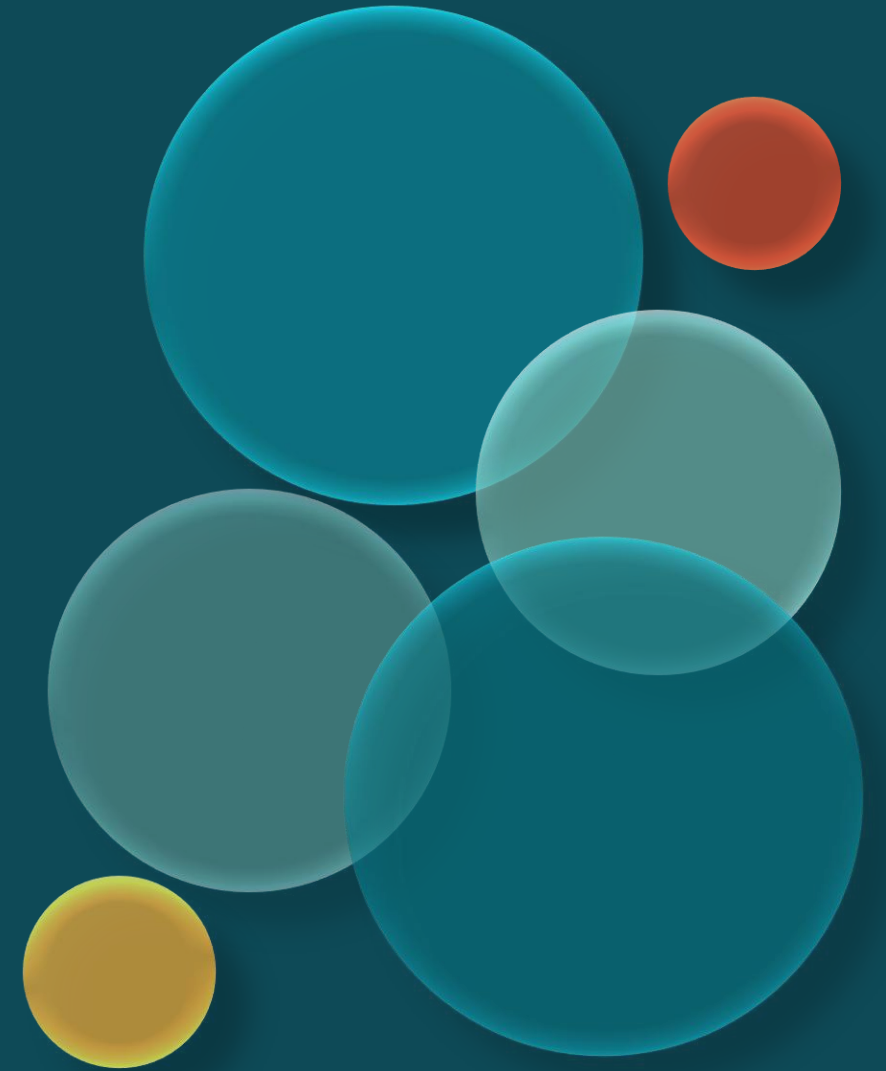


The legal landscape of organoid regulation: a European perspective



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Legal classification of organoids

Law has no category of its own for organoids

Organoid technologies seen as one unified innovation:

- derived from stem cells,
- biologically sophisticated,
- promising health innovation.

But no single legal framework: different regimes for different context of uses.

Is the organoid protocol proposed as...



A fundamental research platform?



A preclinical research tool?



An evidence-gathering method for regulatory decisions?



A clinical diagnostic tool?



A cell therapy?

