



Proposal for a Regulation on standards of quality and safety for substances of human origin intended for human application

**TRIP Biovigilantie Symposium (NL)
16 November 2022**

Presentation Outline

- **Context, objectives and key measures proposed**
- **Key new and changed concepts**

What is this legislation about?

[FIGURES PER YEAR]



>15 MILLION
blood & plasma
donors



4,6 MILLION
patients
transfused



165 000
babies born
from Medically
Assisted
Reproduction



36 000
stem cell
transplants



14 500
cornea
transplants

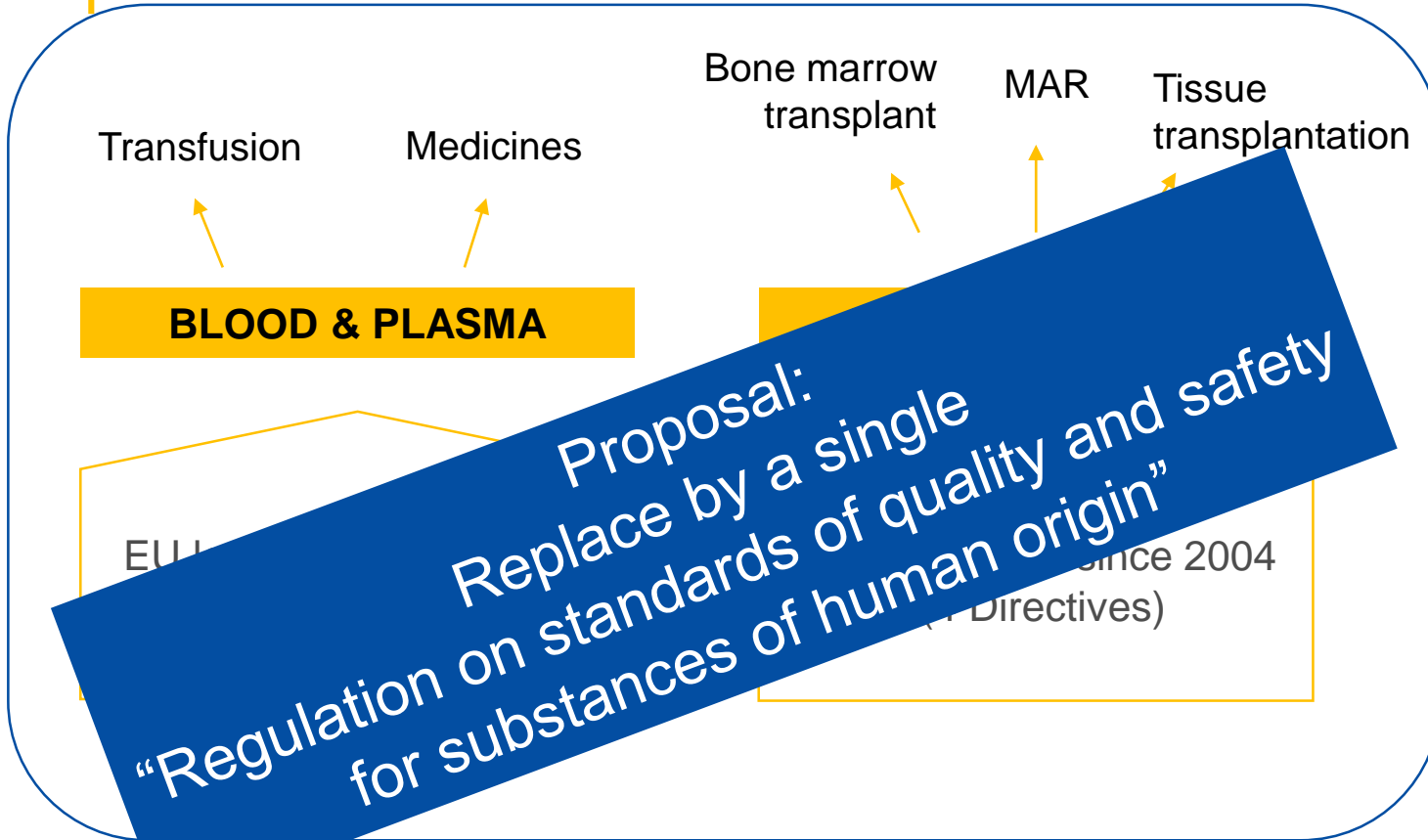


2 000
skin transplants for
burn wounds and
other injuries

Commonly these high-value services are made available at limited cost by public sector organisations and NGOs, such as the Red Cross



