



**2022/0216(COD)**

14.3.2023

# **AMENDMENTS**

## **625 - 874**

**Draft opinion**  
**Nathalie Colin-Oesterlé**  
(PE738.661v01-00)

Standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

Proposal for a regulation  
(COM(2022)0338 – C9-0226/2022 – 2022/0216(COD))



**Amendment 625**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 53 – paragraph 1 – point k**

*Text proposed by the Commission*

(k) develop and implement a plan for monitoring the donor's health after the donation in cases where the SoHO donations imply a **significant** risk to a donor as referred to in paragraph 3;

*Amendment*

(k) develop and implement a plan for monitoring the donor's health after the donation in cases where the SoHO donations imply a risk to a donor as referred to in paragraph 3;

Or. en

**Amendment 626**  
**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**  
**Article 53 – paragraph 2**

*Text proposed by the Commission*

2. In the course of the donor health evaluations referred to in paragraph 1, point (f), SoHO entities shall conduct interviews with the donors and gather information concerning the donors' present and recent state of health and their health histories to assure the safety of the donation process for those donors. SoHO entities may perform laboratory tests as part of the donor health evaluations. They shall perform such tests in cases where evaluations indicate that laboratory tests are necessary to establish the eligibility of those donors from the perspective of their own protection. The physician, as referred to in Article 51, shall approve the procedure and criteria for donor health evaluations.

*Amendment*

2. In the course of the donor health evaluations referred to in paragraph 1, point (f), SoHO entities shall conduct interviews with the donors and gather information concerning the donors' present and recent state of **physical and mental** health and their health histories to assure the safety of the donation process for those donors. SoHO entities may perform laboratory tests as part of the donor health evaluations. They shall perform such tests in cases where evaluations indicate that laboratory tests are necessary to establish the eligibility of those donors from the perspective of their own protection. The physician, as referred to in Article 51, shall approve the procedure and criteria for donor health evaluations.

Or. en

## Amendment 627

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

### Proposal for a regulation

#### Article 53 – paragraph 3

*Text proposed by the Commission*

3. SoHO entities that collect SoHOs from donors that are subjected to a surgical procedure in order to donate, that are treated with hormones to facilitate donation, or that donate on a frequent and repeated basis, shall register such donors and the results of their donor health evaluations in a cross-entity registry that allows interconnection with other such registries, as referred to in paragraph 1, point (j). SoHO entities that manage such registries shall ensure interconnectivity between them.

*Amendment*

3. SoHO entities that collect SoHOs from donors that are subjected to a surgical procedure in order to donate, that are treated with hormones to facilitate donation, or that donate ***SoHO that can be donated*** on a frequent and repeated basis, shall register such donors and the results of their donor health evaluations in a cross-entity registry that allows interconnection with other such registries ***at Union level***, as referred to in paragraph 1, point (j). SoHO entities that manage such registries shall ensure interconnectivity between them.

Or. en

## Amendment 628

Kateřina Konečná

### Proposal for a regulation

#### Article 53 – paragraph 3

*Text proposed by the Commission*

3. SoHO entities that collect SoHOs from donors that are subjected to a surgical procedure in order to donate, that are treated with hormones to facilitate donation, or that donate on a frequent and repeated basis, shall register such donors and the results of their donor health evaluations in a cross-entity registry that allows interconnection with other such registries, as referred to in paragraph 1, point (j). SoHO entities that manage such registries shall ensure interconnectivity between them.

*Amendment*

3. SoHO entities that collect SoHOs from donors that are subjected to a surgical procedure in order to donate, that are treated with hormones to facilitate donation, or that donate ***SoHO that can be donated*** on a frequent and repeated basis , shall register such donors and the results of their donor health evaluations in a cross-entity registry that allows interconnection with other such registries, as referred to in paragraph 1, point (j). SoHO entities that manage such registries shall ensure interconnectivity between them.

Or. en

### *Justification*

*It is important to register donors that can potentially return for a second or multiple donations in the cross-entity register. The donor may be donating in different entities and it will be important to collect their information and, above all, ensure that donors are not donating more frequently than what is safe for them. Also, “frequent and repeated basis” is not defined in the regulation and the proposal as it is would create uncertainty.*

#### **Amendment 629**

**Tilly Metz**

#### **Proposal for a regulation**

#### **Article 53 – paragraph 3**

##### *Text proposed by the Commission*

3. SoHO entities that collect SoHOs from donors that are subjected to a surgical procedure in order to donate, that are treated with hormones to facilitate donation, or that donate on a frequent and repeated basis, shall register such donors and the results of their donor health evaluations in a cross-entity registry that allows interconnection with other such registries, as referred to in paragraph 1, point (j). SoHO entities that manage such registries shall ensure interconnectivity between them.

##### *Amendment*

3. SoHO entities that collect SoHOs from donors that are subjected to a surgical procedure in order to donate, that are treated with hormones to facilitate donation, or that donate ***SoHOs that can be donated*** on a frequent and repeated basis, shall register such donors and the results of their donor health evaluations in a cross-entity registry that allows interconnection with other such registries, as referred to in paragraph 1, point (j). SoHO entities that manage such registries shall ensure interconnectivity between them.

Or. en

### *Justification*

*As donors may be donating in different entities it is important to ensure that they are not donating more frequently than what is safe for them. As “frequent and repeated basis” is not defined in this proposal and frequency of safe donations differ as per different SoHOs based on non-binding EDQM guidance, it is important to specify.*

#### **Amendment 630**

**Joanna Kopcińska**

#### **Proposal for a regulation**

#### **Article 53 – paragraph 6**

*Text proposed by the Commission*

*Amendment*

**6. The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this Regulation in cases where additional standards are needed in order to ensure the protection of donors.**

**deleted**

Or. pl

*Justification*

*The Commission has not set out either a catalogue of additional standards for the protection of donors or the nature of such standards, so such a broad power may concern non-essential elements and thus infringe Article 290 TFEU.*

### **Amendment 631**

**Stelios Kypouropoulos, Tomislav Sokol**

#### **Proposal for a regulation**

#### **Article 54 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for **losses** related to their participation in donations through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for **expenses and inconveniences** related to their participation in donations through, **for example, fixed rate allowances, days off, or tax reduction**. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation. **The compensation shall be limited to travel expenses, loss of earnings, or medical costs related to the medical procedure and possible side effects.**

Or. en

**Amendment 632**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Article 54 – paragraph 2**

*Text proposed by the Commission*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for *losses related to their participation in donations through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.*

*Amendment*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for *making good any expenses and inconveniences associated with their donation. Compensation should not lead to inappropriate competition (e.g. financially-driven competition), including cross-border competition, between establishments and entities over donor recruitment.*

Or. en

*Justification*

*The proposed amendment recognizes that losses associated with the donation can be financial and non-financial. The inconvenience related to the donation can also differ significantly between different SoHO donations.*

*Fixed rate allowances foreseen in this paragraph are incompatible with the principle of financial neutrality. The personal circumstances, costs and inconveniences of each donor will always vary.*

**Amendment 633**  
**Pernille Weiss**

**Proposal for a regulation**  
**Article 54 – paragraph 2**

*Text proposed by the Commission*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for losses related

*Amendment*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for losses related

to their participation in donations through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

to their participation in donations through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation. ***In this regard, the Commission shall support the exchange of best practice between Member States.***

Or. en

**Amendment 634**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Article 54 – paragraph 2**

*Text proposed by the Commission*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for ***losses*** related to their participation in donations through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

*Amendment*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for ***making good any expenses and inconveniences associated with their donation*** related to their participation in donations through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

Or. en

**Amendment 635**



Tilly Metz

**Proposal for a regulation**  
**Article 54 – paragraph 2**

*Text proposed by the Commission*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for losses related to their participation in donations through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

*Amendment*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for losses related to their participation in donations through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit ***and transparent criteria based on quantifiable elements*** that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

Or. en

*Justification*

*The setting of an upper limit does not by itself ensure financial neutrality. Member States should set transparent criteria to determine allowances, to ensure that donors do not gain financially, as per the Council of Europe Committee on Bioethics (DH-BIO) Guide for the implementation of the principle of prohibition of financial gain with respect to the human body and its parts from living or deceased donors.*

**Amendment 636**

**Andreas Glück, Ondřej Knotek, Peter Liese, Susana Solís Pérez, Jan Huitema, Michal Wiezik**

**Proposal for a regulation**  
**Article 54 – paragraph 2**

*Text proposed by the Commission*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for ***losses*** related to their participation in donations through fixed rate allowances. In such case,

*Amendment*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for ***expenses and inconveniences*** related to their participation in donations, ***for example,***

Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

Or. en

#### *Justification*

*This formulation allows for more flexibility with regards to compensation as losses could only be interpreted in financial terms. This is also a formulation that was previously used in the tissues and cells directive (Article 12). It does not oblige any Member State to make use of it, but allows compensations to be maintained as before.*

#### **Amendment 637**

**Adam Jarubas, Ewa Kopacz, Bartosz Arłukowicz**

#### **Proposal for a regulation**

#### **Article 54 – paragraph 2**

##### *Text proposed by the Commission*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for ***losses related to their participation in donations*** through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

##### *Amendment*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for ***any expenses and inconveniences associated with their donation*** through ***among others*** fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

Or. en

## Amendment 638

Peter Liese

### Proposal for a regulation

#### Article 54 – paragraph 2

*Text proposed by the Commission*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for **losses** related to their participation in donations through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

*Amendment*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for **expenses and inconveniences** related to their participation in donations, **for example**, through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

Or. en

*Justification*

*This wording reflects the preceding wording in the tissues and cells directive (Article 12).*

## Amendment 639

Alexandr Vondra

### Proposal for a regulation

#### Article 54 – paragraph 2

*Text proposed by the Commission*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for **losses related to their participation in donations** through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an

*Amendment*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for **making good any expenses and inconveniences associated with their donation** through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national

upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

Or. en

#### **Amendment 640**

**Aldo Patriciello, Salvatore De Meo**

#### **Proposal for a regulation**

#### **Article 54 – paragraph 2**

*Text proposed by the Commission*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for **losses related to their participation in donations** through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

*Amendment*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for **making good any expenses and inconveniences associated with their donation** through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

Or. en

#### **Amendment 641**

**Stanislav Polčák**

#### **Proposal for a regulation**

#### **Article 54 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for ***losses related to their participation in donations*** through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for ***making good any expenses and inconveniences associated with their donation*** through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

Or. en

**Amendment 642**  
**Giuseppe Ferrandino**

**Proposal for a regulation**  
**Article 54 – paragraph 2**

*Text proposed by the Commission*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for ***losses related to their participation in donations*** through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

*Amendment*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for ***making good any expenses and inconveniences associated with their donation*** through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

Or. en

### *Justification*

*The proposed amendment recognizes that losses associated with the donation can be financial and non-financial. The inconvenience related to the donation can also differ significantly between different SoHO donations.*

*The proposed definition is compatible with the Council of Europe's DH BIO Guide interpreting the Oviedo Convention principle of prohibition of financial gain, and reflects wording contained in the EU Tissues and Cells Directive 2004/23/EC (article 12.1).*

#### **Amendment 643**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation**

#### **Article 54 – paragraph 2**

##### *Text proposed by the Commission*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for losses related to their participation in donations through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

##### *Amendment*

2. Member States may allow for the compensation or reimbursement from the SoHO entities to **living** donors for losses related to their participation in donations through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are **transparent**, financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

Or. en

#### **Amendment 644**

**Margarita de la Pisa Carrión**

#### **Proposal for a regulation**

#### **Article 54 – paragraph 2**

##### *Text proposed by the Commission*

2. Member States may allow for the compensation or reimbursement from the

##### *Amendment*

2. Member States may allow for the compensation or reimbursement from the

SoHO entities to donors for losses related to their participation in donations through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

SoHO entities to donors for losses **and expenses** related to their participation in donations through fixed rate allowances. In such case, Member States shall establish the conditions for such allowances in national legislation, including the setting of an upper limit that ensures that allowances are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such allowances to independent bodies that are established in accordance with national legislation.

Or. es

## **Amendment 645**

**Peter Liese**

### **Proposal for a regulation**

#### **Article 54 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***2 a. Member States shall ensure that no payment is made in any case for a donation of human tissues and cells. Any donation of human tissues or cells must be made voluntarily by the donor and without any compensation in cash or in kind that might be regarded as payment. Compensation for costs arising in connection with the donation shall, however, be permitted. Compensation may comprise reimbursement of travel expenses and loss of income for the duration of the journey, the donation and any necessary recuperation, as well as payment of small amounts and refreshments.***

Or. en

#### *Justification*

*This wording reflects the previous position of the European Parliament (first reading) for the tissues and cells directive (Article 12). The rules for tissues and cells must be much more strict because the risks of the donor in case of commercialization are significantly higher, for*

*example egg cell donations include risky medical treatments and the risk of exploitation of women.*

**Amendment 646**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 54 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. Any compensation regime shall not lead to inappropriate financially-driven competition, including cross-border competition, between SoHO establishments and entities over donor recruitment.**

Or. en

*Justification*

*There should be safeguards that private vs publicly organised donations do not really differ and that there are no cross-border trips organised to donate for financial reasons.*

**Amendment 647**  
**Peter Liese**

**Proposal for a regulation**  
**Article 54 – paragraph 2 b (new)**

*Text proposed by the Commission*

*Amendment*

**2 b. Member States shall take the necessary measures to encourage voluntary and unpaid donations of blood and blood components with a view to ensuring that blood and blood components are in so far as possible provided from such donations.**

Or. en

*Justification*

*This wording reflects the preceding wording in the blood directive (Article 20).*



**Amendment 648**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 54 – paragraph 3**

*Text proposed by the Commission*

3. SoHO entities may compensate or reimburse donors as provided for by their competent authorities pursuant to paragraph 2.

*Amendment*

3. SoHO entities may compensate or reimburse **living** donors as provided for by their competent authorities pursuant to paragraph 2. ***SoHO entities shall report transparently to the competent authorities on the compensation used, and on any changes made in this respect.***

Or. en

**Amendment 649**

**Tilly Metz**

**Proposal for a regulation**

**Article 54 – paragraph 3**

*Text proposed by the Commission*

3. SoHO entities may compensate or reimburse donors as provided for by their competent authorities pursuant to paragraph 2.

