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The EU SoHO Regulation: Key Regulatory Changes and Practical Implications

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On **7 August 2027**, Regulation (EU) 2024/1938 (the "SoHO Regulation") will become generally applicable, introducing a new EU framework for substances of human origin ("SoHO"). Replacing Directives 2002/98/EC and 2004/23/EC on blood, tissues and cells, it aims to strengthen the protection of donors, recipients and offspring from medically assisted reproduction, improve SoHO quality and safety, and safeguard the continuity of critical SoHO supply.

With its application date approaching, businesses operating across the SoHO supply chain should assess their activities against the new requirements and prepare for the transition to the revised regulatory regime.

Key Regulatory Developments

1. Wider Regulatory Reach

The Regulation covers a wide range of human-derived substances, including blood, tissues and cells, and regulates activities across their supply chain, from donation and collection to processing, distribution and human application in specialized medical establishments.

Its reach also extends to the pharmaceutical and medical technology sectors. For SoHO collected for the manufacture of certain medicinal products and medical devices, the Regulation covers donor registration, assessment and testing, collection and release, as well as storage, distribution, import and export up to distribution to the manufacturer, where applicable. Narrower rules apply to certain products intended exclusively for therapeutic use on the person from whom the SoHO were collected.

Businesses relying on human-derived materials should therefore consider whether their sourcing and related activities fall within the new framework.

National requirements also remain relevant. Member States may maintain or introduce stricter measures compatible with EU law and proportionate to health risks, while national rules continue to govern matters such as consent, ethics and donor compensation.

2. Registration or Authorization: What Is Required?

The Regulation distinguishes between SoHO entities, SoHO establishments and SoHO preparations, introducing different regulatory requirements depending on the activities performed.

- **SoHO entities:** Organizations carrying out regulated SoHO activities must

register with the competent authorities before commencing operations, providing details of their activities and responsible person.

- **SoHO establishments:** Additional authorization is required for certain activities, including both processing and storage, release, import or export of SoHO. Authorization involves regulatory assessment and on-site inspections. Authorities may also require it for other entities depending on the scale, complexity or criticality of their activities.
- **SoHO preparations:** Processed SoHO intended for specific clinical indications generally require prior authorization based on a risk-based assessment of quality, safety and effectiveness. Additional clinical-outcome monitoring may be necessary depending on the risk and available evidence.

An important exception applies to SoHO distributed for the manufacture of products governed by certain other EU legislation, including medicinal products and medical devices, for which SoHO preparation authorization is waived.

3. Higher Standards for Quality and Compliance

SoHO entities must designate a suitably qualified **responsible person** and establish, maintain and regularly update a **quality management system (QMS)** suited to their activities.

The QMS must cover relevant processes, including personnel qualifications, facilities and equipment, quality controls, internal audits, corrective and preventive actions, and oversight of contracted third parties.

The Regulation also strengthens **traceability and vigilance**, requiring procedures to identify, investigate and report serious adverse reactions and events, enabling timely risk management and corrective action.

4. Stronger Safeguards for Donors and Recipients

The Regulation reinforces protection for donors, recipients and offspring from medically assisted reproduction through requirements on donor eligibility and assessment, informed consent, donor monitoring and risk prevention during collection and human application.

It also upholds voluntary and unpaid donation, while allowing donor compensation under specified conditions and safeguards.

5. Supply Resilience

To protect critical SoHO supply, the Regulation also introduces monitoring, reporting and emergency-planning obligations for relevant operators, aimed at reducing disruptions and improving shortage preparedness.

6. What Happens to Existing Authorizations?

The Regulation provides transitional arrangements to support continuity of existing SoHO activities.

Certain blood and tissue establishments authorized, accredited, designated or licensed under the previous framework are deemed registered and authorized under the new regime. Certain previously authorized

SoHO preparations also benefit from recognition, subject to applicable conditions. **However, existing authorizations do not provide a general exemption from the new requirements.**

A separate transitional regime applies to qualifying activities involving SoHO not expressly covered by the former Directives, where those activities were already carried out before 7 August 2027. They may continue until 8 August 2028, subject to registration, applicable donor- and recipient-protection standards and the submission of any required SoHO preparation or establishment authorization applications by 8 November 2027.

Key Practical Considerations

With the new framework approaching application, businesses involved in SoHO-related activities should consider the following preparatory steps:

- **Assess regulatory scope:** Map activities involving human-derived substances, including those performed by external suppliers and service providers, to identify potential obligations under the Regulation.
- **Review registration and authorization requirements:** Determine whether existing operations require SoHO entity registration, SoHO establishment authorization or SoHO preparation authorization, taking into account applicable exceptions and transitional provisions.
- **Evaluate operational readiness:** Review quality management systems, applicable technical guidelines, traceability, vigilance, and contractual arrangements to identify potential compliance gaps. Critical SoHO entities should also assess stock-monitoring, supply-alert and emergency-planning arrangements.

The SoHO Regulation introduces significant changes for organizations across the SoHO supply chain. Early assessment of its requirements will be important for businesses seeking to ensure regulatory compliance and operational readiness under the new framework.

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