Current EU SoHO legislation on safety and quality



Objectives of this proposal



Presentation Outline

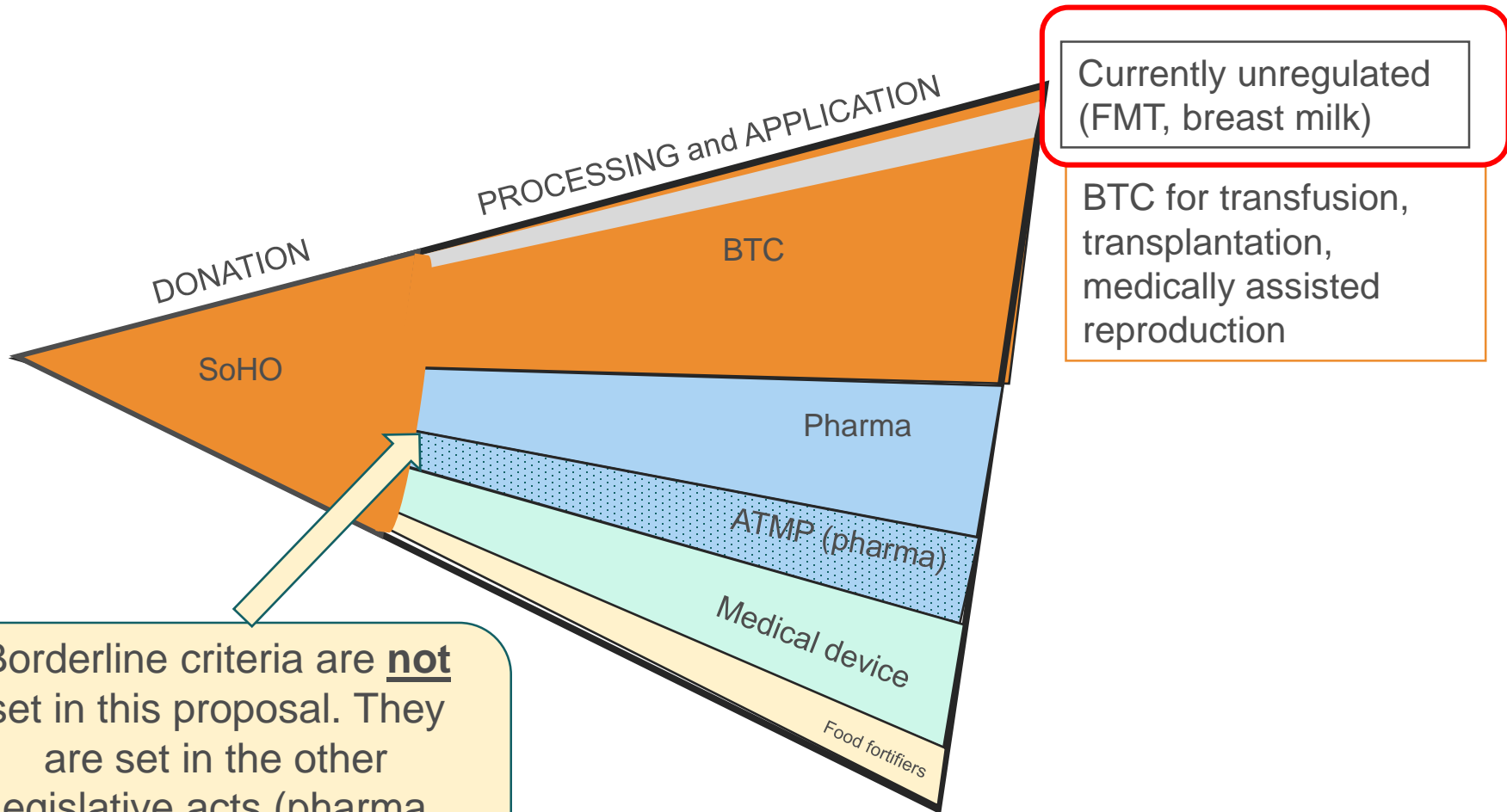