Obligations and procedures will change accordingly

Overview



The EU context

- Overview of the EU rules
- Implemented in varied manners at the national level



The technological pipeline

- Fundamental research
- Pre-clinical
- Clinical trials and clinical investigations
- Medical products and medical devices



Sensitive organoid models

- Brain organoids, stem cell-based embryo models (SCBEMs) and chimeras
- No dedicated EU rules
- Up to Member States

Robust legal frameworks already in place and being updated

Where there is not binding legislation, RECs are at the frontline of novel ethical questions

The legal frameworks applicable to organoids



Cells and Tissues

Ensuring the quality and safety of donated cells and tissues



End-products

What kinds of regulated products organoids can be



Transversal frameworks

Cross-cutting rules that do not depend on the final use of the organoid



Cells and tissues: the upcoming SoHO Regulation

Today

Tissues and Cells Directive (2004) and Blood Directive (2002)



Replaced by

SoHO Regulation (EU) 2024/1938

of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application

7 August 2027

New obligations at this date, transitional extra year

Scope

- Blood, tissues, cells, reproductive cells... Not organs
- Intended for human application

What changes

- Higher safety and quality standards, harmonised at EU level
- Greater protection of donors
- Technical norms set by expert scientific bodies
- Easier cross-border exchanges
- New rules for SoHO entities: **impact on biobanking activities**



End-products: what regulated products can organoids be?

Field	Scope	Main instruments
Medical device (MD) & In Vitro Diagnostic Medical Device (IVDMD)	Medical devices used for the examination of specimens (i.e. organoids, tumoroids...)	Regulation (EU) 2017/745 (MDR), Regulation (EU) 2017/746 (IVDR)
Advanced Therapy Medicinal product (ATMP)	Cells therapies administered to the patient, that undergo substantial manipulation or are used for a different essential function	Regulation (EC) 1394/2007 (ATMP), Directive 2001/83/EC, Clinical Trials Regulation (EU) 536/2014

Companion diagnostic and clinical twins: IVDMD

- Patient-derived organoid used to test which drug a patient is likely to respond to
- Certification of the Medical Device
- Health institutions (hospitals and laboratory) may use the in-house device route (Art. 5(5)): lighter, but conditional

Administered to the patient: ATMP

- Organoid used to repair diseased tissue
- Marketing authorisation, or clinical trial authorisation at experimental stage
- Non-routine individual hospital use: hospital exemption (Art. 3(7), Dir. 2001/83/EC), national rules



Transversal frameworks (1/2)

Field	Main Instruments	Content
Embryo and stem-cell research	National embryo and stem cell laws, Oviedo Convention (Art. 18)	• Restrictions on certain research protocols (in vitro gametogenesis, chimeras...)? • Applicability of embryo research rules to SCBEMs?
Data protection	General Data Protection Regulation (UE) 2016/679 (GDPR), European Health Data Space Regulation (EU) 2025/327	• Genomic data and health data are sensitive data • GDPR does not apply when data or samples are fully anonymised (rare)
Intellectual property	Biotech Directive 98/44/EC (Arts 5-6), CJEU Brüstle (C-34/10) and International Stem Cell Corp. (C-364/13)	• Human body not patentable, but an element isolated from it or produced by a technical process can be (Art. 5) • e. g. methods, cell lines and organoid-derived products • Inventions contrary to ordre public are not patentable, e.g. industrial uses of human embryos (Art. 6) • SCBEMs = embryos?



Transversal frameworks (2/2)

Field	Main Instruments	Content
Animal research	Directive 2010/63/EU (protection of animals used for scientific purposes)	• 3R (replace, reduce, refine) • Animal research must be evaluated by an ethics committee • Replacement of animal use where a scientifically satisfactory alternative exists (Arts 4 and 13)
New Approach Methodologies (NAMs)	REACH Regulation (EC) 1907/2006, CLP Regulation (EC) No 1272/2008..., OECD and EMA guidelines	• Validation of NAMs to replace animal testing
	Upcoming reform of EU pharmaceutical legislation (“Pharma package”)	• Explicit recognition of NAMs • Obligation not to test on animals where satisfactory NAMs are available

Soft law guidance to fill the gaps



European initiatives

- EU funded project : HYBRIDA project ; CHANGER project
- European Society of Human Reproduction and Embryology (ESHRE)



ISSCR Guidelines

The main international reference ; updated to address embryo models ; possible upcoming revision for neural organoids

Take-home messages

1

There is no law of organoids.

Legal classification and applicable frameworks depend on the context of use.

2

Most organoid uses are already well regulated.

Important updates are on their way: the SoHO Regulation and the Pharma package.

3

New sensitive models are mostly left to soft law and ethics committees.

SCBEMs, neural organoids, chimeras...



Thank you for your attention!

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