*Amendment*

3. SoHO entities may compensate or reimburse donors as provided for by their competent authorities pursuant to paragraph 2. ***Any compensation or reimbursement must never serve as an inducement to donate.***

Or. en

**Amendment 650**

**Kateřina Konečná**

**Proposal for a regulation**

**Article 54 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

**3 a. Member States shall submit reports to the Commission on these standards two years after the entry into force of this Regulation, and thereafter every three years. On the basis of these reports the Commission shall inform the European Parliament and the Council of any necessary further measure it intends to take at the EU level.**

Or. en

**Amendment 651**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 54 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

**3 a. Compensation may under no circumstances be used for promotion or as a claim for recruitment, shall not be an incentive to donate and shall not lead to exploitation of the most vulnerable persons in society or to situations of inappropriate competition for the recruitment of donors.**

Or. en

**Amendment 652**

**Tilly Metz**

**Proposal for a regulation**

**Article 54 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

**3 a. Member States shall submit to the Commission and the SCB national provisions setting up the rules for compensation based on financial neutrality and consistent with standards set in this Article.**

**Amendment 653**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 54 – paragraph 3 b (new)**

*Text proposed by the Commission*

*Amendment*

***3 b. The Commission shall assess the ethical aspects of voluntary and unpaid donation and verify that Member States' compensation and reimbursement systems follow the guidelines specified in this Regulation. This assessment shall determine, inter alia, that such compensations and reimbursements under no circumstances constitute an incentive or a claim to recruit donors, that they do not expose vulnerable people in society to exploitation activities, that they do not undermine public confidence in the donation system or that they do not promote competition between SoHO entities for the recruitment of donors. Member States shall provide the Commission with the information requested to perform this assessment. By [one year after the entry into force of this Regulation], and every three years, the Commission shall submit a report to the Council and the European Parliament assessing the compensation and reimbursement systems in the Member States and, where appropriate, making recommendations to the Member States on how they can be improved. These reports shall be made available to the public.***

**Amendment 654**

**Kateřina Konečná**

**Proposal for a regulation**  
**Article 54 – paragraph 3 b (new)**

*Text proposed by the Commission*

*Amendment*

**3 b. On the basis of those reports, the Commission shall be empowered to adopt delegated acts in accordance with Article 77 in order to establish a single register of European donors.**

Or. en

**Amendment 655**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Article 54 – paragraph 3 c (new)**

*Text proposed by the Commission*

*Amendment*

**3 c. Member States shall regulate the advertisement for SOHOs collection. Any advertising of SOHOs donation linked to a financial reward must be strictly banned in all Member States regardless of the medium used. Recruitment campaigns and advertisement should not refer to any compensation.**

Or. en

**Amendment 656**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 55 – title**

*Text proposed by the Commission*

*Amendment*

55 Standards concerning information to be provided prior to consent or authorisation

55 Standards concerning information to be provided prior to consent or authorisation **to donate SoHOs**

Or. en

*Justification*

*To distinguish clearly consent to donate vs consent for data processing, pursuant to EDPS opinion.*

**Amendment 657**  
**Mathilde Androuët**

**Proposal for a regulation**  
**Article 55 – paragraph 3 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

*(ca) the regular renewal of their consent to the donation at the end of a period set by each Member State;*

Or. fr

**Amendment 658**  
**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**  
**Article 55 – paragraph 3 – point d**

*Text proposed by the Commission*

*Amendment*

(d) the intended use of the donated SoHO, in particular covering proven benefits for the future recipients and any possible research or commercial uses to which the donor should consent;

(d) the intended use of the donated SoHO, in particular covering proven benefits for the future recipients and any possible research or commercial uses to which the donor should *give an informed* consent;

Or. en

**Amendment 659**  
**Eric Andrieu**

**Proposal for a regulation**  
**Article 55 – paragraph 3 – point e**

*Text proposed by the Commission*

*Amendment*

(e) the analytical tests that will be performed in course of the donor health evaluation;

(e) ***the purpose of*** the analytical tests that will be performed in course of the donor health evaluation;

Or. en

## **Amendment 660**

**Tilly Metz**

### **Proposal for a regulation**

#### **Article 56 – paragraph 1 – subparagraph 1**

##### *Text proposed by the Commission*

When the Commission deems it necessary to provide binding rules on the implementation of a particular standard or element of a standard referred to in Articles 53, 54 or 55, in order to ensure convergent and high levels of donor safety, the Commission may adopt ***implementing*** acts describing particular procedures to be followed and applied to meet such standard, or element thereof.

##### *Amendment*

When the Commission deems it necessary to provide binding rules on the implementation of a particular standard or element of a standard referred to in Articles 53, 54 or 55, in order to ensure convergent and high levels of donor safety, the Commission may adopt ***delegated*** acts describing particular procedures to be followed and applied to meet such standard, or element thereof.

Or. en

##### *Justification*

*There is not much detail in Article 53,54,55 and it is criteria setting, hence delegated more appropriate;*

## **Amendment 661**

**Tilly Metz**

### **Proposal for a regulation**

#### **Article 56 – paragraph 1 – subparagraph 2**

##### *Text proposed by the Commission*

Those ***implementing*** acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

##### *Amendment*

Those ***delegated*** acts shall be adopted in accordance with the examination procedure referred to in Article 77.

Or. en

## Amendment 662

Tilly Metz

### Proposal for a regulation

#### Article 56 – paragraph 3

*Text proposed by the Commission*

3. In order to apply the standards concerning donor protection or elements thereof, referred to in Articles 53, 54 and 55, SoHO entities shall follow the procedures laid down in any implementing act adopted in accordance with paragraphs 1 and 2 of this Article.

*Amendment*

3. In order to apply the standards concerning donor protection or elements thereof, referred to in Articles 53, 54 and 55, SoHO entities shall follow the procedures laid down in any ***delegated and*** implementing act adopted in accordance with paragraphs 1 and 2 of this Article.

Or. en

## Amendment 663

Margarita de la Pisa Carrión

### Proposal for a regulation

#### Article 56 – paragraph 4 – introductory part

*Text proposed by the Commission*

4. For those standards concerning donor protection or elements thereof for which no implementing act has been adopted, in order to apply such standards or elements thereof, SoHO entities shall follow:

*Amendment*

4. For those standards concerning donor protection or elements thereof for which no implementing act has been adopted, in order to apply such standards or elements thereof ***in accordance with what has been decided by the Member State***, SoHO entities shall follow:

Or. es

*Justification*

*The Member State has the power to apply national measures in order to ensure the health of the donor. The Member State should have the power to impose at national level its rules to ensure the protection of the donor's health.*

## Amendment 664

Alexandr Vondra

**Proposal for a regulation**  
**Article 56 – paragraph 4 – introductory part**

*Text proposed by the Commission*

4. For those standards concerning donor protection or elements thereof for which no implementing act has been adopted, in order to apply such standards or elements thereof, SoHO entities shall follow:

*Amendment*

4. For those standards concerning donor protection or elements thereof for which no implementing act has been adopted, in order to apply such standards or elements thereof, ***and upon decision of EU Member States***, SoHO entities shall follow:

Or. en

**Amendment 665**  
**Susana Solís Pérez, Véronique Trillet-Lenoir**

**Proposal for a regulation**  
**Article 56 – paragraph 4 – point a – introductory part**

*Text proposed by the Commission*

(a) the most recent technical guidelines, as indicated on the EU SoHO Platform referred to in Chapter XI, as follows:

*Amendment*

(a) the most recent technical guidelines ***established through a transparent and comprehensive consultation process with a broad selection of stakeholders based on latest scientific knowledge and relevant expertise***, and as indicated on the EU SoHO Platform referred to in Chapter XI, as follows:

Or. en

*Justification*

*Technical guidelines based on up-to-date scientific expertise*

**Amendment 666**  
**Véronique Trillet-Lenoir, Max Orville**

**Proposal for a regulation**  
**Article 56 – paragraph 4 – point a – introductory part**

*Text proposed by the Commission*

(a) the most recent technical

*Amendment*

(a) ***First of all***, the most recent



guidelines, as indicated on the EU SoHO Platform referred to in Chapter XI, as follows:

technical guidelines, as indicated on the EU SoHO Platform referred to in Chapter XI, as follows:

Or. en

#### **Amendment 667**

**Véronique Trillet-Lenoir, Max Orville**

#### **Proposal for a regulation**

#### **Article 56 – paragraph 4 – point b**

*Text proposed by the Commission*

(b) other guidelines accepted by competent authorities, as achieving an equivalent level of donor safety as set by the technical guidelines referred to in point (a);

*Amendment*

(b) **then**, other guidelines accepted by competent authorities, as achieving an equivalent level of donor safety as set by the technical guidelines referred to in point (a);

Or. en

#### **Amendment 668**

**Alexandr Vondra**

#### **Proposal for a regulation**

#### **Article 56 – paragraph 4 – point b**

*Text proposed by the Commission*

(b) other guidelines accepted by competent authorities, as achieving **an equivalent** level of donor safety as set by the technical guidelines referred to in point (a);

*Amendment*

(b) other guidelines accepted by competent authorities, as achieving **a comparable** level of donor safety as set by the technical guidelines referred to in point (a);

Or. en

#### **Amendment 669**

**Alexandr Vondra**

#### **Proposal for a regulation**

#### **Article 56 – paragraph 4 – point c**

*Text proposed by the Commission*

(c) where the guidelines referred to in points (a) or (b) do not address a particular technical method, other technical methods in line with relevant **international** guidelines and scientific evidence in peer-reviewed scientific publications, where available.

*Amendment*

(c) where the guidelines referred to in points (a) or (b) do not address a particular technical method, other technical methods in line with relevant **internationally recognised** guidelines and scientific evidence in peer-reviewed scientific publications, where available.

Or. en

**Amendment 670**

**Andreas Glück, Susana Solís Pérez**

**Proposal for a regulation  
Article 56 – paragraph 5**

*Text proposed by the Commission*

5. In those cases referred to in paragraph 4, point (a), for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall be able to demonstrate to their competent authorities, for each of the standards or elements thereof, which and to what extent they follow the guidelines referred to in paragraph 4, point (a).

*Amendment*

5. In those cases referred to in paragraph 4, point (a) **and (b)**, for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall be able to demonstrate to their competent authorities, for each of the standards or elements thereof, which and to what extent they follow the **respective** guidelines referred to in paragraph 4, point (a) **and point (b)**.

Or. en

*Justification*

*Due to the deletion of paragraph 6, paragraph 4 point b needs to be added. The reason for the deletion is that Article 4b states already that such other guidelines should be accepted by competent authorities. Is is therefore inadequate to demand further proof of equivalence by the entities.*

**Amendment 671**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation  
Article 56 – paragraph 6**

*Text proposed by the Commission*

*Amendment*

**6.** *In those cases referred to in paragraph 4, point (b), for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall demonstrate to their competent authorities, for each of the standards or elements thereof, the equivalence of the other guidelines applied in terms of the level of safety, quality and efficacy to the level set by the technical guidelines referred to in paragraph 4, point (a).* **deleted**

Or. en

#### **Amendment 672**

**Andreas Glück, Susana Solís Pérez**

#### **Proposal for a regulation Article 56 – paragraph 6**

*Text proposed by the Commission*

*Amendment*

**6.** *In those cases referred to in paragraph 4, point (b), for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall demonstrate to their competent authorities, for each of the standards or elements thereof, the equivalence of the other guidelines applied in terms of the level of safety, quality and efficacy to the level set by the technical guidelines referred to in paragraph 4, point (a).* **deleted**

Or. en

#### *Justification*

*Article 4b it states already that such standards should be accepted by competent authorities. Is is therefore inadequate to demand further proof of equivalence.*

#### **Amendment 673**

**Mathilde Androuët**

**Proposal for a regulation**  
**Chapter VII – title**

*Text proposed by the Commission*

*Amendment*

VII SOHO RECIPIENT **AND**  
**OFFSPRING** PROTECTION

VII SOHO RECIPIENT  
PROTECTION

Or. fr

**Amendment 674**  
**Mathilde Androuët**

**Proposal for a regulation**  
**Article 57 – title**

*Text proposed by the Commission*

*Amendment*

Objectives regarding SoHO recipient **and**  
**offspring** protection

Objectives regarding SoHO recipient  
protection

Or. fr

**Amendment 675**  
**Margarita de la Pisa Carrión**

**Proposal for a regulation**  
**Article 57 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

SoHO entities shall protect the health of  
SoHO recipients and offspring **from**  
**medically assisted reproduction** from risks  
posed by SoHO preparations. They shall do  
so by identifying, minimising or  
eliminating those risks.

SoHO entities shall protect the health of  
SoHO recipients and offspring **conceived**  
**following fertility treatment** from risks  
posed by SoHO preparations. They shall do  
so by identifying, minimising or  
eliminating those risks, **guaranteeing the**  
**right of individuals to know their genetic**  
**origin.**

Or. es

**Amendment 676**  
**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César**

**Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**  
**Article 57 – paragraph 1**

*Text proposed by the Commission*

SoHO entities shall protect the health of SoHO recipients and offspring from medically assisted reproduction from risks posed by SoHO preparations. They shall do so by identifying, minimising or eliminating those risks.

*Amendment*

SoHO entities shall protect the health of SoHO recipients and offspring from medically assisted reproduction from risks posed by SoHO preparations **and their application**. They shall do so by identifying, minimising or eliminating those risks.

Or. en

**Amendment 677**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 57 – paragraph 1**

*Text proposed by the Commission*

SoHO entities shall protect the health of SoHO recipients and offspring from medically assisted reproduction from risks posed by SoHO preparations. They shall do so by identifying, minimising or eliminating those risks.

*Amendment*

SoHO entities shall protect the health of SoHO recipients and offspring from medically assisted reproduction from risks posed by SoHO preparations **and their application**. They shall do so by identifying, minimising or eliminating those risks.

Or. en

*Justification*

*Clinical application of SoHOs can also pose risk to recipients.*

**Amendment 678**  
**Mathilde Androuët**

**Proposal for a regulation**  
**Article 57 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

SoHO entities shall protect the health of SoHO recipients and **offspring** from medically assisted reproduction from risks posed by SoHO preparations. They shall do so by identifying, minimising or eliminating those risks.

SoHO entities shall protect the health of SoHO recipients and **children** from medically assisted reproduction from risks posed by SoHO preparations. They shall do so by identifying, minimising or eliminating those risks.

Or. fr

**Amendment 679**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Cyrus Engerer, Robert Hajšel**

**Proposal for a regulation**

**Article 57 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***SoHO entities shall ensure that recipients are not discriminated on grounds not specified in the technical guidelines listed in Article 56, based on scientific evidence and intended to avoid potential risks to the health of donors or recipients;***

Or. en

**Amendment 680**

**Margarita de la Pisa Carrión**

**Proposal for a regulation**

**Article 58 – title**

*Text proposed by the Commission*

*Amendment*

58 Standards concerning ***SoHO recipient and*** offspring ***protection***

58 Standards concerning ***protection of SoHO recipients and of*** offspring ***conceived following fertility treatment***

Or. es

**Amendment 681**

**Mathilde Androuët**

**Proposal for a regulation**  
**Article 58 – title**

*Text proposed by the Commission*

Standards concerning SoHO recipient **and offspring** protection

*Amendment*

Standards concerning SoHO recipient protection

Or. fr

**Amendment 682**  
**Peter Liese, Andreas Glück**

**Proposal for a regulation**  
**Article 58 – paragraph 1**

*Text proposed by the Commission*

1. SoHO entities shall establish procedures with measures, and, where necessary, combinations of measures, that ensure high levels of safety and quality and demonstrate benefits for SoHO recipients and offspring from medically assisted reproduction that outweigh any risks. They shall, in particular, achieve a high level of assurance that pathogens, toxins or genetic conditions are not transmitted to recipients or offspring from medically assisted reproduction.

