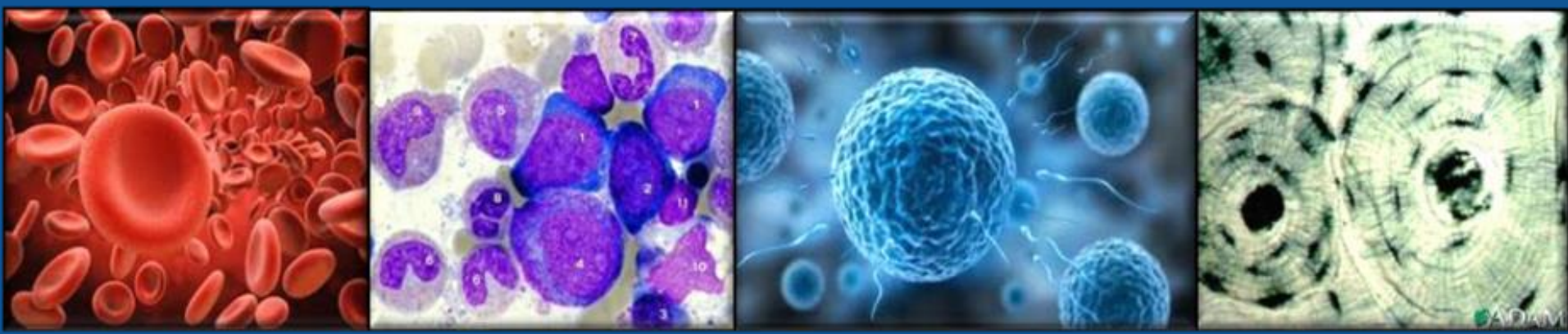


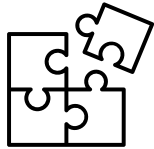
Implementing the new SoHO Regulation

Support from the Commission

Rome, 8th of April 2025



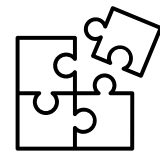
Setting up the new SoHO framework



5 Building blocks

- SoHO Coordination Board (SCB)
- Working groups (mainly on oversight tasks)
- Work with the expert bodies (EDQM and ECDC)
- SoHO digital platform
- SANTE supporting role

The SoHO Coordination Board (SCB) - harmonize EU-wide implementation



Decide on

- ✓ **Best practices** for
 - supervisory functions
 - compensation conditions;
- ✓ **Indicative criteria** for critical SoHO and critical SoHO entities

- ✓ Decide on support for joint oversight activities;
- ✓ Coordination during emergencies

Provide input to COM for the **SoHO Platform**

SCB

Members: 2 per MS + 2 alternates

Co-chairing by Commission and MS

Secretariat: Commission

May invite observers and experts

Compendium on regulatory status; record of:

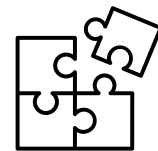
- Advices given by SCB on regulatory status
- National decisions on regulatory status

Advice whether SoHO Reg applies

Exchanges with Advisory bodies under other legislative frameworks

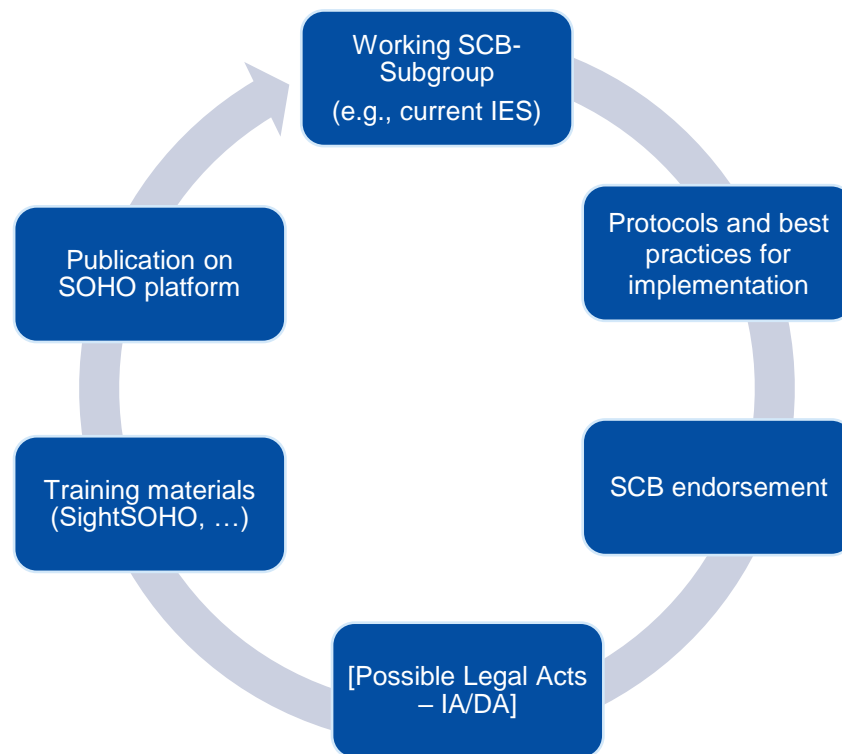
Exchanges on good practices with Expert bodies – ECDC, EDQM and with EMA

