

# The new EU SoHO regulation

## 53th scientific meeting of BSRM

*28th of November 2025*



# Key definitions for MAR – Article 3

(3) ‘reproductive SoHO’ means *human sperm, oocytes, ovarian and testicular tissue* intended to be used for the purpose of medically assisted reproduction *or restoring endocrine function; for the purposes of this definition, embryos are considered reproductive SoHO even though they are not collected from the human body;*

(14) ‘within-relationship use’ means the use of reproductive SoHO for medically assisted reproduction *between* persons with an intimate physical relationship

(15) ‘third-party donation’ means a donation of reproductive SoHO to be used for medically assisted reproduction in a SoHO recipient with whom the SoHO donor does not have an intimate physical relationship;

(16) ‘medically assisted reproduction’ means any laboratory or medical intervention, including any preparatory steps, that involves the handling of reproductive SoHO for the purpose of the facilitation of pregnancy or for preservation of fertility;

(17) ‘preservation of fertility’ means the process of saving or protecting a person’s reproductive SoHO intended to be used later in that person’s life;

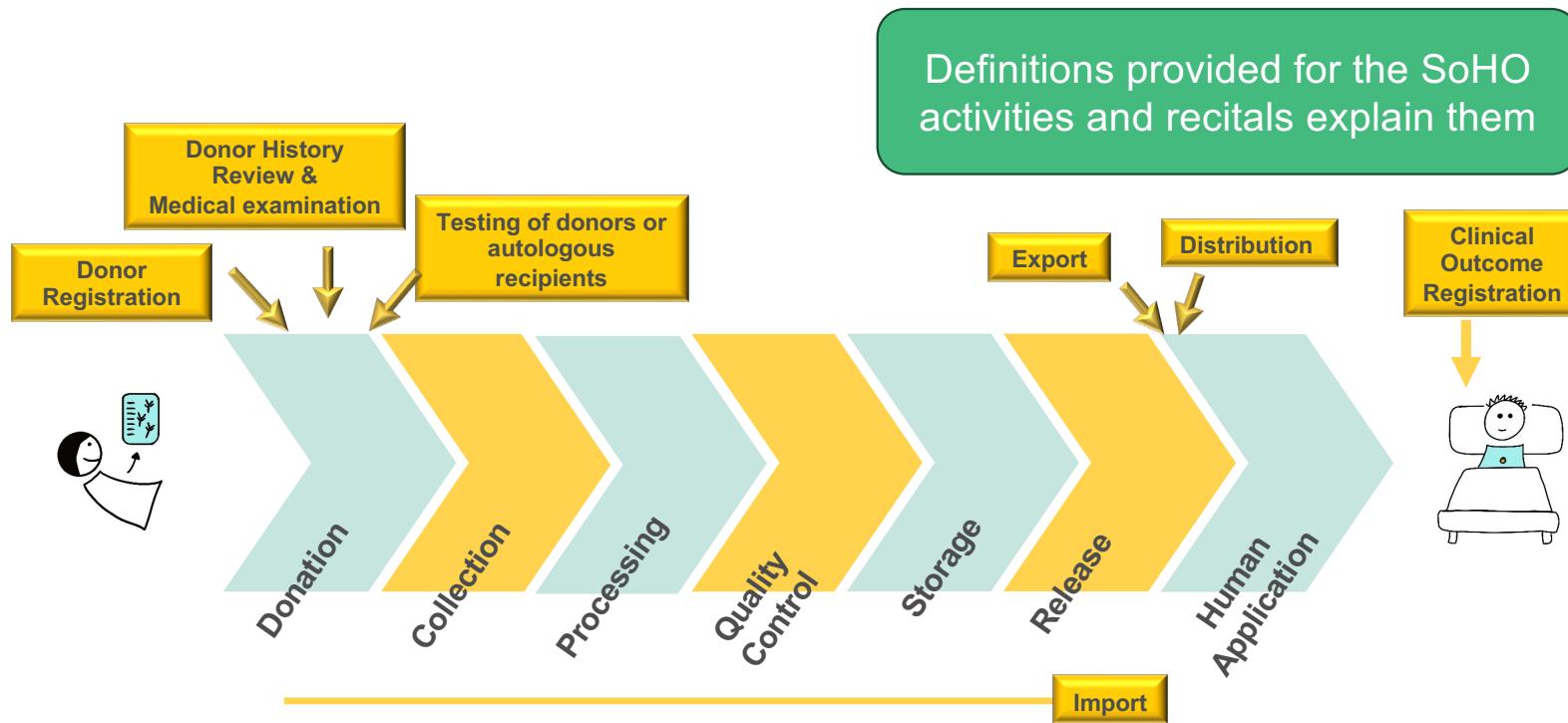
(18) ‘offspring from medically assisted reproduction’ means children born following medically assisted reproduction.