*Amendment*

1. SoHO entities shall establish procedures with measures, and, where necessary, combinations of measures, that ensure high levels of safety and quality and demonstrate benefits for SoHO recipients and offspring from medically assisted reproduction that outweigh any risks. They shall, in particular, achieve a high level of assurance that pathogens, toxins or genetic conditions are not transmitted to recipients or offspring from medically assisted reproduction. ***In the case of medically assisted reproduction, the option of the respective persons refusing genetic screening should be retained and the procedure is subject to national legislation according to the principle of subsidiarity hence with regard to the transmission of genetic diseases to offspring, the provisions apply only if Member States decide to allow this technology, and subsequently if it corresponds to the wish of the donor or the recipient***

Or. en

*Justification*

*In the case of medically assisted reproduction, the option of the respective persons refusing genetic screening should be retained and the procedure is subject to national legislation*

*according to the principle of subsidiarity and should only apply if it corresponds to the wish of the donor or the recipient.*

**Amendment 683**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 58 – paragraph 1**

*Text proposed by the Commission*

1. SoHO entities shall establish procedures with measures, and, where necessary, combinations of measures, that ensure high levels of safety and quality and demonstrate benefits for SoHO recipients and offspring from medically assisted reproduction that outweigh any risks. They shall, in particular, achieve a high level of assurance that pathogens, toxins or genetic conditions are not transmitted to recipients or offspring from medically assisted reproduction.

*Amendment*

1. SoHO entities shall, ***based on latest technical guidelines from the EDQM and the ECDC***, establish procedures with measures, and, where necessary, combinations of measures, that ensure high levels of safety and quality and demonstrate benefits for SoHO recipients and offspring from medically assisted reproduction that outweigh any risks. They shall, in particular, achieve a high level of assurance that pathogens, toxins or genetic conditions are not transmitted to recipients or offspring from medically assisted reproduction.

Or. en

**Amendment 684**  
**Mathilde Androuët**

**Proposal for a regulation**  
**Article 58 – paragraph 1**

*Text proposed by the Commission*

1. SoHO entities shall establish procedures with measures, and, where necessary, combinations of measures, that ensure high levels of safety and quality and demonstrate benefits for SoHO recipients ***and offspring from medically assisted reproduction*** that outweigh any risks. They shall, in particular, achieve a high level of assurance that pathogens, toxins or genetic conditions are not transmitted to recipients

*Amendment*

1. SoHO entities shall establish procedures with measures, and, where necessary, combinations of measures, that ensure high levels of safety and quality and demonstrate benefits for SoHO recipients that outweigh any risks. They shall, in particular, achieve a high level of assurance that pathogens, toxins or genetic conditions are not transmitted to recipients or offspring from medically assisted



or offspring from medically assisted reproduction.

reproduction.

Or. fr

**Amendment 685**  
**Mathilde Androuët**

**Proposal for a regulation**  
**Article 58 – paragraph 1**

*Text proposed by the Commission*

1. SoHO entities shall establish procedures with measures, and, where necessary, combinations of measures, that ensure high levels of safety and quality and demonstrate benefits for SoHO recipients and offspring from medically assisted reproduction that outweigh any risks. They shall, in particular, achieve a high level of assurance that pathogens, toxins or genetic conditions are not transmitted to recipients ***or offspring from medically assisted reproduction.***

*Amendment*

1. SoHO entities shall establish procedures with measures, and, where necessary, combinations of measures, that ensure high levels of safety and quality and demonstrate benefits for SoHO recipients and offspring from medically assisted reproduction that outweigh any risks. They shall, in particular, achieve a high level of assurance that pathogens, toxins or genetic conditions are not transmitted to recipients.

Or. fr

**Amendment 686**  
**Margarita de la Pisa Carrión**

**Proposal for a regulation**  
**Article 58 – paragraph 1**

*Text proposed by the Commission*

1. SoHO entities shall establish procedures with measures, and, where necessary, combinations of measures, that ensure high levels of safety and quality and demonstrate benefits for SoHO recipients ***and offspring from medically assisted reproduction*** that outweigh any risks. They shall, in particular, achieve a high level of assurance that pathogens, toxins or genetic conditions are not transmitted to recipients

*Amendment*

1. SoHO entities shall establish procedures with measures, and, where necessary, combinations of measures, that ensure high levels of safety and quality and demonstrate benefits for SoHO recipients that outweigh any risks. They shall, in particular, achieve a high level of assurance that pathogens, toxins or genetic conditions are not transmitted to recipients or offspring from medically assisted

or offspring from medically assisted reproduction.

reproduction.

Or. es

## **Amendment 687**

**Andreas Glück, Jan Huitema**

### **Proposal for a regulation**

#### **Article 58 – paragraph 2 – introductory part**

##### *Text proposed by the Commission*

2. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks of communicable disease transmission from SoHO donors to recipients ***by combining, at least, the following measures:***

##### *Amendment*

2. In the procedures referred to in paragraph 1, SoHO entities shall ***follow the latest technical guidelines from EDQM and ECDC to mitigate the following risks:***

***(a) the risks of communicable disease transmission from SoHO donors to recipients;***

***(b) the risks of non-communicable disease transmission, including genetic conditions and cancer, from donors to the recipients or to offspring from medically assisted reproduction;***

***(c) the risks of communicable or non-communicable disease transmission to the recipients through cross-contamination of donations during collection, processing, storage and distribution;***

***(d) risks arising from microbial contamination of SoHOs from the environment, the personnel, the equipment, materials or solutions coming into contact with SoHOs during collection, processing, storage or distribution;***

***(e) the risks that any reagents and solutions added to SoHOs or coming in contact with SoHOs during collection, processing, storage and distribution might be transmitted to recipients and have a toxic, or other, detrimental effect on their***

*health;*

*(f) the risks that inherent properties of SoHOs, necessary for clinical efficacy, have been changed by any SoHO activity performed, in a manner that renders SoHO preparations ineffective or less effective when applied to recipients;*

*(g) the risks that SoHOs cause an immune reaction in recipients;*

*(h) any other risk to the health of SoHO recipients or of offspring from medically assisted reproduction arising from the application of SoHOs or SoHO preparations and not addressed in this paragraph.*

Or. en

#### *Justification*

*This amendment significantly shortens the article by summarizing the risks mentioned in paragraphs 3, 4, 5, 6, 7, 8, and 9, which are deleted subsequently. Moreover, it points out, that all technical procedures needed to mitigate the risks should be defined in the guidelines from EDQM and ECDC.*

#### **Amendment 688**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation**

#### **Article 58 – paragraph 2 – introductory part**

##### *Text proposed by the Commission*

2. In the procedures referred to in paragraph 1, SoHO entities shall mitigate ***the risks of communicable disease transmission from SoHO donors to recipients by combining, at least,*** the following ***measures***:

##### *Amendment*

2. In the procedures referred to in paragraph 1, SoHO entities shall ***follow the scientific and technical specifications defined in Article 59 to*** mitigate the following ***risks***:

Or. en

#### **Amendment 689**

**Andreas Glück, Jan Huitema**

**Proposal for a regulation**  
**Article 58 – paragraph 2 – point a**

*Text proposed by the Commission*

*Amendment*

**(a) reviewing and evaluating the donors' current and past health, travel and relevant behavioural histories to allow the application of temporary or permanent deferrals when risks cannot be fully eliminated by donor testing;** *deleted*

Or. en

*Justification*

*Deletion due to change of Article 58 – paragraph 2 – introductory part*

**Amendment 690**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**  
**Article 58 – paragraph 2 – point a**

*Text proposed by the Commission*

*Amendment*

**(a) reviewing and evaluating the donors' current and past health, travel and relevant behavioural histories to allow the application of temporary or permanent deferrals when risks cannot be fully eliminated by donor testing;** *deleted*

Or. en

**Amendment 691**

**Andreas Glück, Jan Huitema**

**Proposal for a regulation**  
**Article 58 – paragraph 2 – point b**

*Text proposed by the Commission*

*Amendment*

**(b) testing of donors for communicable diseases using certified** *deleted*

*and validated testing methods;*

Or. en

*Justification*

*Deletion due to change of Article 58 – paragraph 2 – introductory part*

**Amendment 692**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 58 – paragraph 2 – point b**

*Text proposed by the Commission*

*Amendment*

**(b) testing of donors for communicable diseases using certified and validated testing methods;**

**deleted**

Or. en

**Amendment 693**

**Kateřina Konečná**

**Proposal for a regulation**

**Article 58 – paragraph 2 – point b**

*Text proposed by the Commission*

*Amendment*

**(b) testing of donors for communicable diseases using certified and validated testing methods;**

**(b) testing of donors for communicable diseases using certified and validated testing methods *or other methods deemed adequate by EDQM and ECDC guidelines*;**

Or. en

*Justification*

*Some communicable diseases cannot be tested using certified and validated testing methods. The amendment is meant to allow acceptable and frequently used methods that would otherwise be prohibited, limiting SoHO establishments' capacity to detect all communicable diseases and creating an unacceptable risk to recipients.*

**Amendment 694**

**Tilly Metz**

**Proposal for a regulation**

**Article 58 – paragraph 2 – point b**

*Text proposed by the Commission*

(b) testing of donors for communicable diseases using certified and validated testing methods;

*Amendment*

(b) testing of donors for communicable diseases using certified and validated testing methods *or other methods deemed adequate by EDQM and ECDC guidelines*;

Or. en

**Amendment 695**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 58 – paragraph 2 – point c**

*Text proposed by the Commission*

(c) *when feasible, using processing technologies that reduce or eliminate any potential communicable pathogens.*

*Amendment*

*deleted*

Or. en

**Amendment 696**

**Andreas Glück, Jan Huitema**

**Proposal for a regulation**

**Article 58 – paragraph 2 – point c**

*Text proposed by the Commission*

(c) *when feasible, using processing technologies that reduce or eliminate any potential communicable pathogens.*

*Amendment*

*deleted*

Or. en

*Justification*

*Deletion due to change of Article 58 – paragraph 2 – introductory part*

**Amendment 697**

**Tilly Metz**

**Proposal for a regulation**

**Article 58 – paragraph 2 – point c**

*Text proposed by the Commission*

(c) when feasible, using processing technologies that reduce or eliminate any potential communicable pathogens.

*Amendment*

(c) when feasible ***and deemed appropriate by the relevant technical guidelines***, using processing technologies that reduce or eliminate any potential communicable pathogens.

Or. en

**Amendment 698**

**Mathilde Androuët**

**Proposal for a regulation**

**Article 58 – paragraph 2 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

***(ca) a list of contagious or chronic diseases or infections that are or may be communicable, which must be explicitly formalised and shared between Member States.***

Or. fr

**Amendment 699**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 58 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. of communicable disease transmission from SoHO donors to recipients by combining, at least, the following measures:**

**(i) reviewing and evaluating the donors' current and past health, travel and relevant behavioural histories to allow the application of temporary or permanent deferrals when risks cannot be fully eliminated by donor testing;**

**(ii) testing of donors for communicable diseases using certified and validated testing methods, or other methods considered appropriate in accordance with the guidelines defined in Article 59;**

**(iii) when feasible and suitable according to the guidelines defined in Article 59, using processing technologies that reduce, inactivate or eliminate any potential communicable pathogens.**

Or. en

**Amendment 700**  
**Jessica Polfjärd**

**Proposal for a regulation**  
**Article 58 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. Such measures shall not directly or indirectly be construed to constitute discrimination between donors on any of the grounds of discrimination recognised by Article 21 of the Charter of Fundamental Rights, notably discrimination based on sexual orientation. Member States shall report any restrictions that SoHO entities impose that can reasonably be seen to constitute such discrimination and provide a summary of the scientific evidence used to justify these measures to protect donors or offspring.**



**Amendment 701**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 58 – paragraph 2 b (new)**

*Text proposed by the Commission*

*Amendment*

***2 b. of non-communicable disease transmission, including genetic conditions and cancer, from donors to the recipients or to offspring from medically assisted reproduction by combining, at least, the following measures:***

***(i) reviewing the donors' current and past health to allow temporary or permanent deferral of donors that carry a risk of transmitting cancerous cells or other non-communicable diseases that might be passed to a recipient by SoHO application;***

***(ii) where the transmission of genetic conditions is an identified risk, and in particular in the case of medically assisted reproduction with third party donation:***

***- testing donors for those conditions, as indicated by prevalence or severity as presenting the highest risk; or***

***- testing prospective recipients to identify any relevant genetic risk, combined with testing donors for such identified genetic conditions to ensure matching that will prevent the concerned condition in the offspring.***

**Amendment 702**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**  
**Article 58 – paragraph 2 c (new)**

*Text proposed by the Commission*

*Amendment*

***2 c. of communicable or non-communicable disease transmission to the recipients through cross-contamination of donations during collection, processing, storage and distribution by measures that ensure that physical contact between SoHOs from different donors is avoided or, in cases where combining donations is necessary for efficacy of the SoHO preparation, is minimised.***

Or. en

**Amendment 703**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**  
**Article 58 – paragraph 2 d (new)**

*Text proposed by the Commission*

*Amendment*

***2 d. arising from microbial contamination of SoHOs from the environment, the personnel, the equipment, materials or solutions coming into contact with SoHOs during collection, processing, storage or distribution. SoHO entities shall mitigate such risks by, at least, the following measures:***

***(i) specifying and verifying the cleanliness of collection areas;***

***(ii) specifying, based on a structured and documented risk assessment for each SoHO preparation, validating and maintaining a defined air quality in processing areas;***

***(iii) specifying, procuring and decontaminating equipment, materials and solutions such that their sterility is***

*ensured;*

*(iv) where possible and appropriate, using methods of detection, inactivation or elimination of microorganisms.*

Or. en

#### **Amendment 704**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation**

**Article 58 – paragraph 2 e (new)**

*Text proposed by the Commission*

*Amendment*

*2 e. that any reagents and solutions added to SoHOs or coming in contact with SoHOs during collection, processing, storage and distribution might be transmitted to recipients and have a toxic, or other, detrimental effect on their health by combining, at least, the following measures:*

*(i) specifying such reagents and solutions prior to their purchase;*

*(ii) verifying any required certifications of such reagents and solutions;*

*(iii) demonstrating the removal of such reagents and solutions, when necessary, prior to distribution.*

