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## **Human body elements for human applications / EU Regulation 2024/1938 on substances of human origin intended for human application, EuroGCT website**

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Aurélie Mahalatchimy. Human body elements for human applications / EU Regulation 2024/1938 on substances of human origin intended for human application, EuroGCT website. 2026. <halshs-05582369>

**HAL Id: halshs-05582369**

**<https://shs.hal.science/halshs-05582369v1>**

Submitted on 7 Apr 2026

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## EuroGCT- WP4

Publication in Open Access on the [EuroGCT](#) website.

To be cited as: A. MAHALATCHIMY, [EU Regulation 2024/1938 on substances of human origin intended for human application](#), April 2026, EuroGCT website.

### ELSI G2: “Therapy Classification”

Sous-entrée : **Human body elements for human applications / EU Regulation 2024/1938 on substances of human origin intended for human application**

## EU Regulation 2024/1938 on substances of human origin intended for human application (EU Regulation on SoHO)

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3 April 2026

### INTRODUCTION

The [EU regulation 2024/1938 on standards of quality and safety for substances of human origin intended for human application](#) has been adopted on 13 June 2024.

Apart from a few specific provisions, it will apply from 7 August 2027. It will also repeal the currently applicable [Directive 2002/98/EC](#) on human blood and blood components and [Directive 2004/23/EC](#) on human tissues and cells, from 7 August 2027.

### KEYPOINTS

Please see below the slides of a talk entitled “EU regulation on SoHO: potential consequences on the generation of real-world data”, presented by A. MAHALATCHIMY at the [52<sup>nd</sup> EBMT Annual Meeting](#), 22-25 March 2026, Madrid, Spain, upon invitation by the [GoCART Coalition](#) for the Session on “[The Power of Real-World Education and Real-World Data](#)” chaired by [Marion Subklewe \(Munich, Germany\)](#) and [Julio Delgado \(Barcelona, Spain\)](#).



52<sup>nd</sup> EBMT Annual Meeting  
22-25 March 2026, Madrid, Spain

# EU regulation on SoHO: potential consequences on the generation of real-world data

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## Disclosure statement

This work has been supported by:

- The European Union's Horizon 2020 research and innovation programme under grant agreement No 965241: **European Consortium for Communicating Gene and Cell Therapy Information (EuroGCT)**
- The French National Agency for Research (ANR) under grant agreement No ANR-20-CE26-0007-01: **Fragmentation and defragmentation of the law on biomedical innovations (I-BioLex)**

## Regulation on Substances of Human Origin (SoHO)

- Adopted on 13 June 2024
- Applicable from 7 August 2027 except some specific provisions
- Will repeal, from 7 August 2027:
  - **Directive 2002/98/EC** of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of **human blood and blood components** and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).
  - **Directive 2004/23/EC** of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of **human tissues and cells** (OJ L 102, 7.4.2004, p. 48).

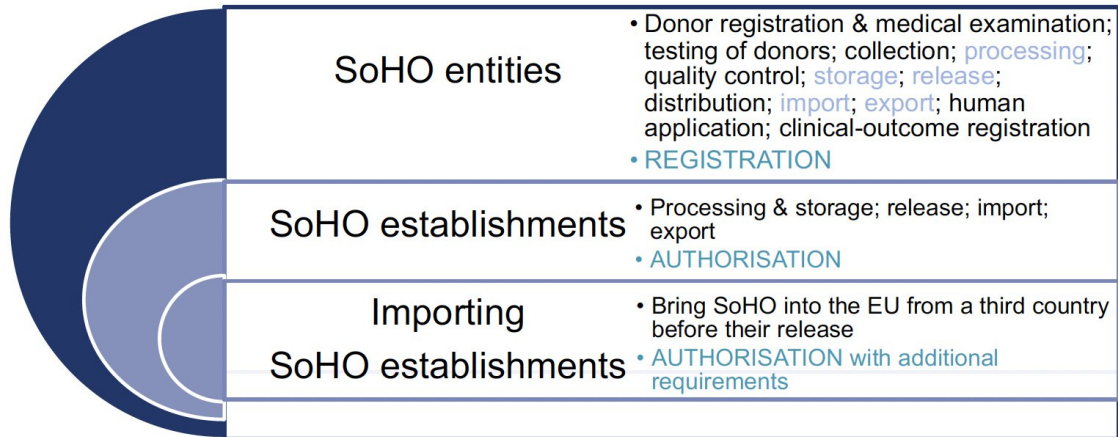
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## Very brief overview of key points