- MAR specific elements
- Implementation (by August 2027)

# Key new and changed concepts

- **Scope and advice**
- **SoHO activities, entities and establishments**
- **SoHO Preparations and their authorisation**
- **Standards and hierarchy of technical guidelines**
- **Donor Protection and Voluntary Unpaid Donation**
- **Recipient and offspring protection**
- **Supply continuity**
- **Digitalisation – the SoHO platform**

## Supervision of all SoHO Activities that directly impact safety, quality or effectiveness



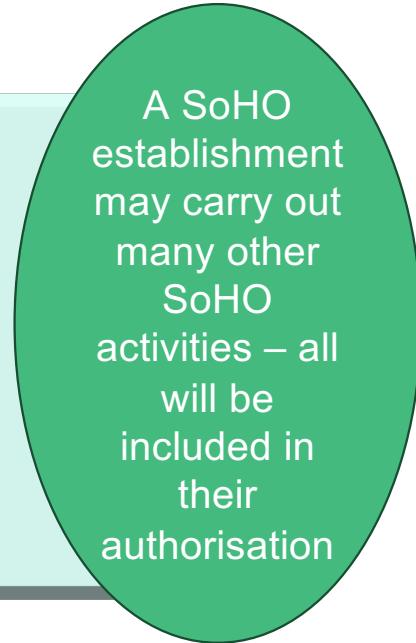
Any actor organising one or more SoHO activity/ies needs to  
register as **SoHO entity** with the Competent Authority

## ....but risk-based authorisation, ensuring efficient use of authority resources

A **SoHO entity** carries out one or more SoHO activities

A **SoHO establishment is a SoHO entity that** carries out at least

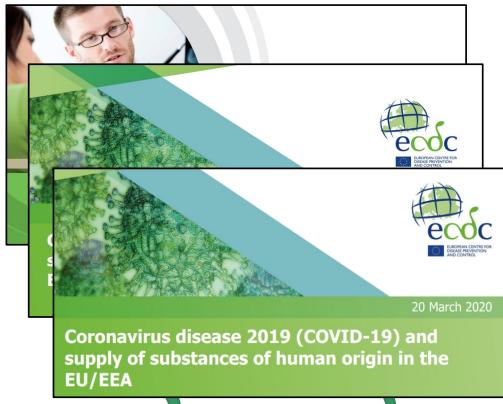
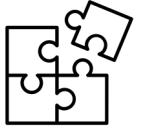
- Both processing and storage, or
- Release, or
- Import, or
- Export



A SoHO establishment may carry out many other SoHO activities – all will be included in their authorisation

**Note:** CAs may regulate a SoHO entity as a SoHO establishment, even if it does not meet the criteria above, if it considers that the entity has a particularly important impact (e.g. a testing laboratory that tests donors for a whole region or country, a register that identifies and selects donors for one or more Member States).

# Guidance by ECDC and EDQM expert bodies



Prevention and management of **donor-derived communicable disease transmission** through SoHO application (HIV, hepatitis, ...)