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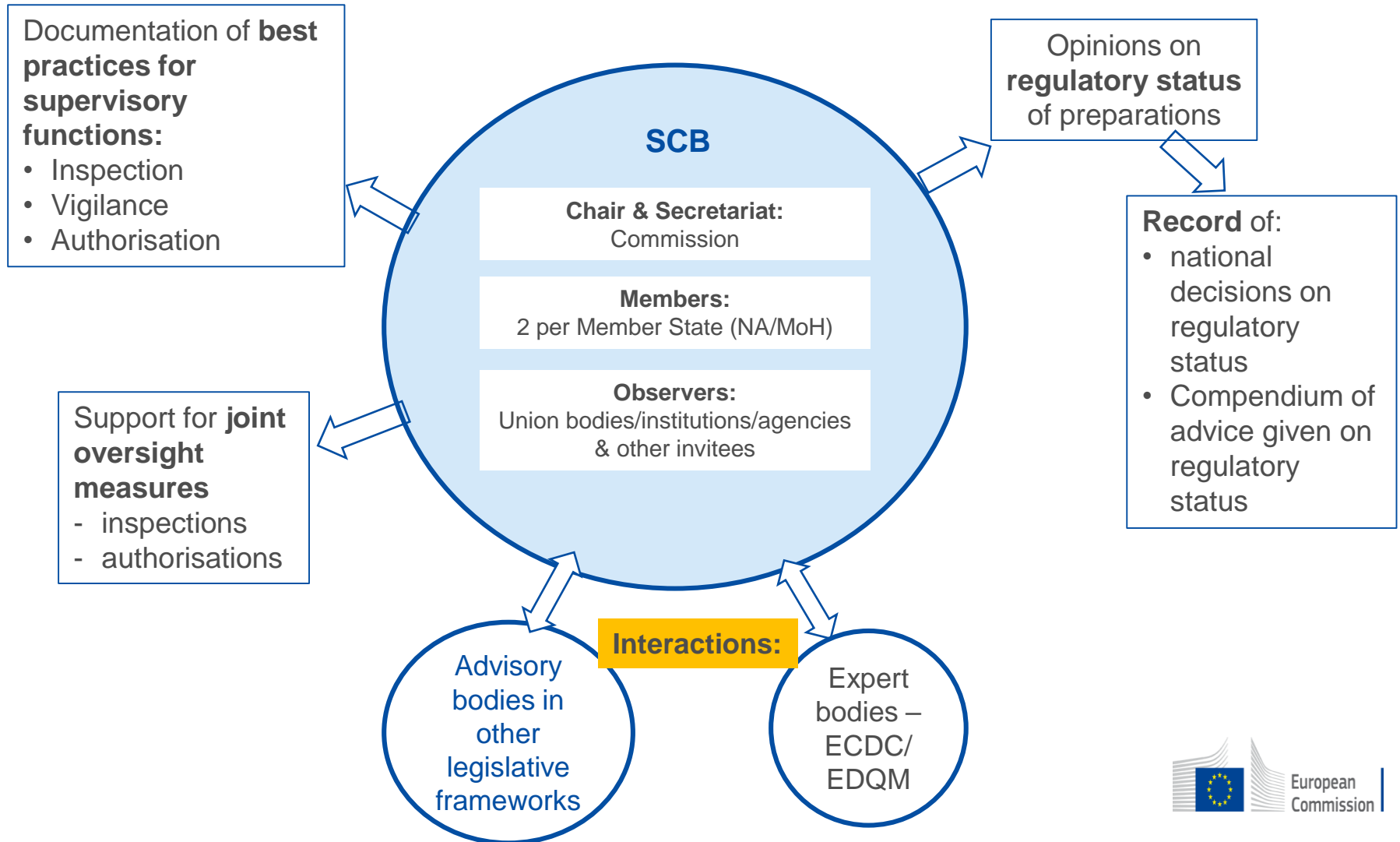
Key new and changed concepts