Or. en

#### **Amendment 705**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation**

**Article 58 – paragraph 2 f (new)**

*Text proposed by the Commission*

*Amendment*

*2 f. that inherent properties of SoHOs,*

*necessary for clinical efficacy, have been changed by any SoHO activity performed, in a manner that renders SoHO preparations ineffective or less effective when applied to recipients by combining, at least, the following measures:*

*(i) conducting comprehensive process validation and equipment qualification as referred to in Article 41(2), point (a)(vii);*

*(ii) gathering evidence of efficacy as referred to in Article 41(4), when needed.*

Or. en

#### **Amendment 706**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation**

**Article 58 – paragraph 2 g (new)**

*Text proposed by the Commission*

*Amendment*

*2 g. that SoHOs cause an immune reaction in recipients by combining, at least, the following measures:*

*(i) accurately typing and matching of patients to donors, when such matching is necessary;*

*(ii) correctly distributing SoHOs to the correct recipients pursuant to Article 45.*

Or. en

#### **Amendment 707**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation**

**Article 58 – paragraph 2 h (new)**

*Text proposed by the Commission*

*Amendment*

*2 h. any other risk to the health of*

*SoHO recipients or of offspring from medically assisted reproduction arising from the application of SoHOs or SoHO preparations and not addressed in paragraphs 2a to 2g by applying procedures that they have validated as safely and effectively mitigating the risk concerned or that are demonstrated as mitigating the risk by published scientific evidence.*

Or. en

### **Amendment 708**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation Article 58 – paragraph 3**

*Text proposed by the Commission*

*Amendment*

**3. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks of non-communicable disease transmission, including genetic conditions and cancer, from donors to the recipients or to offspring from medically assisted reproduction by combining, at least, the following measures:**

**deleted**

**(a) reviewing the donors' current and past health to allow temporary or permanent deferral of donors that carry a risk of transmitting cancerous cells or other non-communicable diseases that might be passed to a recipient by SoHO application;**

**(b) where the transmission of genetic conditions is an identified risk, and in particular in the case of medically assisted reproduction with third party donation:**

**(i) testing donors for those conditions, as indicated by prevalence or severity as presenting the highest risk; or**

**(ii) testing prospective recipients to identify any relevant genetic risk,**

*combined with testing donors for such identified genetic conditions to ensure matching that will prevent the concerned condition in the offspring.*

Or. en

**Amendment 709**  
**Andreas Glück, Jan Huitema**

**Proposal for a regulation**  
**Article 58 – paragraph 3**

*Text proposed by the Commission*

*Amendment*

**3. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks of non-communicable disease transmission, including genetic conditions and cancer, from donors to the recipients or to offspring from medically assisted reproduction by combining, at least, the following measures:**

*deleted*

**(a) reviewing the donors' current and past health to allow temporary or permanent deferral of donors that carry a risk of transmitting cancerous cells or other non-communicable diseases that might be passed to a recipient by SoHO application;**

**(b) where the transmission of genetic conditions is an identified risk, and in particular in the case of medically assisted reproduction with third party donation:**

**(i) testing donors for those conditions, as indicated by prevalence or severity as presenting the highest risk; or**

**(ii) testing prospective recipients to identify any relevant genetic risk, combined with testing donors for such identified genetic conditions to ensure matching that will prevent the concerned condition in the offspring.**

Or. en

*Justification*

*Deletion due to change of Article 58 – paragraph 2 – introductory part*

**Amendment 710**  
**Joanna Kopcińska**

**Proposal for a regulation**  
**Article 58 – paragraph 3 – point b – introductory part**

*Text proposed by the Commission*

(b) where the transmission of genetic conditions is **an** identified risk, and in particular in the case of medically assisted reproduction with third party donation:

*Amendment*

(b) where the transmission of genetic conditions is **a genuinely** identified risk, and in particular in the case of medically assisted reproduction with third party donation:

Or. pl

**Amendment 711**  
**Peter Liese, Andreas Glück**

**Proposal for a regulation**  
**Article 58 – paragraph 3 – point b – point ii**

*Text proposed by the Commission*

(ii) testing prospective recipients to identify any relevant genetic risk, combined with testing donors for such identified genetic conditions to ensure matching that will prevent the concerned condition in the offspring.

*Amendment*

(ii) testing prospective recipients to identify any relevant genetic risk, combined with testing donors for such identified genetic conditions to ensure matching that will prevent the concerned condition in the offspring. ***In the case of medically assisted reproduction, the option of the respective persons refusing genetic screening should be retained and the procedure is subject to national legislation according to the principle of subsidiarity hence with regard to the transmission of genetic diseases to offspring, the provisions apply only if Member States decide to allow this technology, and subsequently if it corresponds to the wish of the donor or the recipient.***

*Justification*

*In the case of medically assisted reproduction, the option of the respective persons refusing genetic screening should be retained and the procedure is subject to national legislation according to the principle of subsidiarity and should only apply if it corresponds to the wish of the donor or the recipient.*

**Amendment 712****Andreas Glück, Jan Huitema****Proposal for a regulation****Article 58 – paragraph 4***Text proposed by the Commission**Amendment*

**4. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks of communicable or non-communicable disease transmission to the recipients through cross-contamination of donations during collection, processing, storage and distribution by measures that ensure that physical contact between SoHOs from different donors is avoided or, in cases where combining donations is necessary for efficacy of the SoHO preparation, is minimised.** *deleted*

*Justification*

*Deletion due to change of Article 58 – paragraph 2 – introductory part*

**Amendment 713****Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel****Proposal for a regulation****Article 58 – paragraph 4***Text proposed by the Commission**Amendment*

**4. In the procedures referred to in paragraph 1, SoHO entities shall mitigate** *deleted*



*the risks of communicable or non-communicable disease transmission to the recipients through cross-contamination of donations during collection, processing, storage and distribution by measures that ensure that physical contact between SoHOs from different donors is avoided or, in cases where combining donations is necessary for efficacy of the SoHO preparation, is minimised.*

Or. en

**Amendment 714**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation  
Article 58 – paragraph 5**

*Text proposed by the Commission*

*Amendment*

**5. In the procedures referred to in paragraph 1, SoHO entities shall mitigate risks arising from microbial contamination of SoHOs from the environment, the personnel, the equipment, materials or solutions coming into contact with SoHOs during collection, processing, storage or distribution. SoHO entities shall mitigate such risks by, at least, the following measures:**

**(a) specifying and verifying the cleanliness of collection areas;**

**(b) specifying, based on a structured and documented risk assessment for each SoHO preparation, validating and maintaining a defined air quality in processing areas;**

**(c) specifying, procuring and decontaminating equipment, materials and solutions such that their sterility is ensured.**

*deleted*

Or. en

**Amendment 715**  
**Andreas Glück, Jan Huitema**

**Proposal for a regulation**  
**Article 58 – paragraph 5**

*Text proposed by the Commission*

*Amendment*

**5. In the procedures referred to in paragraph 1, SoHO entities shall mitigate risks arising from microbial contamination of SoHOs from the environment, the personnel, the equipment, materials or solutions coming into contact with SoHOs during collection, processing, storage or distribution. SoHO entities shall mitigate such risks by, at least, the following measures:**

**(a) specifying and verifying the cleanliness of collection areas;**

**(b) specifying, based on a structured and documented risk assessment for each SoHO preparation, validating and maintaining a defined air quality in processing areas;**

**(c) specifying, procuring and decontaminating equipment, materials and solutions such that their sterility is ensured.**

Or. en

*Justification*

*Deletion due to change of Article 58 – paragraph 2 – introductory part*

**Amendment 716**  
**Andreas Glück, Jan Huitema**

**Proposal for a regulation**  
**Article 58 – paragraph 6**

*Text proposed by the Commission*

*Amendment*

6. *In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks that any reagents and solutions added to SoHOs or coming in contact with SoHOs during collection, processing, storage and distribution might be transmitted to recipients and have a toxic, or other, detrimental effect on their health by combining, at least, the following measures:* *deleted*

*(a) specifying such reagents and solutions prior to their purchase;*

*(b) verifying any required certifications of such reagents and solutions;*

*(c) demonstrating the removal of such reagents and solutions, when necessary, prior to distribution.*

Or. en

*Justification*

*Deletion due to change of Article 58 – paragraph 2 – introductory part*

**Amendment 717**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation  
Article 58 – paragraph 6**

*Text proposed by the Commission*

*Amendment*

6. *In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks that any reagents and solutions added to SoHOs or coming in contact with SoHOs during collection, processing, storage and distribution might be transmitted to recipients and have a toxic, or other, detrimental effect on their health by combining, at least, the following measures:* *deleted*

*(a) specifying such reagents and solutions prior to their purchase;*

*(b) verifying any required certifications of*

*such reagents and solutions;*

*(c) demonstrating the removal of such reagents and solutions, when necessary, prior to distribution.*

Or. en

#### **Amendment 718**

**Andreas Glück, Jan Huitema**

#### **Proposal for a regulation**

#### **Article 58 – paragraph 7**

*Text proposed by the Commission*

*Amendment*

**7. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks that inherent properties of SoHOs, necessary for clinical efficacy, have been changed by any SoHO activity performed, in a manner that renders SoHO preparations ineffective or less effective when applied to recipients by combining, at least, the following measures:**

*deleted*

**(a) conducting comprehensive process validation and equipment qualification as referred to in Article 41(2), point (a)(vii);**

**(b) gathering evidence of efficacy as referred to in Article 41(4), when needed.**

Or. en

#### *Justification*

*Deletion due to change of Article 58 – paragraph 2 – introductory part*

#### **Amendment 719**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation**

#### **Article 58 – paragraph 7**

**7. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks that inherent properties of SoHOs, necessary for clinical efficacy, have been changed by any SoHO activity performed, in a manner that renders SoHO preparations ineffective or less effective when applied to recipients by combining, at least, the following measures:**

**(a) conducting comprehensive process validation and equipment qualification as referred to in Article 41(2), point (a)(vii);**

**(b) gathering evidence of efficacy as referred to in Article 41(4), when needed.**

**deleted**

Or. en

#### **Amendment 720**

**Nathalie Colin-Oesterlé**

#### **Proposal for a regulation**

#### **Article 58 – paragraph 7 – point a**

*Text proposed by the Commission*

*Amendment*

(a) conducting comprehensive process validation and equipment qualification as referred to in Article 41(2), point (a)(vii);

(a) conducting comprehensive process validation and equipment qualification as referred to in Article 41(2), point (a)(vii), **unless the equipment has already been assessed and carries EC certification as provided for in Regulations (EU) 2017/746<sup>1</sup> and (EU) 2017/745 for an identical use;**

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**<sup>1</sup> Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).**

Or. fr

**Amendment 721**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 58 – paragraph 8**

*Text proposed by the Commission*

*Amendment*

**8. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks that SoHOs cause an immune reaction in recipients by combining, at least, the following measures:** **deleted**

**(a) accurately typing and matching of patients to donors, when such matching is necessary;**

**(b) correctly distributing SoHOs to the correct recipients pursuant to Article 45.**

Or. en

**Amendment 722**

**Andreas Glück, Jan Huitema**

**Proposal for a regulation**

**Article 58 – paragraph 8**

*Text proposed by the Commission*

*Amendment*

**8. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks that SoHOs cause an immune reaction in recipients by combining, at least, the following measures:** **deleted**

**(a) accurately typing and matching of patients to donors, when such matching is necessary;**

**(b) correctly distributing SoHOs to the correct recipients pursuant to Article 45.**

Or. en

*Justification*

*Deletion due to change of Article 58 – paragraph 2 – introductory part*

**Amendment 723**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation  
Article 58 – paragraph 9**

*Text proposed by the Commission*

*Amendment*

**9. In the procedures referred to in paragraph 1, SoHO entities shall mitigate any other risk to the health of SoHO recipients or of offspring from medically assisted reproduction arising from the application of SoHOs or SoHO preparations and not addressed in paragraphs 2 to 8 by applying procedures that they have validated as safely and effectively mitigating the risk concerned or that are demonstrated as mitigating the risk by published scientific evidence.** *deleted*

Or. en

**Amendment 724**

**Andreas Glück, Jan Huitema**

**Proposal for a regulation  
Article 58 – paragraph 9**

*Text proposed by the Commission*

*Amendment*

**9. In the procedures referred to in paragraph 1, SoHO entities shall mitigate any other risk to the health of SoHO recipients or of offspring from medically assisted reproduction arising from the application of SoHOs or SoHO preparations and not addressed in paragraphs 2 to 8 by applying procedures that they have validated as safely and effectively mitigating the risk concerned or that are demonstrated as mitigating the** *deleted*

*risk by published scientific evidence.*

Or. en

*Justification*

*Deletion due to change of Article 58 – paragraph 2 – introductory part*

**Amendment 725**

**Andreas Glück, Véronique Trillet-Lenoir, Peter Liese, Susana Solís Pérez**

**Proposal for a regulation**

**Article 58 – paragraph 10 – point a**

*Text proposed by the Commission*

(a) apply SoHO preparations to recipients without proven benefit, except in the context of a clinical investigation approved in the context of a conditional authorisation of the SoHO preparation by their competent authority pursuant to Article 41(4);

*Amendment*

(a) apply SoHO preparations to recipients without proven benefit, except in the context of a clinical investigation approved in the context of a conditional authorisation of the SoHO preparation by their competent authority pursuant to Article 41(4) ***or compassionate use and experimental therapy as described in Article 61;***

Or. en

*Justification*

*For derogations one should also make explicit reference to Article 61 on the exceptional release of SoHO.*

**Amendment 726**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 58 – paragraph 10 – point a**

*Text proposed by the Commission*

(a) apply SoHO preparations to recipients without proven benefit, except in the context of a clinical investigation approved in the context of a conditional authorisation of the SoHO preparation by

*Amendment*

(a) apply SoHO preparations to recipients without proven benefit, except in the context of a clinical investigation approved in the context of a conditional authorisation of the SoHO preparation by



their competent authority pursuant to Article 41(4);

their competent authority pursuant to Article 41(4), *or a clinical study referred to in Article 41(a)*;

Or. en

#### **Amendment 727**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation**

#### **Article 58 – paragraph 10 – point b**

*Text proposed by the Commission*

(b) apply SoHO preparations to recipients unnecessarily;

*Amendment*

(b) apply SoHO preparations to recipients unnecessarily. *SoHO entities shall make an optimal use of SoHO, taking into account therapeutic alternatives, and following the most up-to-date scientific guides specified in Article 59* ;

Or. en

#### **Amendment 728**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation**

#### **Article 58 – paragraph 10 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

*(c a) prioritise cosmetic uses over clinical uses, especially in the event of a possible shortage of SoHO.*

Or. en

#### **Amendment 729**

**Margarita de la Pisa Carrión**

#### **Proposal for a regulation**

**Article 58 – paragraph 10 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

**(ca) undermine the requirements of traceability and the right of individuals to know their genetic origin.**

Or. es

**Amendment 730**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 58 – paragraph 11 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

For the measures referred to in paragraphs 2 and 3, SoHO entities shall verify the eligibility of a donor by means of an interview with him/her, his/her legal guardian or, in case of a donation after death, a relevant individual that is informed regarding the donor's health and lifestyle history. The interview may be combined with any interview conducted as part of the evaluation referred to in Article 53(1), point (f).

