



## Background and Method

The European Union (EU) Regulation 2024/1938 on standards of quality and safety for Substances of Human Origin (SoHO) intended for human application was adopted on 13 June 2024 to solve issues that were not (sufficiently) addressed by the previous EU directives on blood (Directive 2002/98/EC) and tissues and cells (Directive 2004/23/EC). Among them, an extensive evaluation of the EU legislation led by the European Commission highlighted that there were avoidable risks for donors and for children born from donated gametes, and that patients were not fully protected from avoidable risks.

Based on an analysis of the EU regulation on SoHO regarding the protection of SoHO donors, recipients and offspring, this poster clarifies the new EU legal measures targeting the protection of SoHO donors, recipients and offspring.

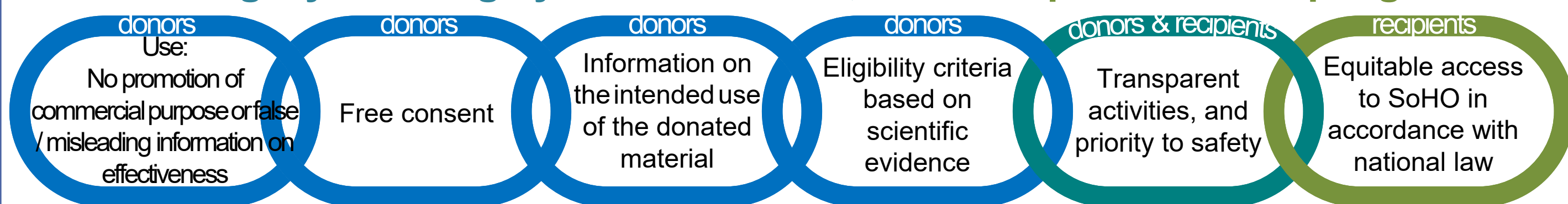
These measures provide obligations mainly for Member States (MS) (and their national SoHO competent authorities (NCAs) by delegation) and SoHO entities which are defined widely as entities legally established in the Union that carry out one or more of the following SoHO activities: SoHO donor registration; SoHO donor history review and medical examination; testing of SoHO donors or of persons from whom SoHO are collected for autologous or within-relationship use; collection; processing; quality control; storage; release; distribution; import; export; human application; clinical-outcome registration.

These new rules shall apply from 7 August 2027.