- **Scope and SoHO Coordination Board**
- **Risk based-approach to SoHO supervisory activities**
 - SoHO activities
 - SoHO entities and SoHO establishments
- **SoHO Preparations and their authorisation**
- **Standards and hierarchy of technical guidelines**
- **Donor Protection and Voluntary Unpaid Donation**
- **Resilience of supply**
- **Digitalisation – the SoHO platform**

Scope: all steps for **all SoHO**, unless certain criteria make them subject to another EU framework at some point during their processing



The SoHO Coordination Board (SCB) - supporting MS to implement the Regulation

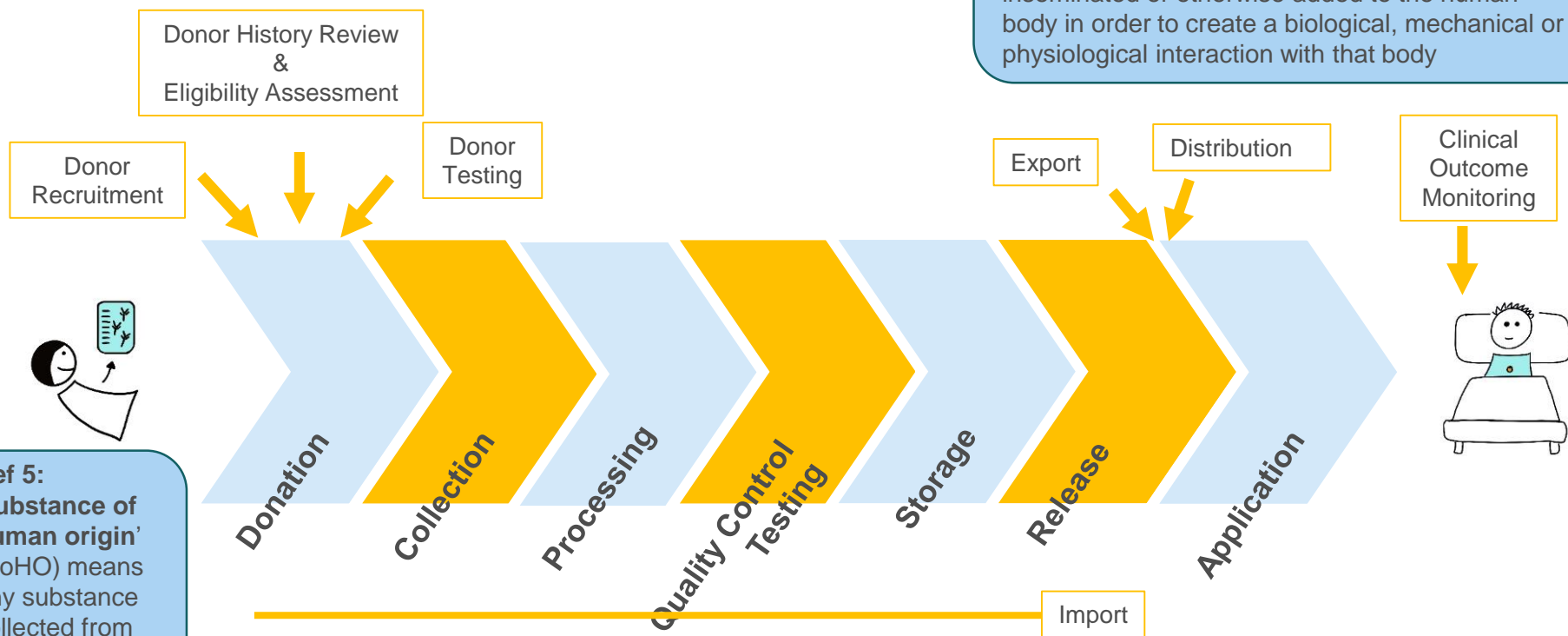