***Without prejudice to Articles 53 (1f) and 2,*** for the measures referred to in paragraphs 2 and 3, SoHO entities shall verify the eligibility of a donor by means of an interview with him/her, his/her legal guardian or, in case of a donation after death, a relevant individual that is informed regarding the donor's health and lifestyle history. The interview may be combined with any interview conducted as part of the evaluation referred to in Article 53(1), point (f).

Or. en

**Amendment 731**

**Andreas Glück**

**Proposal for a regulation**

**Article 58 – paragraph 11 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

For the measures referred to in paragraphs 2 **and 3**, SoHO entities shall verify the eligibility of a donor by means of an interview with him/her, his/her legal

For the measures referred to in paragraphs 2, **point (a) and (b)**, SoHO entities shall verify the eligibility of a donor by means of an interview with him/her, his/her legal

guardian or, in case of a donation after death, a relevant individual that is informed regarding the donor's health and lifestyle history. The interview may be combined with any interview conducted as part of the evaluation referred to in Article 53(1), point (f).

guardian or, in case of a donation after death, a relevant individual that is informed regarding the donor's health and lifestyle history. The interview may be combined with any interview conducted as part of the evaluation referred to in Article 53(1), point (f).

Or. en

### *Justification*

*Addition due to change of Article 58 – paragraph 2 – introductory part*

#### **Amendment 732**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation**

**Article 58 – paragraph 11 – subparagraph 2**

##### *Text proposed by the Commission*

For donors that donate repeatedly, the interviews referred to in the first subparagraph may be limited to aspects that might have changed ***and may be replaced with questionnaires.***

##### *Amendment*

For donors that donate repeatedly, the interviews referred to in the first subparagraph may be limited to aspects that might have changed.

Or. en

#### **Amendment 733**

**Margarita de la Pisa Carrión**

#### **Proposal for a regulation**

**Article 58 – paragraph 14 – subparagraph 2 – point a**

##### *Text proposed by the Commission*

(a) the safeguards intended to protect their data and the data of the offspring ***in the case of medically assisted reproduction;***

##### *Amendment*

(a) the safeguards intended to protect their data and the data of the offspring ***conceived following fertility treatment;***

Or. es

**Amendment 734**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 58 – paragraph 14 – subparagraph 2 – point a a (new)**

*Text proposed by the Commission*

*Amendment*

*(a a) donor anonymity and the possibility of ID release and the implication hereof for medically assisted reproduction with third party donation of reproductive cells, pursuant to provisions laid down in national legislation;*

Or. en

**Amendment 735**  
**Jessica Polfjärd**

**Proposal for a regulation**  
**Article 58 – paragraph 14 – subparagraph 2 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

*(b a) in the case of medically assisted reproduction with third party donation, the applicable rules to protect the data of the donor in the Member State and if the donation was made outside the Member State, the applicable rules in that jurisdiction.*

Or. en

*Justification*

*It is reasonable to lay down that recipients of SoHO for medically assisted reproduction be aware of those rules and if any deviation from the rules normally applicable in the Member State are in place before the donation*

**Amendment 736**  
**Joanna Kopcińska**

**Proposal for a regulation**

## Article 58 – paragraph 15

*Text proposed by the Commission*

*Amendment*

15. *The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this Regulation in cases where additional standards are deemed necessary to ensure the protection of SoHO recipients or offspring from risks posed by the application of SoHO preparations.* **deleted**

Or. pl

*Justification*

*The Commission has not defined either the range or nature of additional standards for the protection of recipients, so such a broad power may concern non-essential elements and thus infringe Article 290 TFEU.*

### **Amendment 737**

**Margarita de la Pisa Carrión**

#### **Proposal for a regulation**

#### **Article 58 – paragraph 16**

*Text proposed by the Commission*

*Amendment*

16. Where, in the case of risk to SoHO recipients and offspring **from medically assisted reproduction** arising from inadequate levels of safety and quality of SoHOs, imperative grounds of urgency so require, the procedure provided for in Article 78 shall apply to delegated acts adopted pursuant to this Article.

16. Where, in the case of risk to SoHO recipients and offspring **conceived following fertility treatment** arising from inadequate levels of safety and quality of SoHOs, imperative grounds of urgency so require, the procedure provided for in Article 78 shall apply to delegated acts adopted pursuant to this Article.

Or. es

### **Amendment 738**

**Mathilde Androuët**

#### **Proposal for a regulation**

#### **Article 59 – title**

*Text proposed by the Commission*

*Amendment*

Implementation of the standards concerning recipient **and offspring** protection

Implementation of the standards concerning recipient protection

Or. fr

**Amendment 739**

**Véronique Trillet-Lenoir, Max Orville**

**Proposal for a regulation**

**Article 59 – paragraph 4 – point a – introductory part**

*Text proposed by the Commission*

*Amendment*

(a) the most recent technical guidelines, as indicated on the EU SoHO Platform referred to in Chapter XI, as follows:

(a) **First of all**, the most recent technical guidelines, as indicated on the EU SoHO Platform referred to in Chapter XI, as follows:

Or. en

**Amendment 740**

**Véronique Trillet-Lenoir, Max Orville**

**Proposal for a regulation**

**Article 59 – paragraph 4 – point b**

*Text proposed by the Commission*

*Amendment*

(b) other guidelines accepted by competent authorities as achieving an equivalent level of safety and quality of SoHOs as set by the technical guidelines referred to in point (a);

(b) **then**, other guidelines accepted by competent authorities as achieving an equivalent level of safety and quality of SoHOs as set by the technical guidelines referred to in point (a);

Or. en

**Amendment 741**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

## Article 59 – paragraph 6

*Text proposed by the Commission*

*Amendment*

**6. In those cases referred to in paragraph 4, point (b), for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall demonstrate to their competent authorities, for each of the standards or elements thereof, the equivalence of the other guidelines applied in terms of the level safety, quality and efficacy to the level set by the technical guidelines referred to in paragraph 4, point (a).**

*deleted*

Or. en

### **Amendment 742**

**Nicolás González Casares, Sara Cerdas, João Albuquerque, Romana Jerković, Biljana Borzan, César Luena, Tudor Ciuhodaru**

### **Proposal for a regulation Article -62 (new)**

*Text proposed by the Commission*

*Amendment*

#### **Article -62**

***Establishment of national plans to ensure continuity of supply of SoHO***

***1. Member States, in cooperation with National SoHO Authorities, shall draw up national plans to ensure the continuity of SoHO supply, setting out the measures to be implemented in order to ensure a sufficiently broad base of donors to meet the usual national demand. The plans shall also include actions to be taken to make a more efficient use of SoHO, to monitor trends in the supply of critical SOHOs, to prioritise certain patients in the event of shortages and measures to be followed in case that national SoHO stocks exceed the national demand and export to other countries with SoHO shortages can be considered. Member States shall take into account the***

*recommendations issued by the Commission in accordance with Article 62 (a) when drawing up and reviewing their national plans.*

*2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular with regard to critical SoHO, with a view to ensuring a resilient supply and a significant increase in donation rates where risks of shortages are identified. In doing so, they shall encourage the acquisition of SoHO through strong public and non-profit sector involvement.*

*3. SoHO entities shall report to the competent authorities on their availability of SoHO as specified in Article 46 (a) and the competent authorities shall be responsible for monitoring the availability of SoHO at national level in accordance with Article 34 (a).*

*4. In cases where the availability of SoHOs or products derived from them depends on potential commercial interests, such as some plasma-derived products, Member States shall ensure, through negotiations, incentives or public service obligations, that those SoHO entities, within the limits of their responsibilities, provide an appropriate and continuous supply of SoHOs, or their derivatives, to patients in each Member State. Member States shall negotiate fair and transparent prices for SoHO-derived products, which are based on altruistic and unpaid donations. Member States shall also ensure that low-profit products are also available to patients and that there is a continuous investment on research and innovation for those products.*

*5. Member States shall review their national plans every 3 years, as specified in paragraph 1, to ensure continuity of SoHO supply, to take into account changes in the organisation of the competent authorities, the experience*



*gained from the implementation of the plan and simulation exercises, and the recommendations issued by the Commission, as referred to in Article 62 (a).*

*6. The Commission may adopt implementing acts describing:*

*a) rules for the establishment of national plans to ensure continuity of SoHO supply provided for in paragraph 1 to the extent necessary to ensure coherent and efficient supply management;*

*b) the role of stakeholders and the supporting role of EDQM and ECDC for the establishment and operation of national plans to ensure continuity of SoHO supply.*

*Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).*

Or. en

**Amendment 743**  
**Margarita de la Pisa Carrión**

**Proposal for a regulation**  
**Article 62 – title**

*Text proposed by the Commission*

Establishment of national SoHO  
*emergency* plans

*Amendment*

Establishment of national SoHO plans

Or. es

**Amendment 744**  
**Pernille Weiss**

**Proposal for a regulation**  
**Article 62 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. Member States, in collaboration with National SoHO Authorities, shall draw up national SoHO emergency plans setting out measures to be applied without undue delay when the supply situation for critical SoHOs presents or is likely to present a serious risk to human health.

1. Member States, in collaboration with National SoHO Authorities, shall draw up national SoHO emergency plans setting out measures to be applied without undue delay when the supply situation for critical SoHOs presents or is likely to present a serious risk to human health. ***In this regard, the Commission shall support the exchange of best practice between Member States.***

Or. en

**Amendment 745**  
**Margarita de la Pisa Carrión**

**Proposal for a regulation**  
**Article 62 – paragraph 1**

*Text proposed by the Commission*

1. Member States, in collaboration with National SoHO Authorities, shall draw up national SoHO ***emergency*** plans setting out measures to be applied without undue delay when the supply situation for critical SoHOs presents or is likely to present a serious risk to human health.

*Amendment*

1. Member States, in collaboration with National SoHO Authorities, shall draw up national SoHO plans setting out measures to be applied without undue delay when the supply situation for critical SoHOs presents or is likely to present a serious risk to human health.

Or. es

**Amendment 746**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 62 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1 a. The Commission and the SCB shall provide guidance and support to the Member States when establishing national emergency plans and promote best-practice sharing within the Union.***

Or. en

#### Amendment 747

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

#### Proposal for a regulation

#### Article 62 – paragraph 2

*Text proposed by the Commission*

2. *Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of SoHO with a strong public and non-profit sector involvement.*

*Amendment*

*deleted*

Or. en

#### Amendment 748

Tilly Metz

#### Proposal for a regulation

#### Article 62 – paragraph 2

*Text proposed by the Commission*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of SoHO with a strong public and non-profit sector involvement.

*Amendment*

2. Member States shall make all reasonable efforts, ***in line with voluntary unpaid principle established in this Regulation***, to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of SoHO with a strong public and non-profit sector involvement.

Or. en

## Amendment 749

Andreas Glück, Ondřej Knotek, Peter Liese, Jan Huitema

### Proposal for a regulation

#### Article 62 – paragraph 2

*Text proposed by the Commission*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of SoHO ***with a strong public and non-profit sector involvement.***

*Amendment*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of SoHO.

Or. en

*Justification*

*In several Members States donation to the private sector is possible in addition to donation to the public and non-profit sector. This should be reflected in this proposal and does not mean that Member States have to change their current practices. Much rather, it ensures that Member States with private collection can keep their approach in securing the supply of SoHO.*

## Amendment 750

Stelios Kypouropoulos, Tomislav Sokol, Peter Liese

### Proposal for a regulation

#### Article 62 – paragraph 2

*Text proposed by the Commission*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of SoHO with ***a strong public and non-profit sector involvement.***

*Amendment*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall ***strongly*** encourage the collection of SoHO with ***the involvement of all relevant stakeholders.***

**Amendment 751**  
**Sunčana Glavak**

**Proposal for a regulation**  
**Article 62 – paragraph 2**

*Text proposed by the Commission*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of ***SoHO with a strong public and non-profit sector*** involvement.

*Amendment*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of ***SoHOs with the involvement of all relevant stakeholders***.

Or. en

**Amendment 752**  
**Stanislav Polčák**

**Proposal for a regulation**  
**Article 62 – paragraph 2**

*Text proposed by the Commission*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of ***SoHO with a strong public and non-profit sector*** involvement.

*Amendment*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of ***SoHOs with the involvement of all relevant stakeholders***.

Or. en

**Amendment 753**  
**Aldo Patriciello, Salvatore De Meo**

**Proposal for a regulation**  
**Article 62 – paragraph 2**

*Text proposed by the Commission*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of ***SoHO with a strong public and non-profit sector*** involvement.

*Amendment*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of ***SoHOs with the involvement of all relevant stakeholders***.

Or. en

**Amendment 754**  
**Giuseppe Ferrandino**

**Proposal for a regulation**  
**Article 62 – paragraph 2**

*Text proposed by the Commission*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of ***SoHO with a strong public and non-profit sector*** involvement.

*Amendment*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of ***SoHOs with the involvement of all relevant stakeholders***.

Or. en

*Justification*

*While the public and non-profit sectors have an important role to play in addressing (risks of) shortages, national emergency plans should involve all relevant stakeholders on a non-discriminatory basis, including the private sector. It is not objectively justified to single out only the public and non-profit sector, as the private sector can also make important*

*contributions to addressing supply issues, subject to the same quality and safety standards.*

#### **Amendment 755**

**Pernille Weiss**

#### **Proposal for a regulation**

#### **Article 62 – paragraph 2**

*Text proposed by the Commission*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of SoHO with ***a strong public and non-profit sector*** involvement.

*Amendment*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of SoHO with ***the involvement of all relevant stakeholders***.

Or. en

#### **Amendment 756**

**Cristian-Silviu Buşoi**

#### **Proposal for a regulation**

#### **Article 62 – paragraph 2**

*Text proposed by the Commission*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of SoHO with ***a strong public and non-profit sector*** involvement.

*Amendment*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of SoHO with ***the involvement of all relevant stakeholders***.

Or. en

## **Amendment 757**

**Adam Jarubas, Ewa Kopacz, Bartosz Arłukowicz**

### **Proposal for a regulation**

#### **Article 62 – paragraph 2**

*Text proposed by the Commission*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of *SoHO with a strong public and non-profit sector* involvement.