## New EU law provisions strengthening the protection of donors, recipients and offspring

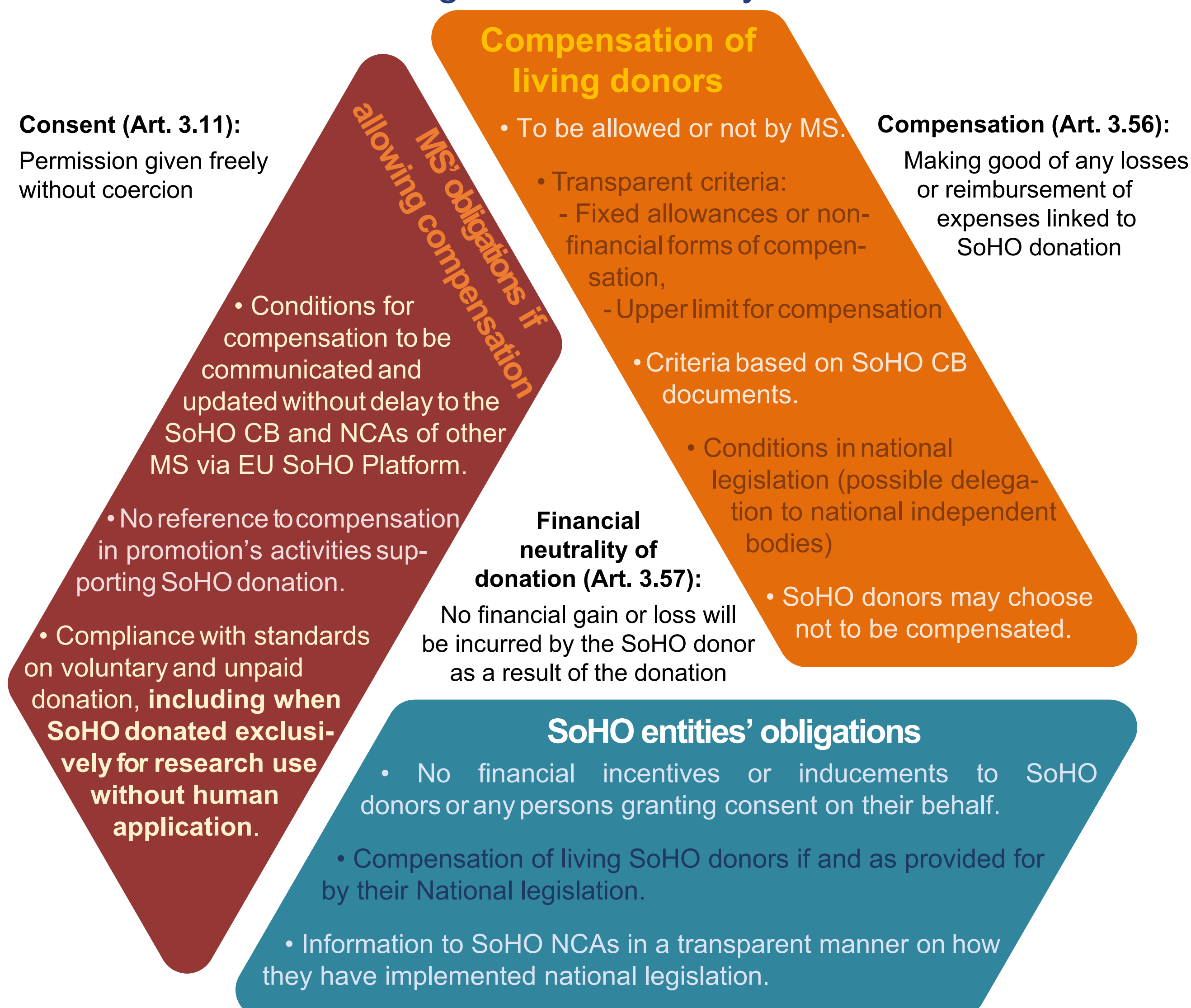
### Fundamental principles

#### Dignity and integrity of SoHO donors, SoHO recipients and offspring



### The principle of voluntary & unpaid donation

does not prohibit compensation BUT compensation is framed by EU rules ensuring financial neutrality of donation



### Informed consent (Art. 55)

#### SoHO entities:

To provide living SoHO donors (or, where applicable, any persons granting consent on behalf of a SoHO donor), with all appropriate information on the SoHO donation process, in accordance with national legislation: before the consent is granted, in an accurate and clear manner (easily understandable terms), no misleading information.

#### Content of information to living SoHO donors OR to person granting consent on behalf of deceased SoHO donors:

- (a) purpose and nature of donation;
- (b) intended use of the donated SoHO (proven benefits and any possible research or commercial uses, **specific consent for the use of SoHO to manufacture medical devices and medicinal products**);
- (d) obligation for consent to collect SoHO;
- (e) right to revoke consent and any restrictions on that right after the collection;

#### Additional information to living SoHO donors:

- (c) consequences and risks of donation;
- (f) purpose of the tests conducted for donor health evaluation;
- (g) right of donor to receive the confirmed results of their health relevant tests (in accordance with national legislation);
- (h) recording and protection of donor's personal data;
- (i) possibility to reveal donor identity to offspring born from SoHO donation (if allowed by national legislation);
- (j) other applicable safeguards to protect the donor.

## Conclusion

The EU regulation on SoHO operates a major shift from the quality and safety of SoHO to the wider protection of SoHO donors, recipients and offspring which is either strengthened or newly covered.

Such protection is also enhanced due to the wider meaning of SoHO in comparison with the previous directives on tissues and cells and blood and blood components. Indeed, SoHO meaning "any substance collected from the human body, whether it contains cells or not and whether those cells are living or not, including SoHO preparations resulting from the processing of such substance", more persons are considered SoHO donors, recipients and offspring and thus protected in accordance with this new EU regulation.