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Supervision of all SoHO Activities that directly impact safety or quality

Def 6: 'human application' means inserted, implanted, injected, infused, transfused, transplanted, ingested, transferred (as in transfer to the uterus or fallopian tube of a woman), inseminated or otherwise added to the human body in order to create a biological, mechanical or physiological interaction with that body

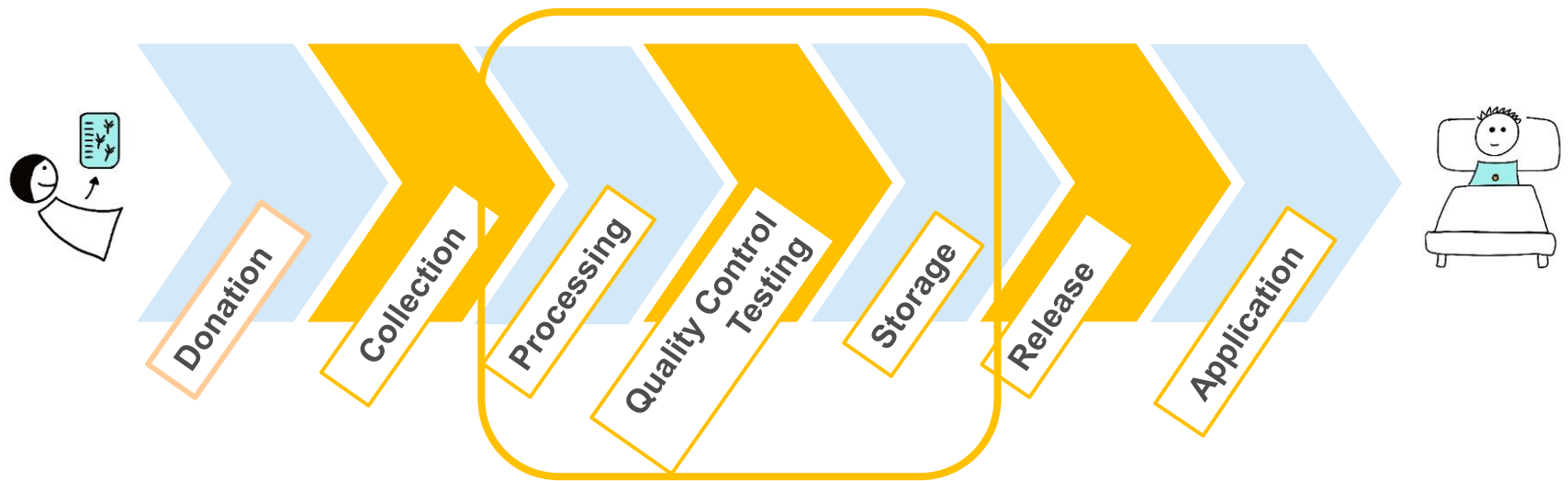


Def 5: 'substance of human origin' (SoHO) means any substance collected from the human body in whatever manner, whether it contains cells or not and whether those cells are living or not.