SCB supported by 6 working groups



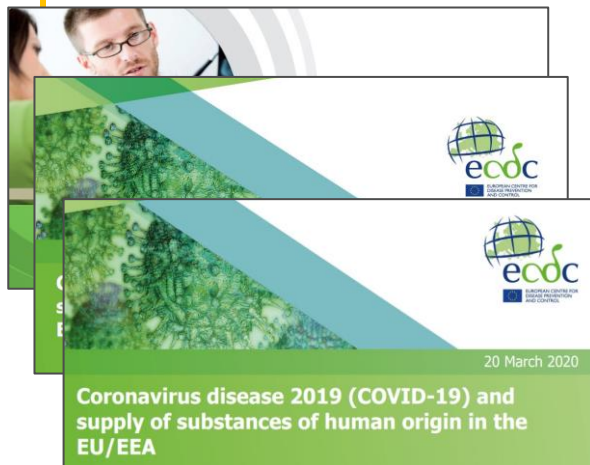
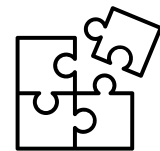
Area's to cover

1. Inspection
2. Vigilance and traceability
3. **NEW!** Registration of entities and authorisation of establishments
4. **NEW!** SoHO preparation authorisations
5. **NEW!** Activity data collection and supply alerts
6. (Kind of) **NEW!** Regulatory questions



Sharing/engaging CAs in work +
Possible EU funding for some tasks

Guidance expert bodies – ECDC+EDQM



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

New ECDC recommendations integrated in the next update of EDQM guidelines

Regulation-proof versions of guidelines, in 2026

Clarity/legal alignment/user-friendliness
comprehensive guides (EDQM+ECDC)

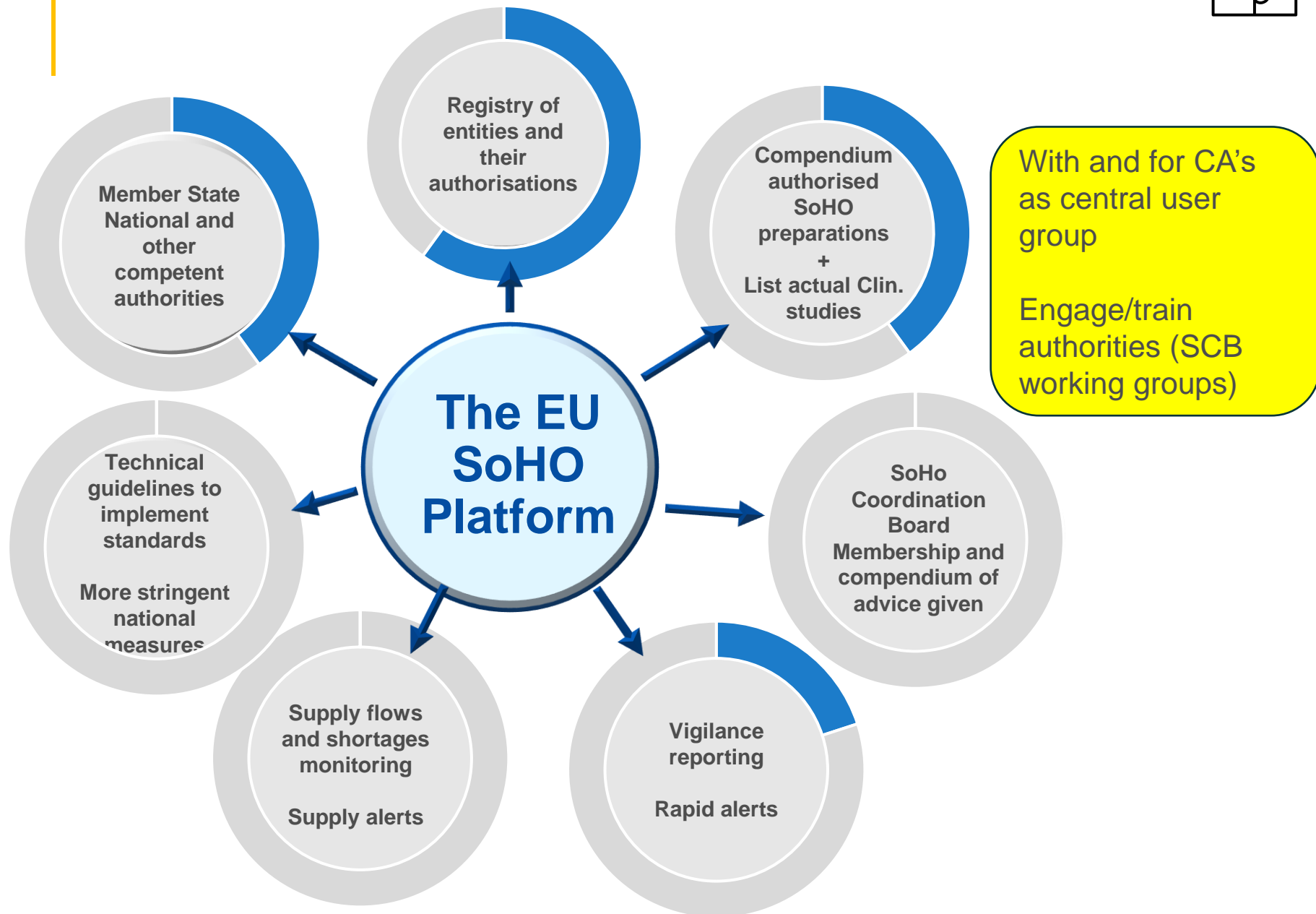
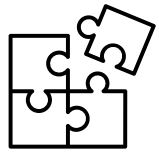
Tools for inspectors