- **SoHO:** A wide definition
  - *“any substance collected from the human body, whether it contains cells or not and whether those cells are living or not, including SoHO preparations resulting from the processing of such substance”*
- **SoHO activities:** from SoHO donation to human application & follow-up
- **Distinction between SoHO entities and establishments**
- **Authorisations of SoHO establishments and SoHO preparations**
- **Strengthened protection of SoHO donors, recipients, and offspring**
- **Coordination at EU level** with a new SoHO Coordination board (set up 01/2025)
- **Stricter oversight:** SoHO establishments, SoHO competent authorities
- **Digitalisation:** new EU SoHO platform
- **Vigilance:** Rapid alerts and use of EU SoHO platform
- **Self-sufficiency & sustainability of supply:** Critical SoHO (entities) & Emergency plans

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# SoHO entities and establishments



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## SoHO preparations

- What are SoHO preparations?
  - **3 cumulative conditions** for SoHO
 

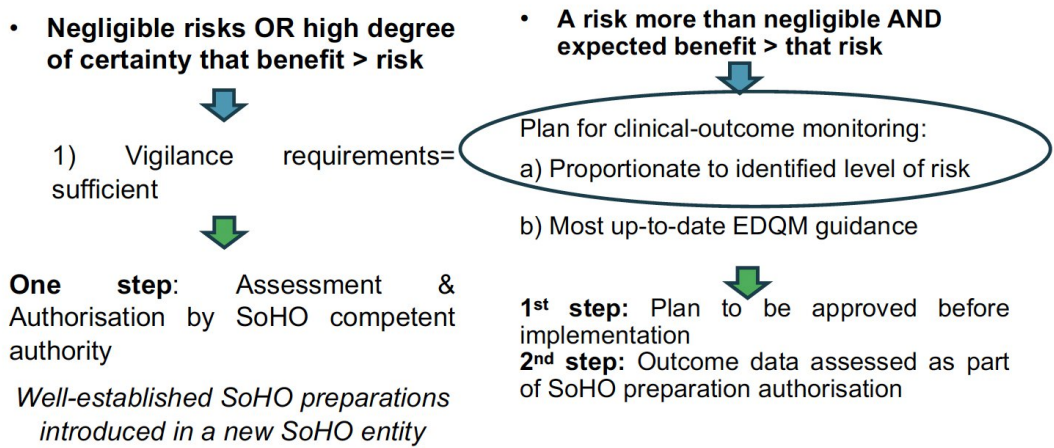
<b>AND</b>	<ol style="list-style-type: none"> <li>1. <b>Processing</b> (+ 1 or more other SoHO entities' activities where relevant)</li> <li>2. <b>A specific clinical indication</b></li> <li>3. <b>Human application OR distribution</b></li> </ol>
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- SoHO preparations need to be authorised
  - Prior to release and distribution
  - By SoHO competent authorities and after their (joint) assessment
  - SoHO establishments have to prove safety and effectiveness in SoHO recipients by means of **clinical-outcome data collection and review**

↓

Significant role for RWD to generate evidence (RWE) for SoHO preparation authorisation

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## Proportionality of clinical-outcome monitoring to the level of risk



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## Proportionality of clinical-outcome monitoring PLAN to the level of risk