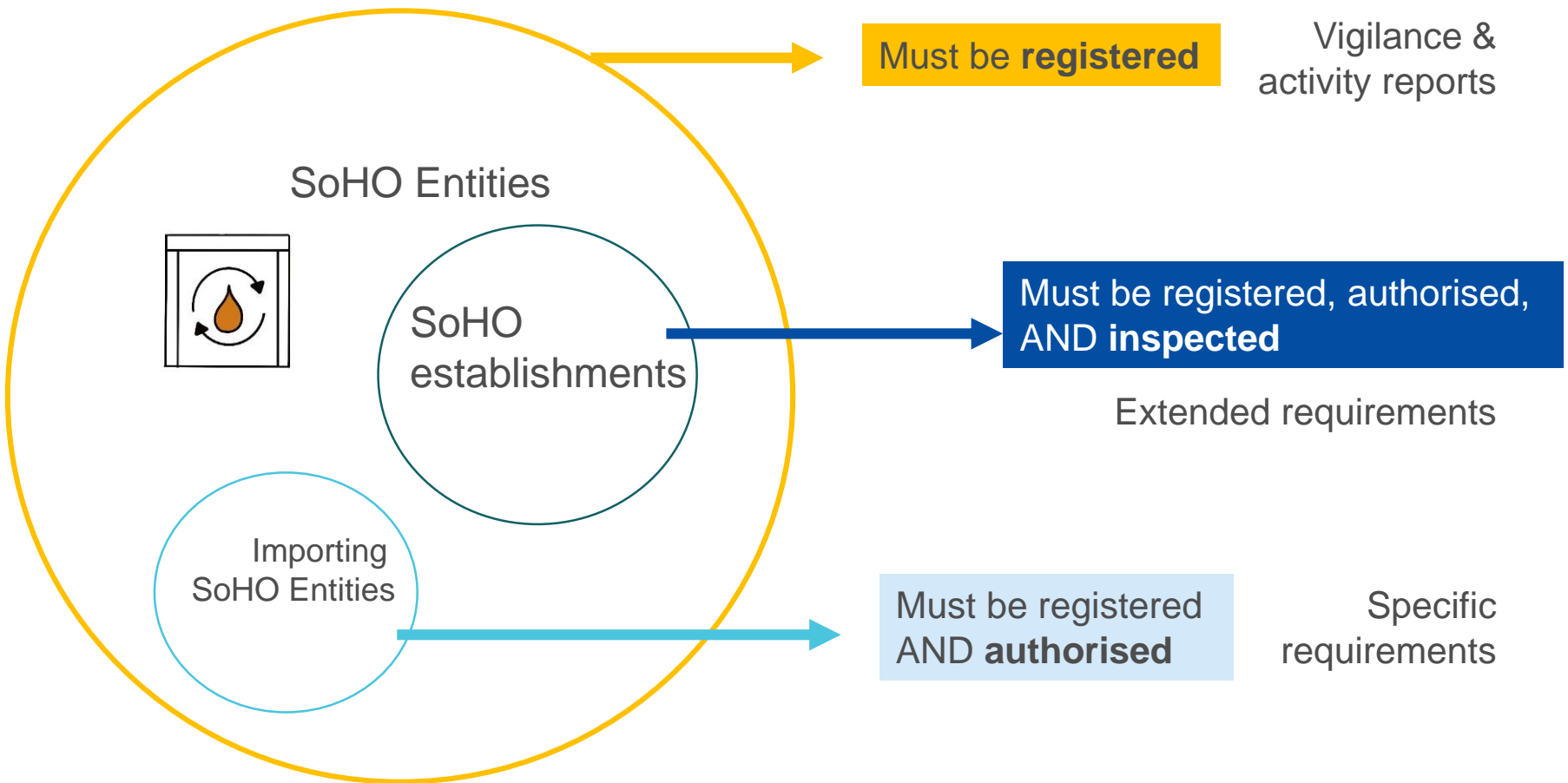
....but risk based measures for efficient use of authority resources