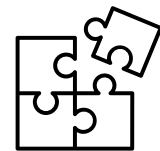
Comprehensive guidelines on quality and safety per type of SoHO (blood, cornea, stem cells, ...)

Digitalisation - efficiency, transparency, monitoring

progress per module SoHO platform (Feb '25)



SANTE role - Mandatory EU Support



- a. **SCB secretariat** and co-chair - facilitate cooperation other advisory bodies (Art. 72)
- b. Develop and host **SoHO platform** - annual aggregated SoHO reports (with EDQM) (Art 31)
- c. **Funding** for collaborative work CA and professional societies – focus on supply/donation/optimal use, and for technical guidelines updating (Art 72)
- d. Union **training for SoHO CAs** – EU-27 / EEA / candidate countries, dissemination materials, exchange programmes, list of trained staff (Art 70)
- e. **Commission controls** – of NCA/CA/delegated bodies (Art 71, not before 2028)
- f. Providing more clarity by adopting (6) **Implementing Acts** and (one) **Delegated Act**

Legal Acts SoHO regulation

- IA on SoHO platform – DDL August 2025 (Art 74(4))
- DA on import – DDL August 2027 (Art 47(4))
- IA on import – DDL August 2027 (Art 48(7))
- IA on data sets for activity data – DDL August 2027 (Art 41(3))
- IA on data for traceability – DDL August 2027 (Art 42(7))
- IA on Single European Code (SEC) – DDL August 2027 (Art 43(3))

Current & future EU4H actions SoHO



Support implementation
Focus on implementation

Project name (year)	Scope
1. EGALITE (2021)	Availability, accreditation (Tissues)
2. BRAVEST (2021)	Crisis resilience (Organs)
3. <u>EuroTRACTOR</u> (2021)	Outcome registry (HSC)
4. EUMAR (2021)	Outcome registry (MAR)
5. <u>SIGHTSoHO</u> (2021)	Training authorities (B, TC – different oversight functions)
6. Cooperation Agreement EDQM (2021)	Guidelines, vigilance, support <u>professionals</u> , <u>supply</u> (B, TC, O)
7. Readership (2022)	New obligations <u>entities in hospitals</u> (B, TC)
8. GAPP-Pro (2022)	New obligations process authorisation (B, TC)
9. IMAGINE(2023)	Implementation new requirements for Breast milk banks
10. HARMONIZE (2024)	Implementation new requirements for FMT
11. Paired kidney exchange (2023)	Organs
12. Cooperation Agreement EDQM (2024)	Guidelines, vigilance, support <u>professionals</u> , <u>supply</u> (B, TC, O)
13. <u>SoHO-X</u> ICT (2024)	<u>SoHO</u> digital platform – new Regulation (B, TC)
14. Organisational support CA's (eval.)	Change and organisational management
15. Regulatory Coherence (starting)	Topics of concern across EU frameworks (<u>SoHO</u> /pharma/MD)

Thank you