New ECDC recommendations integrated in next update of EDQM guidelines



**Comprehensive guidelines on quality and safety** per type of SoHO (blood, cornea, stem cells, ...)



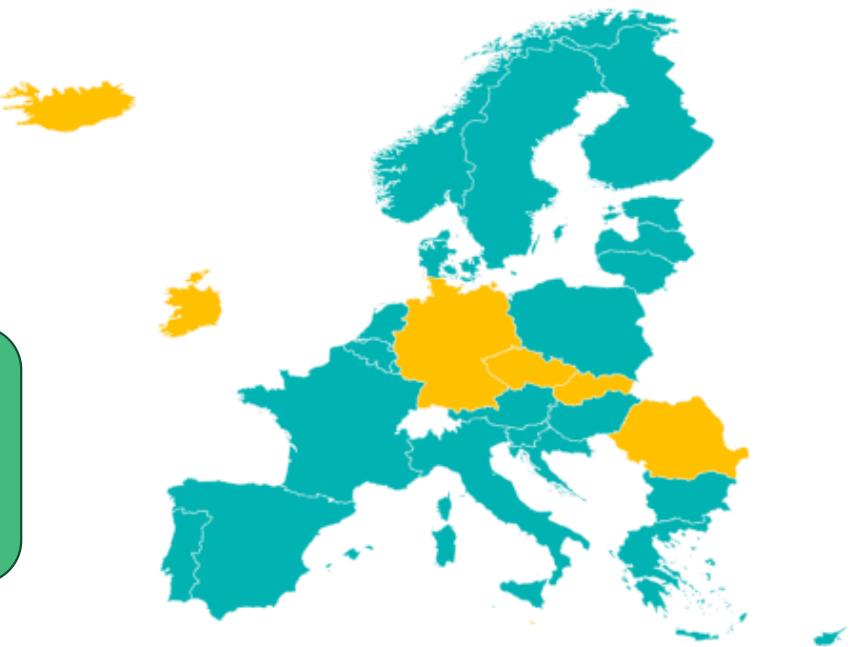
# Recipient and offspring protection

- Identification and mitigation of risks from **transmissible infectious, genetic, malignant diseases (where national legislation allows, genetic testing of donors, and recipients)**
- Identification and mitigation of risks from **toxins, contaminants** from the environment, other donations, the personnel, the equipment, reagents etc.
- Identification and mitigation of risks of **detrimental effects on inherent properties of the SoHO concerned**
- Identification and mitigation of risks of **harmful immune reactions**
- Application of national rules regarding the **maximum numbers of offspring** from one SoHO donor
- **No application of SoHO unnecessarily** or in cases where there is no proven benefit
- No promotion of SoHO application based on **misleading information**



# Current national limits for sperm donation in EU/EEA countries

Reflection group  
within SCB,  
involving ESHRE  
  
(Limits, monitoring,  
enforcement, ...)



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- Legal limit or strict code of practice
- No legal limit

➤ Existing limits range from 1 family (Cyprus) to 12 families (Denmark, the Netherlands)

## Vigilance enhancements



Best practices  
agreed and  
documented by  
SCB

- Inclusion of SAR reporting requirement for SAR in **living SoHO donors**
- Clarification that **SAR/E detected during clinical outcome monitoring** must be reported
- Obligation for reasonable efforts to encourage recipients of MAR donations to communicate information on **genetic conditions in offspring** – when serious these are reportable as SAR
- **Role of ECDC** for SAR concerning infectious disease transmissions
- Formalisation of **communication** requirements with **CAs in other sectors**, when appropriate
- Clarification that **loss of critical SoHO** constitutes an SAE in defined situations
- CAs to provide **guidance and templates** to professionals and to **inform relevant SoHO entities of Rapid Alerts** received

## Serious Adverse Reaction – definition art 3.45

‘serious adverse *reaction*’ or ‘SAR’ means an adverse *reaction* that *results* in any of the following:

[...]

- (c) **transmission of a genetic disorder that:**
  - (i) in the case of medically assisted reproduction *with third-party donation*, resulted in pregnancy loss or might result in a life-threatening, disabling or incapacitating condition in the offspring from medically assisted reproduction; or
  - (ii) in the case of medically assisted reproduction in the context of *within-relationship use*, resulted in pregnancy loss or might result in a life-threatening, disabling or incapacitating condition in the offspring from medically assisted reproduction, *due to a pre-implantation genetic test error*;

- MAR specific elements

- Implementation (by August 2027)

# Setting up the SoHO framework



## Building blocks

- **SoHO Coordination Board (SCB)**
- **Working Sub-groups on oversight tasks**
- **SoHO digital platform**
- **Work of the expert bodies (EDQM and ECDC)**