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

A **SoHO establishment** carries out at least **processing and storage**



Proportionate approach for efficient use of authority resources



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

A **SoHO establishment** carries out at least **processing and storage**

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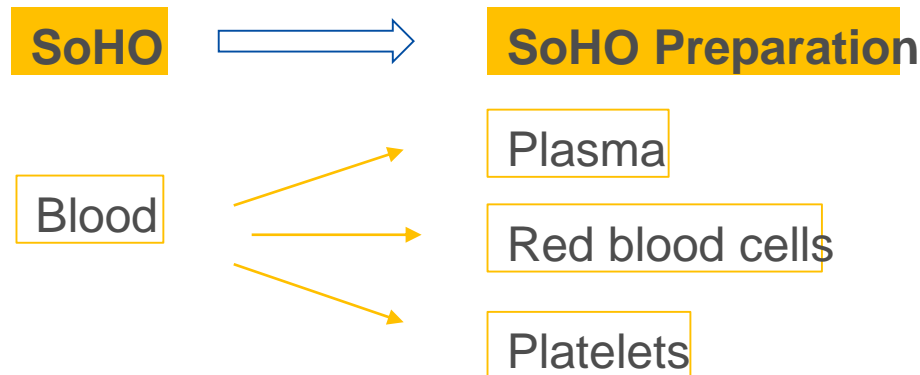
SoHO Preparation Authorisation – robust evidence of safety and efficacy

What is a ‘SoHO Preparation’?

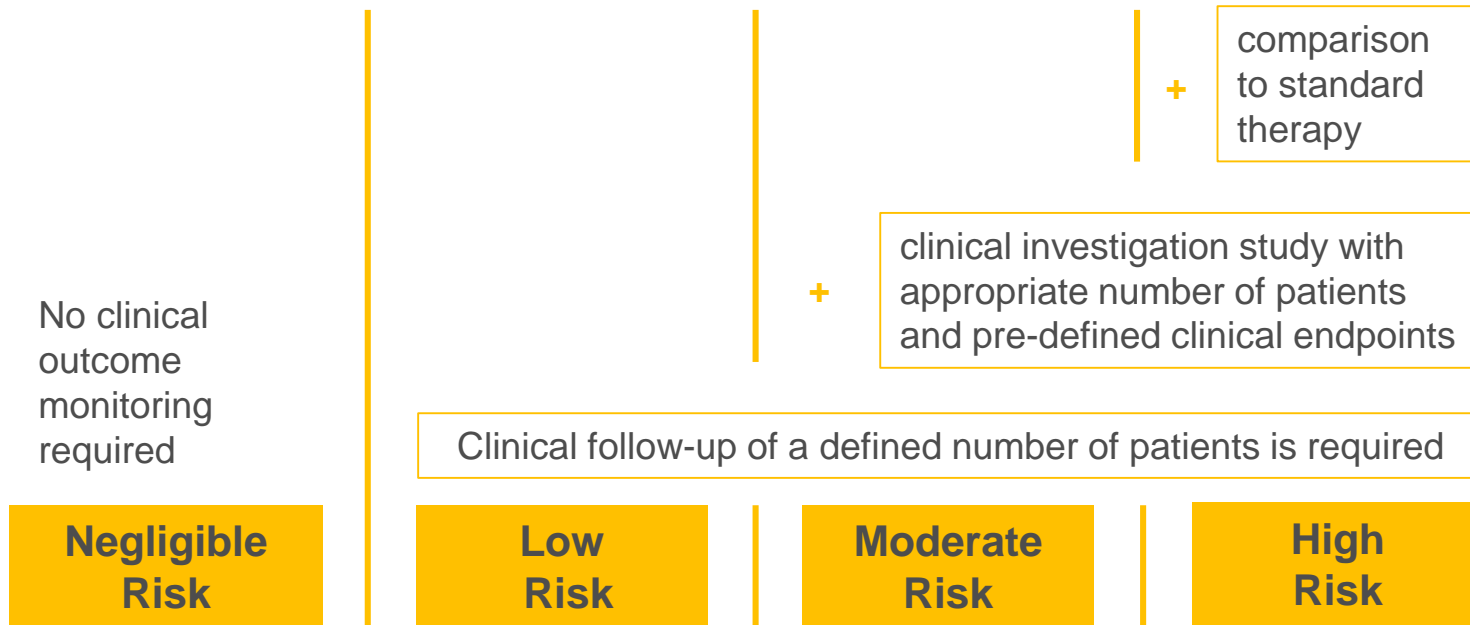
A particular SoHO that has been **subjected to one or more SoHO activities, including processing**, with pre-defined specification and **specific clinical indication**