*Amendment*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of *SoHOs with the involvement of all relevant stakeholders*

Or. en

## **Amendment 758**

**Alexandr Vondra**

### **Proposal for a regulation**

#### **Article 62 – paragraph 2**

*Text proposed by the Commission*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of SoHO with *a strong public and non-profit sector* involvement.

*Amendment*

2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of SoHO with involvement *of all relevant stakeholders*.

Or. en

## **Amendment 759**

**Giuseppe Ferrandino**

### **Proposal for a regulation**



## Article 62 – paragraph 2 – point 1 (new)

*Text proposed by the Commission*

*Amendment*

**(1) Member States shall also establish national plans to increase sufficiency for critical SoHOs in the Union. The European Commission shall provide guidance and support, such as promoting the exchange of best practices and relevant evidence and experience, across Member States.**

Or. en

*Justification*

*The proposed EU Regulation foresees that Member States must proceed to a mandatory “establishment of national SoHO emergency plans”, which include some regulatory and monitoring measures to be taken. However, it is also necessary to establish sufficiency plans to reduce structural dependence on imports from third countries and thereby increase the Union’s strategic autonomy in the area of SoHOs.*

### **Amendment 760**

**Pernille Weiss**

#### **Proposal for a regulation**

#### **Article 62 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. Member States, in collaboration with National SoHO Authorities, shall draw up national SoHO plans setting out measures to support the open strategic autonomy for supply of critical SoHOs, in the context of resilient global supply chains. In this regard, the Commission shall support the exchange of best practice between Member States.**

Or. en

### **Amendment 761**

**Kateřina Konečná**

**Proposal for a regulation**  
**Article 62 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. Member States shall also establish national plans to increase sufficiency for critical SoHOs in the Union. The European Commission shall provide guidance and support, such as promoting the exchange of best practices and relevant evidence and experience, across Member States.**

Or. en

*Justification*

*It is also necessary to establish sufficiency plans to reduce structural dependence on imports from third countries and thereby increase the Union's strategic autonomy in the area of SoHOs.*

*The EU reliance today on U.S. plasma is almost 40% . In addition, data demonstrates that “recovered” (indirect) plasma collection levels from whole blood have even declined over time. The EU should be more ambitious and recommend that Member States establish national plans addressing the need to collect more plasma.*

**Amendment 762**  
**Stanislav Polčák**

**Proposal for a regulation**  
**Article 62 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. Member States shall also establish national plans to increase sufficiency for critical SoHOs in the Union. The European Commission shall provide guidance and support, such as promoting the exchange of best practices and relevant evidence and experience, across Member States.**

Or. en

**Amendment 763**

**Cristian-Silviu Buşoi**

**Proposal for a regulation  
Article 62 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. Member States shall also establish national plans to increase sufficiency for critical SoHOs in the Union. The European Commission shall provide guidance and support, such as promoting the exchange of best practices and relevant evidence and experience, across Member States.**

Or. en

**Amendment 764  
Aldo Patriciello, Salvatore De Meo**

**Proposal for a regulation  
Article 62 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. Member States shall also establish national plans to increase sufficiency for critical SoHOs in the Union. The European Commission shall provide guidance and support, such as promoting the exchange of best practices and relevant evidence and experience, across Member States.**

Or. en

**Amendment 765  
Alexandr Vondra, Joanna Kopcińska**

**Proposal for a regulation  
Article 62 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. Member States shall also establish**

*national plans to increase sufficiency for critical SoHOs in the Union. The European Commission shall provide guidance and support, such as promoting the exchange of best practices and relevant evidence and experience across Member States.*

Or. en

**Amendment 766**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 62 – paragraph 3 – point a a (new)**

*Text proposed by the Commission*

*Amendment*

*(a a) evidence-based measures that impact demand of critical SoHOs;*

Or. en

**Amendment 767**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 62 – paragraph 3 – point a b (new)**

*Text proposed by the Commission*

*Amendment*

*(a b) quantitative targets to ensure self-sufficiency of supply of critical SoHOs;*

Or. en

**Amendment 768**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 62 – paragraph 3 – point a c (new)**

*Text proposed by the Commission*

*Amendment*

*(a c) strategy on optimisation of use of critical SoHOs;*

Or. en

**Amendment 769**

**Tilly Metz**

**Proposal for a regulation**

**Article 62 – paragraph 3 – point a d (new)**

*Text proposed by the Commission*

*Amendment*

*(a d) critical SoHO donor recruitment and retainment strategy, including communication campaigns and education programmes;*

Or. en

**Amendment 770**

**Tilly Metz**

**Proposal for a regulation**

**Article 62 – paragraph 3 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

*(c a) stakeholder engagement;*

Or. en

**Amendment 771**

**Mathilde Androuët**

**Proposal for a regulation**

**Article 62 – paragraph 3 – point f a (new)**

*Text proposed by the Commission*

*Amendment*

*(fa) a list of contagious or chronic diseases or infections that are or may be communicable, which must be explicitly formalised and shared between Member*

*States.*

Or. fr

**Amendment 772**

**Pernille Weiss**

**Proposal for a regulation**

**Article 62 – paragraph 3 – point f a (new)**

*Text proposed by the Commission*

*Amendment*

***(f a) a strategy for communication to and with citizens and national authorities.***

Or. en

**Amendment 773**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 62 – paragraph 3 – point f a (new)**

*Text proposed by the Commission*

*Amendment*

***(f a) communication strategy for the general public.***

Or. en

**Amendment 774**

**Tilly Metz**

**Proposal for a regulation**

**Article 62 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***3 a. Member States shall submit their emergency plans to the Commission and the SCB within 2 years after entry into force of this Regulation.***

**Amendment 775**

**Tilly Metz**

**Proposal for a regulation**

**Article 62 – paragraph 6**

*Text proposed by the Commission*

6. Member States shall review regularly their national SoHO emergency plans to take into account changes in the organisation of competent authorities and experience gained from implementing the plans and simulation exercises.

*Amendment*

6. Member States shall review regularly their national SoHO emergency plans to take into account changes in the organisation of competent authorities and experience gained from implementing the plans and simulation exercises. ***Member States shall inform without delay the Commission and the SCB of any substantial revision of the national plans.***

Or. en

**Amendment 776**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 62 – paragraph 6**

*Text proposed by the Commission*

6. Member States shall review ***regularly*** their national SoHO emergency plans to take into account changes in the organisation of competent authorities ***and*** experience gained from implementing the plans and simulation exercises.

*Amendment*

6. Member States shall review their national SoHO emergency plans ***at least every 3 years and whenever necessary*** to take into account changes in the organisation of competent authorities, experience gained from implementing the plans and simulation exercises ***and the recommendations issued by the Commission, as referred to in Article 62(a).***

Or. en

**Amendment 777**

**Pernille Weiss**

**Proposal for a regulation**

**Article 62 – paragraph 6**

*Text proposed by the Commission*

6. Member States shall review **regularly** their national SoHO emergency plans to take into account changes in the organisation of competent authorities and experience gained from implementing the plans and simulation exercises.

*Amendment*

6. Member States shall **at least on an annual basis** review their national SoHO emergency plans to take into account changes in the organisation of competent authorities and experience gained from implementing the plans and simulation exercises.

Or. en

**Amendment 778**

**Tilly Metz**

**Proposal for a regulation**

**Article 62 – paragraph 7 – subparagraph 1 – introductory part**

*Text proposed by the Commission*

The Commission may adopt **implementing** acts describing:

*Amendment*

The Commission may adopt **delegated** acts describing:

Or. en

**Amendment 779**

**Tilly Metz**

**Proposal for a regulation**

**Article 62 – paragraph 7 – subparagraph 1 – point b**

*Text proposed by the Commission*

(b) the role of stakeholders and the supportive role of the ECDC in the establishment and operation of national SoHO emergency plans.

*Amendment*

(b) the role of stakeholders and the supportive role of the ECDC **and the EDQM** in the establishment and operation of national SoHO emergency plans.

Or. en



**Amendment 780**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 62 – paragraph 7 – subparagraph 2**

*Text proposed by the Commission*

Those **implementing** acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

*Amendment*

Those **delegated** acts shall be adopted in accordance with the examination procedure referred to in Article 77.

Or. en

**Amendment 781**  
**Nathalie Colin-Oesterlé**

**Proposal for a regulation**  
**Article 62 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 62a**

***Development of a strategy for the promotion of European SoHO supply self-sufficiency***

***1. Within two years after adoption of this Regulation, the Commission shall publish a strategy for the promotion of European SoHO supply self-sufficiency. That strategy shall set ambitious targets for each SoHO, laid down by the Commission in coordination with national competent authorities, the European Parliament, scientists from professional associations and patient associations, as well as all other relevant stakeholders. Without prejudice to Articles 53 and 54, and in particular the principle of voluntary and unpaid donation, it shall promote action to:***

***(a) publicise at European level the various types of SoHO donations that are achievable;***

- (b) introduce a European day given over to the donation of essential SoHOs;*
- (c) promote an increase in the number of collection centres and extend the opening days and hours of SoHO collection entities and establishments outside traditional working hours;*
- (d) make the professions essential for carrying out SoHO donations more attractive;*
- (e) raise awareness in connection with SoHO donations by healthcare workers in hospitals and healthcare facilities;*
- (f) ensure sound blood stock management in accordance with patient blood management practices.*
- 2. Within two years after publication of that European strategy, Member States shall adopt national priority action programmes for donor recruitment.*
- 3. Those national plans shall take into account the Commission's strategy for promoting European SoHO self-sufficiency and the SoHO supply guidelines issued by the EDQM.*
- 4. The strategy for promoting European SoHO self-sufficiency shall be revised by the Commission every five years from 2030 onwards. National plans shall be reviewed accordingly within no more than two years after publication of the revised strategy.*

Or. fr

**Amendment 782**  
**Eric Andrieu**

**Proposal for a regulation**  
**Article 62 a (new)**

*Text proposed by the Commission*

*Amendment*

*Article 62 a*

***Development of a strategy for the promotion of European SoHO supply self-sufficiency***

***1. Within two years of the entry into force of this Regulation, the Commission shall publish a strategy for the promotion of European ethical SoHO supply self-sufficiency. That strategy shall set ambitious targets for each SoHO, laid down by the Commission in coordination with national competent authorities, the European Parliament, scientists from professional associations and patient associations, as well as all other relevant stakeholders. Without prejudice to Articles 53 and 54, and in particular the principle of voluntary and unpaid donation, it shall include recommendations aiming to:***

***(a) publicise at European level the various types of SoHO donations that are achievable;***

***(b) introduce a European day given over to the donation of essential SoHOs;***

***(c) encourage extending opening days and hours of SoHO collection entities and establishments outside traditional working hours;***

***(d) make the professions essential for carrying out SoHO donations more attractive;***

***(e) raise awareness in connection with SoHO donations by healthcare workers in hospitals and healthcare facilities;***

***(f) ensure sound blood stock management in accordance with patient blood management practices.***

***2. Within two years of the publication of that European strategy, Member States shall adopt national priority action programmes for donor recruitment.***

***3. Those national plans shall take into account the Commission's strategy for promoting European SoHO self-sufficiency and the SoHO supply***

*guidelines issued by the EDQM.*

***4. The strategy for promoting European SoHO self-sufficiency shall be revised by the Commission every five years from 2030 onwards. National plans shall be reviewed accordingly within no more than two years after publication of the revised strategy.***

Or. en

#### *Justification*

*Union dependence on third countries for SoHOs, in particular for plasma, is not inevitable. It is essential that the autonomy of the Union is gradually built on the basis of an ambitious and achievable European strategy. Relying on imports exposes Member States and the Union to supply disruptions in the event of a sudden interruption of trade with exporting third countries.*

**Amendment 783**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 62 a (new)**

*Text proposed by the Commission*

*Amendment*

#### ***Article 62 a***

***EU Strategy for critical SoHO supply sufficiency***

***1. The Commission shall, in cooperation with the SCB, the ECDC, the EDQM and in consultation with relevant national authorities and stakeholders, develop a strategy for supply sufficiency of critical SoHOs, within two years of entry into force of this Regulation.***

***2. The Strategy shall include:***

***(a) a list of SoHOs which are considered 'critical' pursuant to definition in Article 3(40) of this Regulation;***

***(b) a monitoring system for supply and demand of critical SoHOs with a view of identifying any actual and potential shortages which would endanger patient***

*health;*

*(c) obligations for SoHO entities and national authorities to report on the supply chain of critical SoHOs;*

*(d) quantitative targets to ensure self-sufficiency of critical SoHOs based on supply and demand forecast;*

*(e) best practices linked to optimisation of use of critical SoHOs;*

*(f) links to national emergency plans set in Article 62 of this Regulation.*

*3. The Commission shall as a part of the EU SoHO Platform develop streamlined monitoring and reporting system.*

*4. The Commission shall establish monitoring and reporting obligations set in this Article in a delegated act adopted pursuant to Article 77 of this Regulation.*

Or. en

**Amendment 784**

**Susana Solís Pérez, Véronique Trillet-Lenoir**

**Proposal for a regulation**

**Article 62 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 62 a**

***European autonomy in the supply of SoHO***

***The Commission shall, within two years of the entry into force of this Regulation, publish a strategy for promoting increased European autonomy in the provision of SoHOs. The strategy shall contain specific objectives and an accompanying calendar to be defined jointly by the European Commission in consultation with relevant national authorities, the European Parliament and relevant professional, scientific, industry, donor and patient representative groups.***

*Justification*

*Need for a European approach to strategic autonomy in SoHO, particularly in the context of ever-growing relevance of biologics.*

**Amendment 785**

**Andreas Glück, Ondřej Knotek, Véronique Trillet-Lenoir, Peter Liese, Susana Solís Pérez**

**Proposal for a regulation**

**Article 62 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 62 a**

***Public Service Obligation***

***SoHO entities collecting or processing blood or blood components in a Member State are, within the limits of their responsibilities, obliged to ensure an appropriate and continuous supply of these SoHOs and SoHO preparations in that Member State in order to meet the needs of patients.***

**Amendment 786**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 62 b (new)**

*Text proposed by the Commission*

*Amendment*

**Article 62 b**

***European SoHO autonomy***

***1. By two years after the entry into force of this Regulation, the Commission shall submit a report to the Council and the European Parliament assessing the different measures applicable to secure***

*the SoHO supply at national level, in the Member States, and at Union level. This report shall include measures to promote donation, in a manner compatible with the principles of voluntary and unpaid donation defined in paragraph 54 – such as informative and awareness-raising campaigns for citizens on the benefits of donation, as well as measures for the efficient use of SoHO. Based on the results of this report, the Commission shall develop a plan to promote European SoHO autonomy and give recommendations to Member States to implement measures in this regard in their national plans, described in Article 61 (a).*

*2. The plan for a European autonomy proposed by the Commission shall be reviewed every 5 years.*

*3. The Commission shall work with Member States to promote public participation in SoHO donation activities, in particular with regard to critical SoHO, with a view of ensuring resilient supply and a significant increase in donation rates where risks of shortages are identified. In doing so, it shall encourage the collection of SoHO through strong public and non-profit sector participation.*

Or. en

#### **Amendment 787**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation Article 63 – paragraph 1**

##### *Text proposed by the Commission*

1. Critical SoHO entities shall without undue delay launch a SoHO supply alert to their competent authorities in case of a significant interruption, indicating the underlying reason, the expected impact on

##### *Amendment*

1. Critical SoHO entities shall without undue delay launch a SoHO supply alert to their competent authorities in case of a significant interruption, indicating the underlying reason, the expected impact on

patients and any mitigating actions taken including possible alternative supply channels if appropriate. Interruptions shall be considered significant when the application of critical SoHO is cancelled or postponed due to unavailability and this poses a serious risk to health.

patients and any mitigating actions taken including possible alternative supply channels if appropriate. Interruptions shall be considered significant when the application of critical SoHO is cancelled or postponed due to unavailability and this poses a serious risk to *human* health.