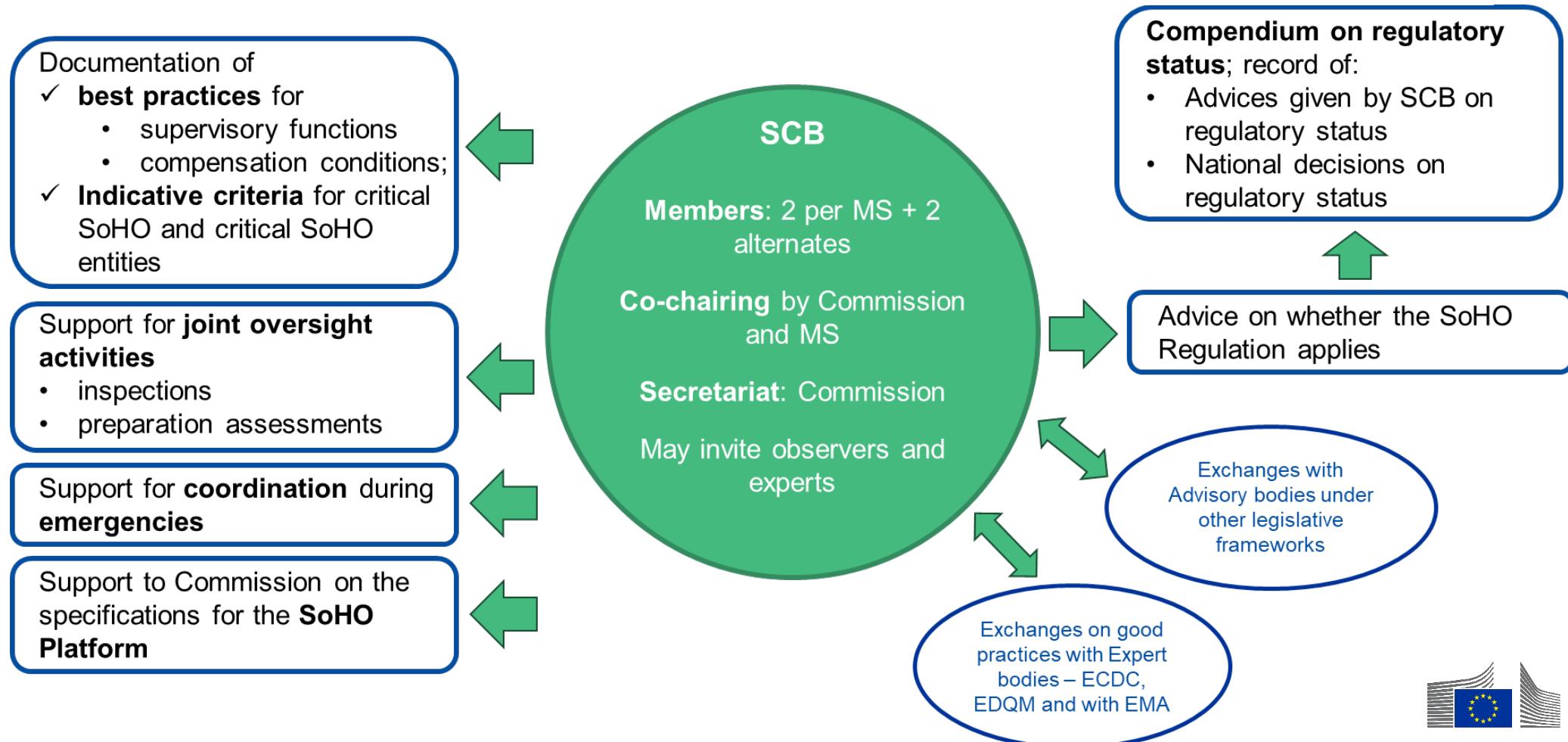
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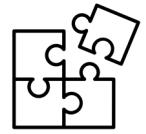
- **EU4H**
- **Implementing legal**
- **Other tasks**