Must be authorised

Example:



Clinical Outcome Monitoring Plans for Conditional authorisation



Based on preparatory work done by GAPP Joint Action (incl. stakeholders from 17 countries: 15 CAs & professional associations)



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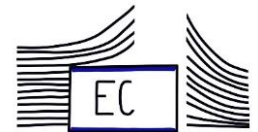
Implementation of high level standards through technical guidelines – staying up-to-date with the science in an agile way

SoHO entities shall follow the highest available levels of standards (Art. 56 & 59):

Level 1

Commission Implementing Legislation

“where the Commission deems necessary”



If none:

Technical Guidance on the EU SoHO Platform

Published & updated by ECDC/EDQM

“Inspectors shall accept”

Level 2

OR:

“Equivalent” Guidance

Deemed by CAs to achieve equivalent standards

“Entities shall demonstrate equivalence to inspectors”



If none:

Level 3

Methods based on international standards or scientific evidence

“Entities shall demonstrate equivalence to inspectors”



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SoHO Donor Protection – significantly strengthened

SoHO entities shall ensure high levels of safety of SoHO living donors (...) before, during, and after the donation. (Art. 52)

Standards for Donor Protection (Art. 53)

- Including for donations by relatives
- Information & consent
- Data protection & safeguarding of anonymity
- Donor health evaluation
- Risk-proportionate approach to donor monitoring: registration of donors subject to
 - surgical procedures,
 - hormone treatment,
 - frequent or repeated donations.

+ Donor adverse occurrence reporting requirements
+ Possibility for self reporting (Art. 35 and 47)

Voluntary & Unpaid Donation

Principle maintained
Based on Recommendations of the
Council of Europe Committee on
Bioethics

SoHO entities shall not provide financial incentives or inducements to SoHO donors or their relatives or any persons granting authorisation on behalf of the prospective donors, in accordance with national legislation (Art. 54)

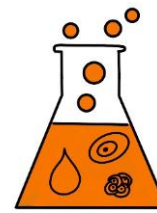
SoHO entities may compensate or reimburse SoHO donors as provided for by their competent authorities (...)

- **Compensation** or reimbursement for losses related to donation are permissible
- Based on fixed-rate allowances within **an upper limit set by Member State**
- Allowances must be **financially neutral** and consistent with standards for VUD

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Resilience of Supply



Critical SoHO

‘**Critical SoHO**’ are SoHO that for which an insufficient supply will result in serious harm or risk of harm to patients (Art. 3)

A ‘**critical SoHO entity**’ is a SoHO entity that carries out activities contributing to the supply of critical SoHOs and the scale of those activities is such that a failure to carry them out cannot be compensated by activities of other entities or alternative substances or products for patients (Art. 3)

Supply of **critical SoHO** is protected by:

- **Activity data collection** and reporting (Art.44)
- Supply **alerts** (Art. 63)
- National **SoHO emergency plans** & SoHO Entity emergency plans (Art. 62 & 66)
- **Derogations** and additional measures in emergency situations (Art. 64 & 65)

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Digitalisation – efficiency, transparency, monitoring



Thank you