Or. en

#### **Amendment 788**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation**

#### **Article 63 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

**1 a. In cases where a SoHO supply alert can be considered a health emergency due to its implications, or for the purpose of preventing potential threats, the provisions of Regulation (EU) 2022/2371 on serious cross-border threats to health shall be followed.**

Or. en

*(Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU)*

#### **Amendment 789**

**Tilly Metz**

#### **Proposal for a regulation**

#### **Article 63 – paragraph 3**

*Text proposed by the Commission*

*Amendment*

3. The SoHO National Authorities *may* submit to the EU SoHO Platform the SoHO supply alert received ***in cases where the supply interruption might affect other Member States or where such interruption might be addressed through cooperation***

3. The SoHO National Authorities ***shall without undue delay*** submit to the EU SoHO Platform the SoHO supply alert received.



*between Member States pursuant to Article 62(3), point (d).*

Or. en

#### **Amendment 790**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation Article 63 – paragraph 3**

*Text proposed by the Commission*

3. The SoHO National Authorities *may* submit to the EU SoHO Platform the SoHO supply alert received in cases where the supply interruption might affect other Member States or where such interruption might be addressed through cooperation between Member States pursuant to Article 62(3), point (d).

*Amendment*

3. The SoHO National Authorities *shall* submit to the EU SoHO Platform the SoHO supply alert received, *especially* in cases where the supply interruption might affect other Member States or where such interruption might be addressed through cooperation between Member States pursuant to Article 62(3), point (d).

Or. en

#### **Amendment 791**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation Article 64 – title**

*Text proposed by the Commission*

Derogation from the obligations to authorise SoHO preparations in emergency situations

*Amendment*

Derogation from the obligations to authorise SoHO preparations in *public health* emergency situations

Or. en

#### **Amendment 792**

**Margarita de la Pisa Carrión**

#### **Proposal for a regulation**

## Article 65 – title

*Text proposed by the Commission*

Additional **emergency** measures by Member States

*Amendment*

Additional measures by Member States

Or. es

## Amendment 793

**Margarita de la Pisa Carrión**

### Proposal for a regulation

#### Article 65 – paragraph 1

*Text proposed by the Commission*

Member States may take additional measures to the ones set out in their national SoHO emergency plans to ensure critical SoHOs supply in case of shortages on their territory, on a case-by-case basis. Member States taking such measures shall inform the other Member States and the Commission without undue delay and give reasons for the measures taken.

*Amendment*

Member States may take additional measures to the ones set out in their national SoHO emergency plans to ensure critical SoHOs supply in case of shortages on their territory, on a case-by-case basis. Member States taking such measures shall inform the other Member States and the Commission without undue delay and give reasons for the measures taken. ***Member States may also exercise their powers to develop national plans to increase donations or ensure the quality supply of SoHOs.***

Or. es

## Amendment 794

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

### Proposal for a regulation

#### Article 65 – paragraph 1

*Text proposed by the Commission*

Member States may take additional measures to the ones set out in their national SoHO emergency plans to ***ensure critical SoHOs*** supply in case of shortages

*Amendment*

Member States may take additional measures to the ones set out in their national SoHO ***plans to ensure continuity of SoHO supply, as well as in the national***

on their territory, *on a case-by-case basis*. Member States taking such measures shall inform the other Member States and the Commission without undue delay and give reasons for the measures taken.

*SoHO* emergency plans to *secure SoHO* supply, *especially* in case of shortages on their territory. Member States taking such measures shall inform the other Member States and the Commission without undue delay and give reasons for the measures taken.

Or. en

**Amendment 795**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 65 – paragraph 1**

*Text proposed by the Commission*

Member States may take additional measures to the ones set out in their national SoHO emergency plans to ensure critical SoHOs supply in case of shortages on their territory, on a case-by-case basis. Member States taking such measures shall inform the other Member States and the Commission without undue delay and give reasons for the measures taken.

*Amendment*

Member States may take additional measures to the ones set out in their national SoHO emergency plans to ensure critical SoHOs supply in case of shortages on their territory, on a case-by-case basis. Member States taking such measures shall inform the other Member States, *the SCB* and the Commission without undue delay and give reasons for the measures taken.

Or. en

**Amendment 796**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Article 65 – paragraph 1**

*Text proposed by the Commission*

Member States *may* take additional measures to the ones set out in their national SoHO emergency plans to ensure critical SoHOs *supply in case of shortages on their territory, on a case-by-case basis*. Member States taking such measures shall inform the other Member States and the Commission without undue delay and give

*Amendment*

Member States *shall* take additional measures to the ones set out in their national SoHO emergency plans to ensure *availability of* critical SoHOs, *such as the creation of national plans to increase donations*. Member States taking such measures shall inform the other Member States and the Commission without undue

reasons for the measures taken.

delay and give reasons for the measures taken

Or. en

*Justification*

*The addition of the requirement to develop emergency measures to address supply of SoHOs introduced by the proposal for a Regulation is a positive step to improve the resiliency of the supply chain. However, this alone will be insufficient to address Europe's longstanding reliance*

*on third countries to ensure sufficiency of supply of certain SoHOs, for instance, plasma for further manufacture. This amendment aims to improve the EU's strategic autonomy by encouraging*

*Member States to be more ambitious and to establish national plans to increase SoHO donations.*

**Amendment 797**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 65 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 65 a**

***Plans to ensure continuity of supply to SOHO entities***

***SoHO entities carrying out SoHO activities related to critical SoHOs shall have in place a plan to ensure continuity of supply of its own entity that supports the implementation of the national SoHO continuity of supply plan referred to in Article 61 (a).***

Or. en

**Amendment 798**

Stanislav Polčák

**Proposal for a regulation**  
**Article 67 – paragraph 2**

*Text proposed by the Commission*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board *may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate.* Other Union institutions, bodies, offices and agencies shall have an observer role.

*Amendment*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board ***shall, in agreement with the Commission, invite representatives of the industry, including both the public and private sector, as well as consumers, patients and health professionals, to participate in certain aspects of the Board's work, under conditions determined beforehand by the Board.*** Other Union institutions, bodies, offices and agencies shall have an observer role.

Or. en

**Amendment 799**  
**Alexandr Vondra**

**Proposal for a regulation**  
**Article 67 – paragraph 2**

*Text proposed by the Commission*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board *may*

*Amendment*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board

*also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate.*

Other Union institutions, bodies, offices and agencies shall have an observer role.

*shall, in agreement with the Commission, invite representatives of the industry, including both the public and private sector, as well as consumers, patients and health professionals, to participate in certain aspects of the Board's work, under conditions determined beforehand by the Board.* Other Union institutions, bodies, offices and agencies shall have an observer role.

Or. en

## **Amendment 800**

**Aldo Patriciello, Salvatore De Meo**

### **Proposal for a regulation**

#### **Article 67 – paragraph 2**

##### *Text proposed by the Commission*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board *may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate.* Other Union institutions, bodies, offices and agencies shall have an observer role.

##### *Amendment*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board *shall, in agreement with the Commission, invite representatives of the industry, including both the public and private sector, as well as consumers, patients and health professionals, to participate in certain aspects of the Board's work, under conditions determined beforehand by the Board.* Other Union institutions, bodies, offices and agencies shall have an observer role.

Or. en

## **Amendment 801**

**Giuseppe Ferrandino**

**Proposal for a regulation**  
**Article 67 – paragraph 2**

*Text proposed by the Commission*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board *may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate.* Other Union institutions, bodies, offices and agencies shall have an observer role.

*Amendment*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board *shall, in agreement with the Commission, invite representatives of the industry, including both the public and private sector, as well as consumers, patients and health professionals, to participate in certain aspects of the Board's work, under conditions determined beforehand by the Board.* Other Union institutions, bodies, offices and agencies shall have an observer role.

Or. en

*Justification*

*It is key that provisions and guidelines that will be developed, are based on the latest evidence and science. To that end, it is critical to ensure that all stakeholders are involved in the development and consultation of provisions and guidelines. Therefore, designated expert bodies should follow the stakeholder engagement principles of the EMA. . . This will ensure an open and constructive dialogue with the involvement of stakeholders with relevant expertise and understanding in standards of quality and safety for substances of human origin.*

**Amendment 802**

**Véronique Trillet-Lenoir, Max Orville, Susana Solís Pérez**

**Proposal for a regulation**  
**Article 67 – paragraph 2**

*Text proposed by the Commission*

2. Each Member State shall nominate

*Amendment*

2. Each Member State shall nominate

two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices **and agencies shall** have an observer role.

two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, **agencies**, bodies, offices **or services shall** have an observer role. ***The European Parliament shall designate a technical representative to participate in the SoHO Coordination Board as an observer.***

Or. en

**Amendment 803**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Article 67 – paragraph 2**

*Text proposed by the Commission*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board **may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate.** Other Union institutions, bodies, offices and agencies shall have an observer role.

*Amendment*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board **shall, in agreement with the Commission, permanently invite patients, consumers, and health professionals as well as representatives of the industry, to participate in certain aspects of the Board's work, under conditions determined beforehand by the Board.** Other Union institutions, bodies, offices



and agencies shall have an observer role.

Or. en

*Justification*

*It is key that provisions and guidelines that will be developed, are based on the latest evidence and science. To that end, it is critical to ensure that all stakeholders are involved in the development and consultation of provisions and guidelines.*

**Amendment 804**

**Pernille Weiss**

**Proposal for a regulation**

**Article 67 – paragraph 2**

*Text proposed by the Commission*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board *may also* invite experts and *observers* to attend its meetings, *and may* cooperate *with other external experts as appropriate*. Other Union institutions, bodies, offices and agencies shall have an observer role.

*Amendment*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board *shall, where relevant,* invite experts and *other relevant stakeholders* to attend its meetings *and to* cooperate *on aspects of its work. Such stakeholders may include actors of the public and private sector, patients, health professionals, and researchers*. Other Union institutions, bodies, offices and agencies shall have an observer role.

Or. en

**Amendment 805**

**Cristian-Silviu Buşoi**

**Proposal for a regulation**

**Article 67 – paragraph 2**

*Text proposed by the Commission*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board **may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate.** Other Union institutions, bodies, offices and agencies shall have an observer role.

*Amendment*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board **shall, in agreement with the Commission, invite representatives of different stakeholders, including industry representatives, to participate in certain aspects of the Board's work, under conditions determined beforehand by the Board.** Other Union institutions, bodies, offices and agencies shall have an observer role.

Or. en

**Amendment 806**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 67 – paragraph 2**

*Text proposed by the Commission*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies shall have an observer role.

*Amendment*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate, **in order to ensure a multidisciplinary and diverse representation of stakeholders in the**

**SoHO sector.** Other Union institutions, bodies, offices and agencies shall have an observer role.

Or. en

### **Amendment 807**

**Andreas Glück, Ondřej Knotek, Véronique Trillet-Lenoir, Peter Liese**

#### **Proposal for a regulation**

#### **Article 67 – paragraph 2**

##### *Text proposed by the Commission*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies shall have an observer role.

##### *Amendment*

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board may also invite experts, **stakeholders** and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, **particularly the ones defining boardelines with other legislation**, shall have an observer role.

Or. en

### **Amendment 808**

**Tilly Metz**

#### **Proposal for a regulation**

#### **Article 67 – paragraph 2 a (new)**

##### *Text proposed by the Commission*

##### *Amendment*

**2 a. Permanent and alternate members of the SCB shall act independently, in the public interest and free from any external influence. SCB permanent and alternate**

*members shall have no direct or indirect economic, financial or personal interest that might be considered prejudicial to their independence and, in particular, that they are not in a situation that may, directly or indirectly, affect the impartiality of their professional conduct. Permanent and alternate members of the SCB shall make an annual declaration of their interests, which shall be available in the EU SoHO Platform.*

Or. en

### **Amendment 809**

**Véronique Trillet-Lenoir, Max Orville, Susana Solís Pérez**

#### **Proposal for a regulation**

#### **Article 67 – paragraph 3**

*Text proposed by the Commission*

3. Member States shall submit the names and affiliation of their nominated members to the Commission, who shall publish the membership list in the EU SoHO Platform.

*Amendment*

3. Member States shall submit the names and affiliation of their nominated members to the Commission, who shall publish the membership list in the EU SoHO Platform. *The list setting out the authorities, organisations or bodies to which the SoHO Coordination Board participants belong shall be published on the Commission's website.*

Or. en

### **Amendment 810**

**Tilly Metz**

#### **Proposal for a regulation**

#### **Article 67 – paragraph 3**

*Text proposed by the Commission*

3. Member States shall submit the names and affiliation of their nominated members to the Commission, who shall **publish** the membership list in the EU

*Amendment*

3. Member States shall submit the names and affiliation of their nominated members to the Commission, who shall **make** the membership list **publicly**

SoHO Platform.

*available* in the EU SoHO Platform.

Or. en

#### **Amendment 811**

**Tilly Metz**

#### **Proposal for a regulation**

#### **Article 67 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

**3 a. The Commission shall make publicly available SCB agendas, minutes and guidance documents on the EU SoHO Platform.**

Or. en

#### **Amendment 812**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation**

#### **Article 67 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

4. The Commission shall *chair the meetings of* the SCB. The chair shall not take part in votes of the SCB.

**4. The Board shall be co-chaired by a representative of the Commission and by one rotating representative of the Member States, who shall be elected by and from among the representatives of the Member States in the SCB.** The chair shall not take part in votes of the SCB.