## High level of safety and health protection of SoHO donors, recipients and offspring from MAR

### Obligations for SoHO entities when collecting SoHO (regardless of the intended recipient) (Art. 53):

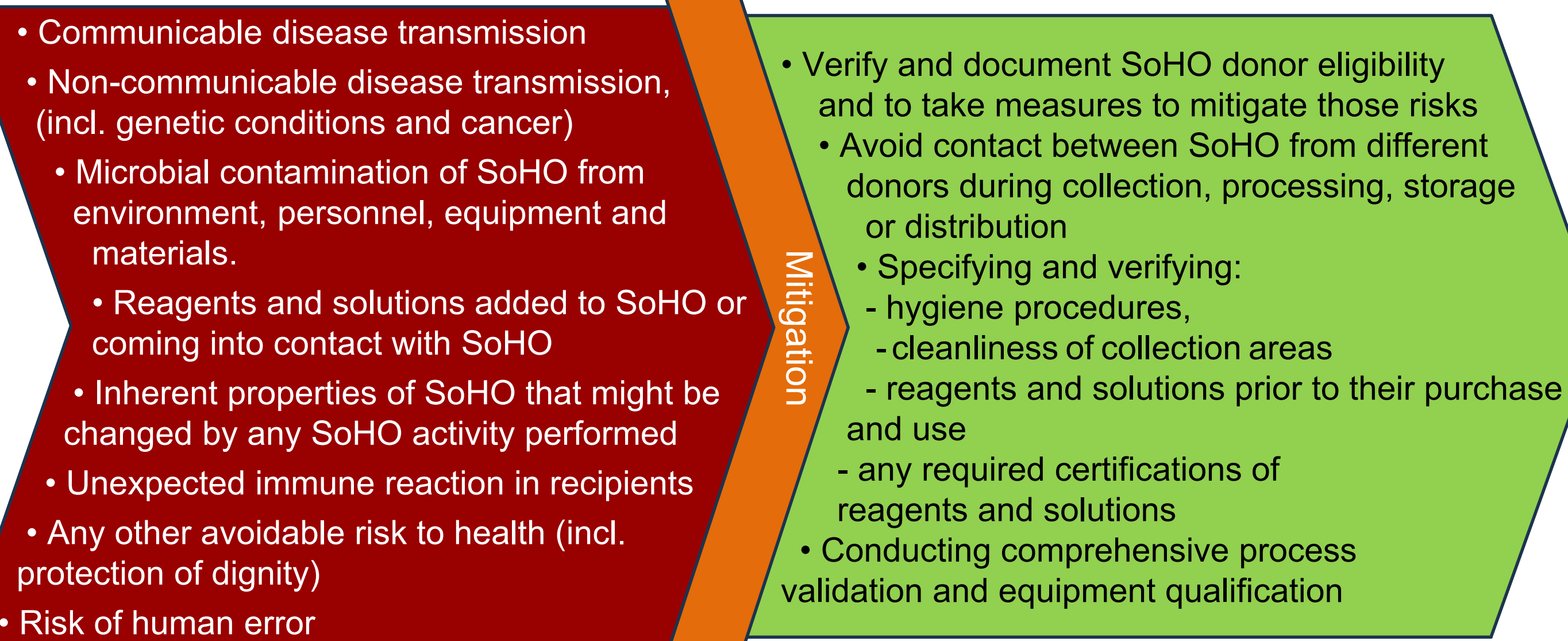
- (a) To meet all applicable consent or authorisation requirements at National level;
- (b) To provide donors with adequate information (understandable) and contact details of SoHO entity;
- (c) To safeguard rights of living donor to physical and mental integrity, non-discrimination, privacy and protection of their personal data;
- (d) To ensure that donation is voluntary and unpaid;
- (e) To verify the eligibility of the living donor;
- (f) To document results of living donor health evaluation;
- (g) To communicate and clearly explain the results of the living donor health evaluation to the living donor;
- (h) To identify and minimise risks to health of living donor during SoHO collection procedure;
- (i) If repeated SoHO donations, to register donors in a SoHO entity registry or in national / international registries (donation frequency and monitoring of relevant health indicators);
- (j) If significant risk to a living donor (surgical procedure or prescribed medication), to develop and implement a plan for monitoring the donor's health after donation;
- (k) If unrelated SoHO donation, to refrain from revealing the donor's identity to the recipient or to the offspring from MAR, except if allowed by MS concerned.

### Obligations for SoHO entities in procedures with SoHO recipients (Art. 58)

Procedures shall high levels of quality and safety of SoHO AND Ensure a positive benefit/risk balance for SoHO recipients and offspring from MAR.

SoHO entities shall inform and obtain consent from SoHO recipients AND ensure that procedures achieve a high level of assurance that pathogens, toxins or genetic conditions potentially life-threatening, disabling or incapacitating and originate from a third-party donor, are not transmitted to recipients or offspring from MAR.

### Risks to be mitigated by SoHO entities



### SoHO entities shall not:

- apply SoHO preparations to SoHO recipients unnecessarily or without proven benefit (except clinical-outcome monitoring plan approved by SoHO NCA, individual treatment by treating physician's therapeutic decision, or health emergency situation);
- advertise / promote particular SoHO to potential recipients or to healthcare professionals using misleading information;
- distribute / apply allogeneic SoHO for purposes other than the prevention or treatment of a medical condition (incl. reconstructive surgery), or for MAR.

Note: Additional EU rules for SoHO establishments regarding SoHO release (Art. 60) and exceptional release (Art. 61) also contributes to the protection of recipients and offspring from medically assisted reproduction.

## The European Commission can adopt additional binding

### Delegated acts regarding SoHO donors and recipients

- Where additional standards are deemed necessary to ensure the protection of recipients or offspring from MAR from risks associated with SoHO (Art. 58.16 & 77)
- Where additional standards are needed to ensure donors' protection (Art. 53.5 & 77)
- Imperative grounds of urgency linked to risk to recipients and offspring from MAR arising from inadequate levels of SoHO quality and safety (Art. 58.17 & 78)
- Imperative grounds of urgency linked to risk to living donors' safety (Art. 53.6 & 78)

### Delegated acts regarding SoHO donors

- Duly justified imperative grounds of urgency relating to a risk to donor health (Art. 56.2 & 79.3)
- Implementation of a particular standard or element of a standard on donors' protection (voluntary and unpaid donors, informed consent, and health protection) to ensure convergent and high levels of donors' protection

### Abbreviations

**MAR:** Medically Assisted Reproduction  
**MS:** Member state  
**NCAs:** National Competent Authorities  
**SoHO CB:** SoHO Coordination Board