Levels of Risk  Legal requirements	Low risk & positive benefit-risk assessment	Moderate risk & positive benefit-risk assessment	High risk & positive benefit-risk assessment + risk or benefit not evaluable
1) Mandatory continuous vigilance reporting	✓	✓	✓
2) Proactive clinical follow-up for defined number of SoHO recipients	✓	✓	✓
3) A SoHO clinical study with monitoring of pre-defined clinical end-points	✗	✓	✓
4) SoHO clinical studies including comparison with a standard therapy	✗	✗	✓



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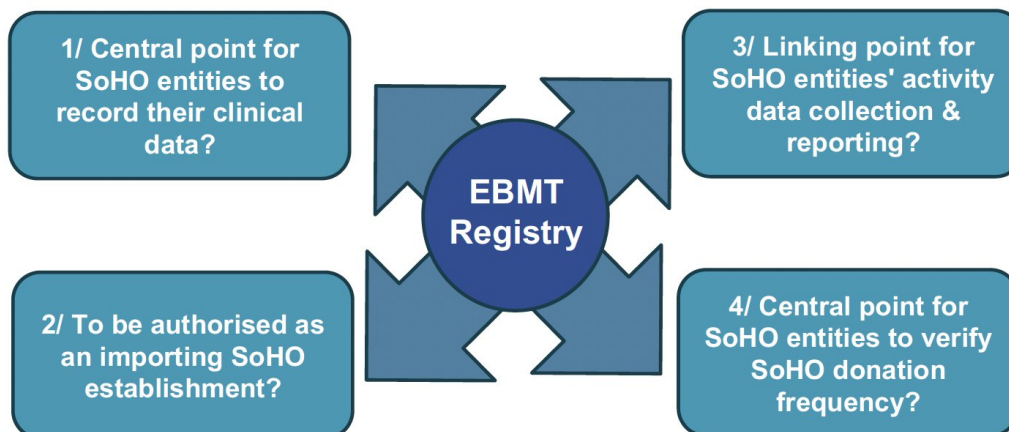
## How to implement clinical-outcome monitoring plans?

### Options to record generated clinical data

- 1) Using the Clinical Trials framework is permitted (without change of regulatory status)
    - When SoHO entities wish to do so
  - 2) SoHO entities record clinical data by themselves
  - 3) To use existing clinical registries BUT conditions }
    - verified by the SoHO competent authority
    - certified by an external institution
- The reliability of their data quality management procedures has been:
- EBMT registry?
- Balance?  
Complementarity?
- To consider other approved SoHO clinical studies in the EU:
- New registry at the EU level via new EU SoHO platform, with 3 aims:
    - facilitate patient participation in SoHO clinical studies
    - boost multi-centre studies and foster collaboration to generate more robust results
    - Make generated knowledge generated available (other researchers, healthcare professionals, studies' participants, general public)

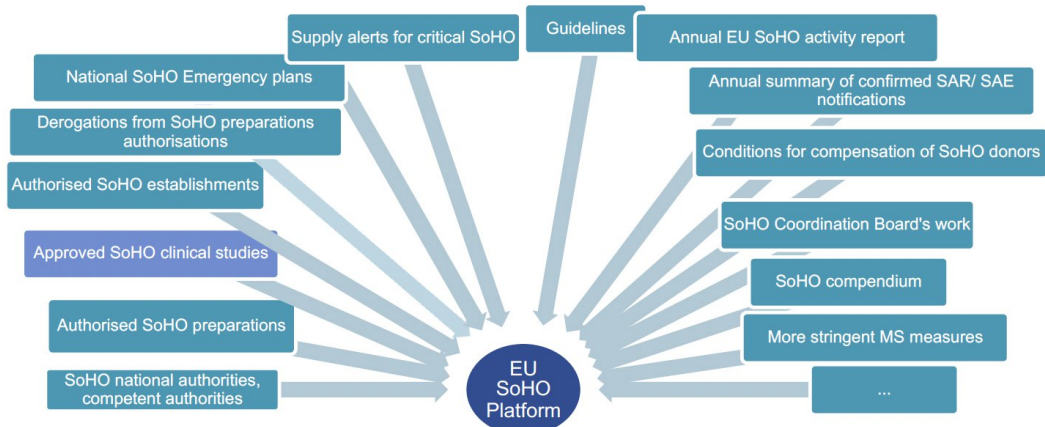
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## New opportunities for the EBMT registry?



