
EDQM Tissues and Cells Guide (6th Edition)	Collection (Chapter 8)

SoHO activities in SoHO Entity:

It is the responsibility of the SoHO Entity, to assess if the retrieved organ has been stored and transported in conditions compatible with the requirements of the quality and safety criteria defined in the EDQM Technical Guidelines (EDQM Tissue and Cells Guide - Guide to the quality and safety of tissues and cells for human application and Guide to the quality and safety of organs for transplantation).

SoHO Entities receiving SoHO from repurposed organs should have policies and procedures for reviewing and confirming SoHO donor eligibility especially if there are differences in organ and SoHO acceptance criteria for the repurposed organs. In these cases, a risk-benefit analysis shall be carried out by the SoHO Entity, and the information must be shared with the clinical user of the SoHO Preparation, which can assist in the decision of accepting the SoHO preparation under exceptional release criteria, if applicable.

Activity related to the organ donation and procurement (performed by the *Ad hoc* procurement organisations) should be included in the activity data of the SoHO Entity that receives the organ for processing and reported to the SoHO Competent Authority(ies)¹⁰. Organ procurement organisations may, in turn, specify in their activity data reports¹¹, with regard to organs not used for transplantation, the number that have been transferred to SoHO entities.

The following table summarizes the references which are relevant for these requirements:

¹⁰ Without prejudice to the activity reporting obligations of organ procurement organisations, which will also be responsible for reporting the collection activity relating to organs procured under the Organs Directive.

¹¹ Examples: National Reports or Newsletter Transplant -EDQM

Source	Information
EDQM Tissue and Cells Guide (6 th Edition)	Part A: General Requirements Donor Evaluation (Cardiovascular Tissue) (Chapter 23.2) Donor evaluation (Pancreatic Islets) (Chapter 27.3)