## The SoHO Coordination Board (SCB) - supporting implementation in MS

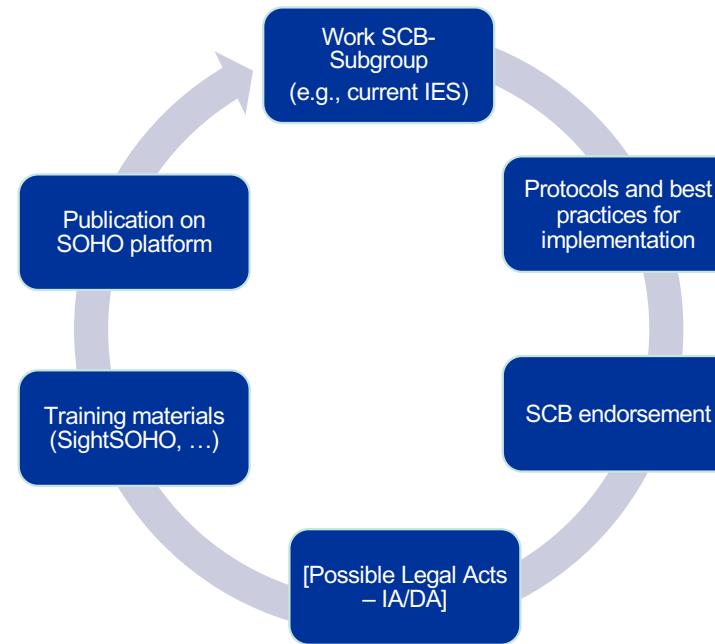




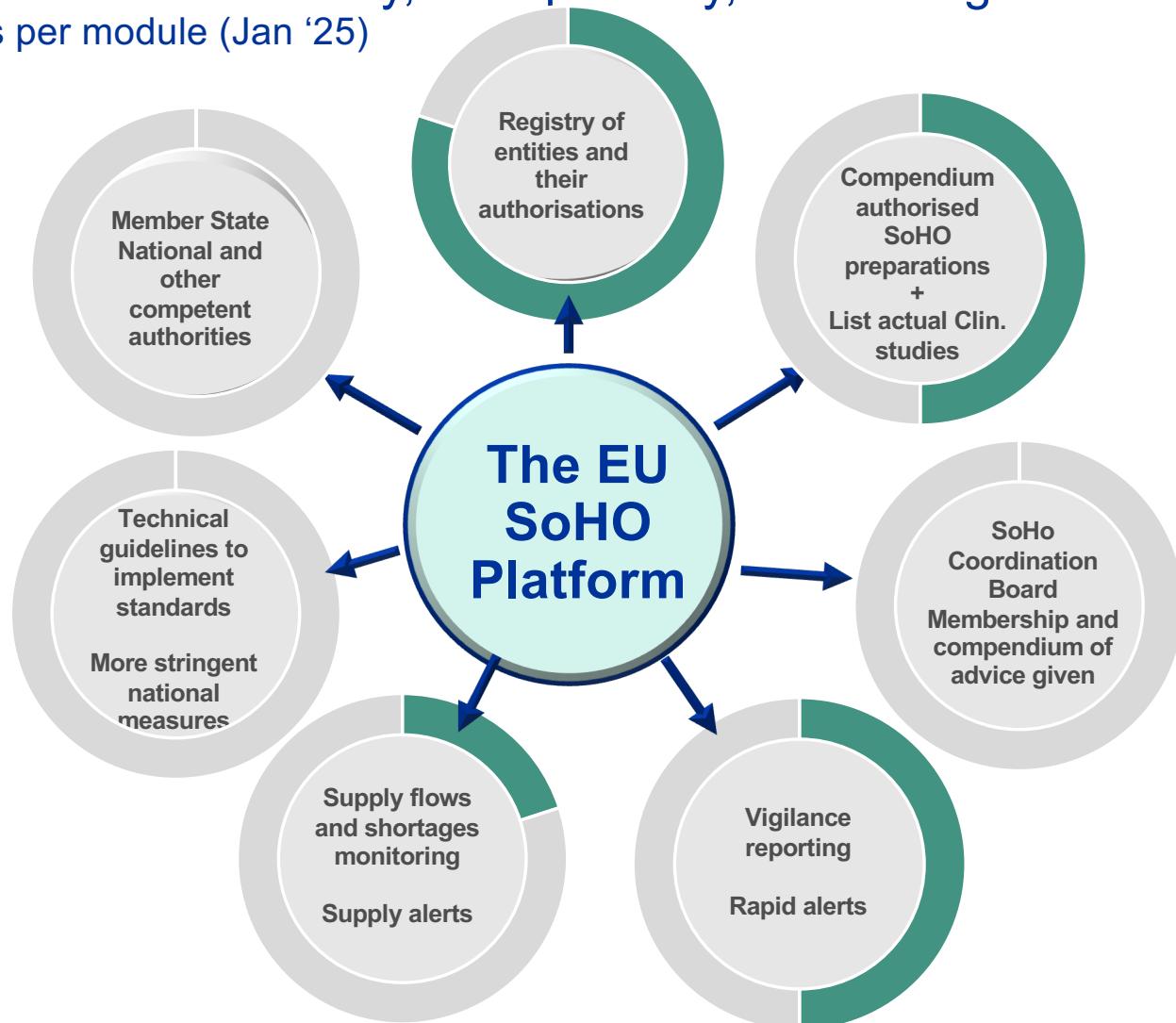
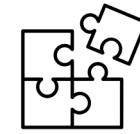
# SCB gets support from 6 sub-groups

## Area's to cover

1. Inspection
2. Vigilance and traceability
3. Registration of entities and authorisation of establishments
4. SoHO preparation authorisations
5. Activity data collection and supply alerts
6. Regulatory questions, including classification



## Digitalisation - efficiency, transparency, monitoring progress per module (Jan '25)



# Awareness building and training

Leverage public SoHO platform (i.e. Use and functionalities)

Common Q&A/FAQ

Trainings foreseen in EU4H actions

- SightSoHO
- 'REFORM'
- New training for CA's (EU4H2025)
- Leveraging professional societies (EU4H2025)
- EDQM
- National training by CA's
- ...

Ensure alignment in messages/content between training programmes



# Observers and Invited Experts

ECDC, EMA, EDQM (observers): in SCB, can be invited to WG

EEA countries (observers): nominees for SCB and for WGs

Stakeholders (invited experts):

- can be invited by co-chairs
- participate in specific agenda items
- Resource for extra capacity/expert inputs
- Ensure deliverables are effectively used in the SOHO sector



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# Thank you



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