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## What information on the new EU SoHO platform?



EBMT should think about what is needed as regards what is required to be on the EU SoHO platform

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More information on regulatory aspects (ATMP, SoHO, Medical devices based on tissues and cells,...) are available on [www.eurogct.org](http://www.eurogct.org)

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## Thank you for your attention!



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A complete summary of the EU Regulation on SoHO is available on the EUR-Lex website [here](#) in the 24 official languages in the European Union.

### STRENGTHENED PROTECTION OF SOHO DONORS, RECIPIENTS, AND OFFSPRING

Please see below the poster entitled “The new EU regulation on SoHO: strengthening the protection of donors, recipients and offspring”, presented by A. MAHALATCHIMY, V. ROBY, C. CHABANNON, at the 52<sup>nd</sup> EBMT Annual Meeting, 22-25 March 2026, Madrid, Spain.



# The new EU regulation on SoHO: strengthening the protection of donors, recipients and offspring

Aurélie Mahalatchimy<sup>1</sup>, Valentin Roby<sup>2</sup>, Christian Chabannon<sup>3</sup>

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<sup>3</sup> Centre de Thérapie Cellulaire, Institut Paoli-Calmettes Comprehensive Cancer Center & module Biothérapies du Centre d'Investigations Cliniques de Marseille, Inserm CBT-1409 -AMU -AP-HM -IPC.



## Background and Method

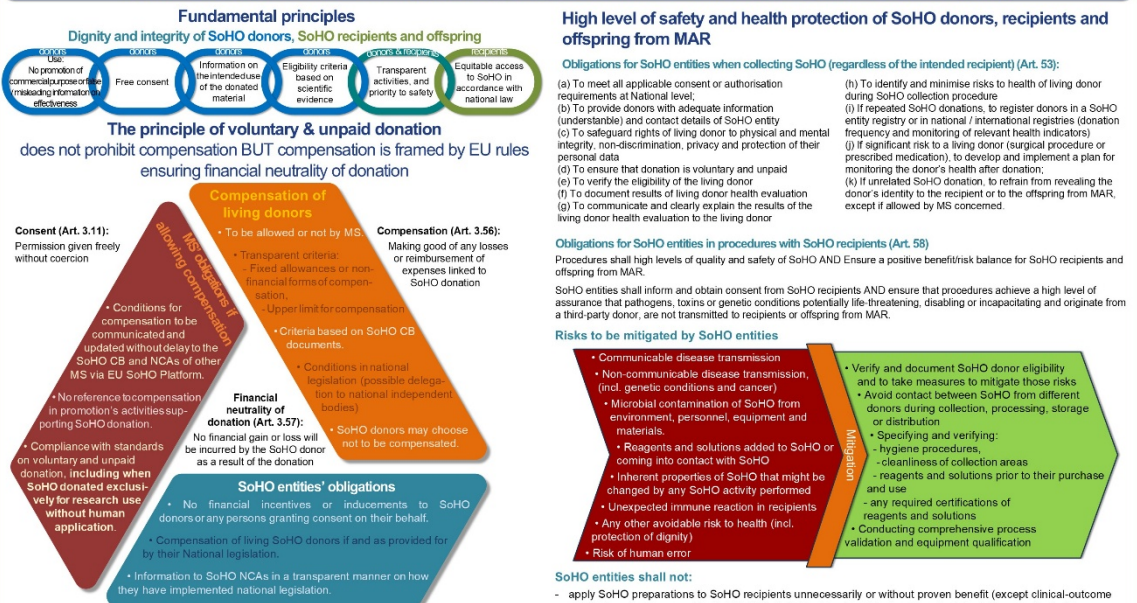
The European Union (EU) Regulation 2024/1938 on standards of quality and safety for Substances of Human Origin (SoHO) intended for human application was adopted on 13 June 2024 to solve issues that were not (sufficiently) addressed by the previous EU directives on blood (Directive 2002/98/EC) and tissues and cells (Directive 2004/23/EC). Among them, an extensive evaluation of the EU legislation led by the European Commission highlighted that there were avoidable risks for donors and for children born from donated gametes, and that patients were not fully protected from avoidable risks.

Based on an analysis of the EU regulation on SoHO regarding the protection of SoHO donors, recipients and offspring, this poster clarifies the new EU legal measures targeting the protection of SoHO donors, recipients and offspring.

These measures provide obligations mainly for Member States (MS) (and their national SoHO competent authorities (NCAs) by delegation) and SoHO entities which are defined widely as entities legally established in the Union that carry out one or more of the following SoHO activities: 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; processing; quality control; storage; release; distribution; import; export; human application; clinical-outcome registration.

These new rules shall apply from 7 August 2027.

## New EU law provisions strengthening the protection of donors, recipients and offspring



**Conclusion**

The EU regulation on SoHO operates a major shift from the quality and safety of SoHO to the wider protection of SoHO donors, recipients and offspring which is either strengthened or newly covered.

Such protection is also enhanced due to the wider meaning of SoHO in comparison with the previous directives on tissues and cells and blood and blood components. Indeed, SoHO meaning "any substance collected from the human body, whether it contains cells or not and whether those cells are living or not, including SoHO preparations resulting from the processing of such substance", more persons are considered SoHO donors, recipients and offspring and thus protected in accordance with this new EU regulation.

**Abbreviations**  
 MAR: Medically Assisted Reproduction  
 MS: Member state  
 NCAs: National Competent Authorities  
 SoHO CB: SoHO Coordination Board

[www.ebmt.org](http://www.ebmt.org)

## LAY-OUT of the EU Regulation 2024/1938 on SoHO

- CHAPTER I: GENERAL PROVISIONS (Articles 1-4)
- CHAPTER II: MEMBER STATES' SOHO COMPETENT AUTHORITIES (Articles 5-15)
- CHAPTER III: SOHO SUPERVISORY ACTIVITIES (Articles 16- 34)
- CHAPTER IV: GENERAL OBLIGATIONS ON SOHO ENTITIES (Articles 35- 44)
- CHAPTER V: GENERAL OBLIGATIONS ON SOHO ESTABLISHMENTS (Articles 45- 51)
- CHAPTER VI: SOHO DONOR PROTECTION (Articles 52- 56)
- CHAPTER VII: PROTECTION OF SOHO RECIPIENTS AND OFFSPRING FROM MEDICALLY ASSISTED REPRODUCTION (Articles 57- 61)
- CHAPTER VIII: SUPPLY CONTINUITY (Articles 62-67)
- CHAPTER IX: SOHO COORDINATION BOARD (Articles 68- 69)
- CHAPTER X: UNION ACTIVITIES (Articles 70- 72)
- CHAPTER XI: EU SOHO PLATFORM (Articles 73- 74)
- CHAPTER XII: PROCEDURAL PROVISIONS (Articles 75- 80)
- CHAPTER XIII: TRANSITIONAL PROVISIONS (Articles 81- 84)
- CHAPTER XIV: FINAL PROVISIONS (Articles 85-87)

The 80 pages-full text is available on the EUR-Lex website [here](#) in the 24 official languages in the European Union.

## MORE information on the EU Regulation on SoHO

Please find more information on the European Commission website:

- [SoHO Regulation](#)
- [New EU rules on substances of human origin](#)
- [Blood, tissues, cells and organs](#)

Please find relevant information on Substances of human origin on the website of the European Centre for Disease Prevention and Control (An agency of the European Union)

- [Substances of human origin](#)

Please find relevant information on Substances of human origin on the website of the European Directorate for the Quality of Medicines & HealthCare (A Directorate of the Council of Europe):

- [Substances of human origin](#)