Or. en

#### **Amendment 813**

**Tilly Metz**

#### **Proposal for a regulation**

#### **Article 67 – paragraph 6 – point j**

*Text proposed by the Commission*

(j) the rules for declarations regarding conflict of interests of invited experts;

*Amendment*

(j) the rules for declarations regarding conflict of interests of **SCB members, alternates, observers and** invited experts;

Or. en

**Amendment 814**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 67 – paragraph 6 – point k a (new)**

*Text proposed by the Commission*

*Amendment*

**(k a) make available to the public a summary of the topics discussed at the meetings.**

Or. en

**Amendment 815**

**Tilly Metz**

**Proposal for a regulation**

**Article 67 – paragraph 7 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

The Commission shall, by means of **implementing** acts, adopt the necessary measures for the establishment, management and functioning of the SCB.

The Commission shall, by means of **delegated** acts, adopt the necessary measures for the establishment, management and functioning of the SCB.

Or. en

**Amendment 816**

**Tilly Metz**

**Proposal for a regulation**

**Article 67 – paragraph 7 – subparagraph 2**

*Text proposed by the Commission*

Those **implementing** acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

*Amendment*

Those **delegated** acts shall be adopted in accordance with the examination procedure referred to in Article 77.

Or. en

#### **Amendment 817**

**Véronique Trillet-Lenoir, Max Orville, Susana Solís Pérez**

#### **Proposal for a regulation**

**Article 67 – paragraph 7 a (new)**

*Text proposed by the Commission*

*Amendment*

**7 a. The rules of procedure, guidance, agendas and minutes of the meetings of the the SoHO Coordination Board shall be published on the Commission's website unless such publication undermines the protection of a public or private interest, as defined in Article 4 of Regulation (EC) No 1049/2001.**

Or. en

#### **Amendment 818**

**Kateřina Konečná**

#### **Proposal for a regulation**

**Article 67 a (new)**

*Text proposed by the Commission*

*Amendment*

#### **Article 67 a**

**European and national SoHO strategies**

**1. The European Commission shall publish a European strategy to increase SoHO sufficiency in the European Union within 2 years following the adoption of this regulation, with ambitious targets per SoHO sector, to be set by the European Commission in discussion with national competent authorities, the European**

*Parliament, professional scientific associations, patients' organizations and other relevant stakeholders. The strategy shall be reviewed every 5 years.*

*2. Member States shall develop national strategic plans addressing the sufficiency of supply of SoHO. The plans shall set strategic objectives proportionate to each Member State's needs. They should be adopted within 2 years following the adoption of this regulation and must be reviewed every 5 years. The plans shall include recommendations to SoHO establishments and entities on issues such as: efficiency of collection, recruitment and retention of a large donor population through education and communication programs, donor care.*

Or. en

#### *Justification*

*Europe is currently dependent on third countries for some SoHO, to varying degrees but that in some case is almost half of the substances required as is the case for plasma. This puts the EU, and the concerned patients in particular, in a very fragile situation. This situation has been acknowledged by the European Commission and the European Parliament. Only through concerted action, with EU objectives and Member State-specific measures, can the EU collectively address this challenge.*

#### **Amendment 819**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation**

#### **Article 68 – paragraph 1 – point a**

##### *Text proposed by the Commission*

(a) preparing opinions at the request of competent authorities in accordance with Article **14(2) first sub-paragraph**, on the regulatory status under this Regulation of a substance, product or activity and transmitting its opinions to the compendium;

##### *Amendment*

(a) ***in collaboration with other authorities designated in other relevant Union legislation***, preparing opinions at the request of competent authorities in accordance with Article **14(1)**, on the regulatory status under this Regulation of a substance, product or activity and transmitting its opinions to the



compendium;

Or. en

#### **Amendment 820**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation**

#### **Article 68 – paragraph 1 – point b**

*Text proposed by the Commission*

(b) when preparing the opinions referred to in point (a) of this paragraph, ***initiating, at Union level, a consultation with equivalent advisory bodies established in other relevant Union legislation in accordance with Article 14(2) second sub-paragraph, and including in the compendium the opinions concerning the Union legislation to be applied in cases where there is agreement with the equivalent advisory bodies;***

*Amendment*

(b) when preparing the opinions referred to in point (a) of this paragraph, ***participate in the Classification Advisory Council as defined in Article 68 (a);***

Or. en

#### **Amendment 821**

**Susana Solís Pérez, Ondřej Knotek, Véronique Trillet-Lenoir**

#### **Proposal for a regulation**

#### **Article 68 – paragraph 1 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

***(b a) participating in the permanent panel referred to in Article 14(2 a) and in the procedure referred to in that paragraph.***

Or. en

*Justification*

*Coherence with the introduction of the joint EMA-SCB panel for a unified and science-based approach in borderline classification cases.*

## **Amendment 822**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

### **Proposal for a regulation**

#### **Article 68 – paragraph 1 – point d**

*Text proposed by the Commission*

(d) recording information notified in accordance with Article **14(3)**, and including such information in the compendium;

*Amendment*

(d) recording information notified in accordance with Article **14(2)**, and including such information in the compendium;

Or. en

## **Amendment 823**

**Alexandr Vondra, Joanna Kopcińska**

### **Proposal for a regulation**

#### **Article 68 – paragraph 1 – point e**

*Text proposed by the Commission*

(e) liaising for the exchange of experience and good practices, as relevant, with the EDQM and the ECDC regarding technical standards, and with the EMA on authorisations and supervisory activities concerning the implementation of the PMF certification pursuant to Directive 2003/63/EC, to support the harmonised implementation of standards and technical guidelines;

*Amendment*

(e) liaising for the exchange of experience and good practices, as relevant, with the EDQM and the ECDC regarding technical standards ***within their respective areas of expertise***, and with the EMA on authorisations and supervisory activities concerning the implementation of the PMF certification pursuant to Directive 2003/63/EC, to support the harmonised implementation of standards and technical guidelines;

Or. en

## **Amendment 824**

**Tilly Metz**

### **Proposal for a regulation**

#### **Article 68 – paragraph 1 – point f a (new)**

*Text proposed by the Commission*

*Amendment*

***(f a) ensuring coordination regarding supply continuity and sufficiency of critical SoHOs;***

Or. en

**Amendment 825**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 68 – paragraph 1 – point g a (new)**

*Text proposed by the Commission*

*Amendment*

***(g a) in the event of a SoHO-related health emergency or for the purpose of preventing potential threats, collaborate with the Commission, the Advisory Committee on Public Health Emergencies and the ECDC, as established in Regulation (EU) 2022/2371, on serious cross-border threats to health.***

Or. en

*(Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU)*

**Amendment 826**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 68 a (new)**

*Text proposed by the Commission*

*Amendment*

***Article 68 a***

***Classification Advisory Council***

***1. The Classification Advisory Council is hereby established to assist the Member States and the Commission in determining the regulatory status of a substance,***

*product or activity covered by this Regulation, as referred to in Article 14(4). The Classification Advisory Council shall prepare opinions on the regulatory status of a substance, product or activity covered by this Regulation at the request of the competent authorities or the European Commission in accordance with Article 14(2).*

*2. The Classification Advisory Council shall be composed of representatives of the SCB, the EMA and the Medical Devices Coordination Group (MDCG). The members of the Classification Advisory Council shall be appointed based on their specific expertise including, for the EMA in particular, expertise in the area of medicinal products and advanced therapies.*

*3. The Commission shall provide the secretariat of the Classification Advisory Council in accordance with Article 72. The secretariat of the Classification Advisory Council shall collaborate with the SCB in maintaining the compendium.*

*4. The rules of procedure of the Classification Advisory Council proposed by the Commission shall, in particular, lay down the procedures for:*

*(a) meeting scheduling;*

*(b) reaching consensus and voting;*

*(c) the adoption of opinions or other positions, including in cases of urgency;*

*(d) requesting advice to the Classification Advisory Council, including eligibility criteria for requests for advice to the Classification Advisory Council, and for other communications with the Classification Advisory Council;*

*(e) invitation of experts to take part in the work of the Classification Advisory Council on the basis of their experience and knowledge;*

*(f) the rules for declarations regarding conflict of interests of invited experts;*

***(g) make available to the public a summary of the topics discussed at the meetings.***

***5. The Commission shall, by means of implementing acts, adopt the measures necessary for the establishment, management and functioning of the Classification Advisory Council. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).***

Or. en

**Amendment 827**  
**Véronique Trillet-Lenoir, Max Orville**

**Proposal for a regulation**  
**Article 68 a (new)**

*Text proposed by the Commission*

*Amendment*

***Article 68 a***

***New Article-Transparency and conflict of interest***

***1. The SoHO Coordination Board shall carry out its activities in an independent, impartial and transparent manner and shall undertake to act in the public interest.***

***2. Representatives appointed to the SoHO Coordination Board and, where relevant, observers shall not have any financial or other interests which might be considered prejudicial to their independence.***

***3. The representatives appointed to the SoHO Coordination Board and, where relevant, observers shall make a declaration of their financial and other interests and update them annually and whenever necessary. They shall disclose any other facts of which they become aware that might in good faith reasonably be expected to involve or give rise to a conflict of interest.***

*4. Representatives who participate in meetings of the SoHO Coordination Board and, where relevant, observers, shall declare, before each meeting, any interests which could be considered to be prejudicial to their independence or impartiality with regard to the items on the agenda.*

*5. Where the Commission decides that a representative's declared interest constitutes a conflict of interest, that representative shall not take part in any discussions or decisions, nor shall that representative obtain any information concerning that item of the agenda. Such declarations of representatives and the decision of the Commission shall be recorded in the summary minutes of the meeting.*

*6. Representatives who participate in meetings of the SoHO Coordination Board, and, where relevant, observers shall be subject to requirements of professional secrecy, even after their duties have ceased.*

Or. en

**Amendment 828**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 69 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

The Commission shall organise Union training in cooperation with the Member States *concerned*.

*Amendment*

The Commission shall organise Union training in cooperation with the Member States.

Or. en

**Amendment 829**

**Joanna Kopcińska**

**Proposal for a regulation**  
**Article 70 – paragraph 1 – introductory part**

*Text proposed by the Commission*

1. The Commission shall perform controls, including audits, in the Member States to verify the effective application of the requirements relating to:

*Amendment*

1. The Commission, ***with the agreement of the Member State and in duly justified cases***, shall perform controls, including audits, in the Member States to verify the effective application of the requirements relating to:

Or. pl

**Amendment 830**  
**Mathilde Androuët**

**Proposal for a regulation**  
**Article 70 – paragraph 1 – introductory part**

*Text proposed by the Commission*

1. The Commission ***shall*** perform controls, including audits, ***in the*** Member States to verify the effective application of the requirements relating to:

*Amendment*

1. The Commission ***may*** perform controls, including audits, ***at the request of*** Member States to verify the effective application of the requirements relating to:

Or. fr

**Amendment 831**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 71 – paragraph 1**

*Text proposed by the Commission*

The Commission shall establish and maintain cooperation with the EDQM in relation to the guidelines published by the EDQM.

*Amendment*

The Commission shall establish and maintain cooperation with the EDQM in relation to the guidelines published by the EDQM. ***In order to ensure impartiality and independence and safeguard public interest, the Commission shall establish a memorandum of understanding with the EDQM related to high standards of***

*transparency of membership and outputs and conflict of interest rules for experts and stakeholders involved in drafting of EDQM guidelines. The Commission shall make publicly available in the EU SoHO Platform a list of all members, experts and stakeholders involved in EDQM committees and their conflict of interest declarations.*

Or. en

#### **Amendment 832**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

#### **Proposal for a regulation Article 71 – paragraph 1**

*Text proposed by the Commission*

The Commission shall establish and maintain cooperation with the EDQM in relation to the guidelines published by the EDQM.

*Amendment*

The Commission shall establish and maintain cooperation with the EDQM in relation to the guidelines published by the EDQM. *Such cooperation shall be based on the highest scientific standards, be proactive in identifying future needs and be transparent, involving the relevant stakeholders in consultations related to the development of the technical guidelines.*

Or. en

#### **Amendment 833 Kateřina Konečná**

#### **Proposal for a regulation Article 71 – paragraph 1**

*Text proposed by the Commission*

The Commission shall establish and maintain cooperation with the EDQM in relation to the guidelines published by the EDQM.

*Amendment*

The Commission shall establish and maintain cooperation with the EDQM in relation to the guidelines published by the EDQM. *Such cooperation shall occur by*



*respecting the autonomy of EU legislation and shall take into account EU principles on transparency and stakeholder participation.*

Or. en

**Amendment 834**  
**Alexandr Vondra, Joanna Kopcińska**

**Proposal for a regulation**  
**Article 71 – paragraph 1**

*Text proposed by the Commission*

The Commission shall establish and maintain cooperation with the EDQM in relation to the guidelines published by the EDQM.

*Amendment*

The Commission shall establish and maintain cooperation with the EDQM in relation to the guidelines published by the EDQM. *Such cooperation is without prejudice to the autonomy of Union law and should take into account Union principles on transparency and stakeholder participation.*

Or. en

**Amendment 835**  
**Mathilde Androuët**

**Proposal for a regulation**  
**Article 71 – paragraph 1**

*Text proposed by the Commission*

The **Commission shall** establish and maintain cooperation with the EDQM in relation to the guidelines published by the EDQM.

*Amendment*

The **Member States may** establish and maintain cooperation with the EDQM in relation to the guidelines published by the EDQM.

Or. fr

**Amendment 836**  
**Mathilde Androuët**

**Proposal for a regulation**  
**Article 71 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***The Commission shall ensure that those guidelines reflect the interests of Member States and, where appropriate, may adopt implementing acts laying down standards in line with those interests.***

Or. fr

**Amendment 837**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**  
**Article 71 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***The Commission shall evaluate the transparency in the procedures and development of the technical guidelines by the EDQM and their suitability to the needs and interests of the Member States.***

Or. en

**Amendment 838**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**  
**Article 72 – paragraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

(a) providing secretariat and technical, scientific and logistic support to the SCB and its working groups;

(a) providing secretariat and technical, scientific and logistic support to the SCB and its working groups ***and to the Classification Advisory Council;***

Or. en

### Amendment 839

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

#### Proposal for a regulation

##### Article 72 – paragraph 2

*Text proposed by the Commission*

2. With regard to the support referred to in paragraph 1, point (a), the Commission shall, in particular, organise the meetings of the SCB and its working groups, the travel of members of the SCB, reimbursement and special allowances for scientific experts that participate in those meetings, and ensure the appropriate follow-up.

*Amendment*

2. With regard to the support referred to in paragraph 1, point (a), the Commission shall, in particular, organise the meetings of the SCB and its working groups **and of the Classification Advisory Council**, the travel of members of the SCB **and the Classification Advisory Council** reimbursement and special allowances for scientific experts that participate in those meetings, and ensure the appropriate follow-up.

Or. en

### Amendment 840

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

#### Proposal for a regulation

##### Article 73 – paragraph 1

*Text proposed by the Commission*

1. The Commission shall establish, manage and maintain the EU SoHO Platform to facilitate effective and efficient exchange of information concerning SoHO activities in the Union, as provided for in this Regulation.

*Amendment*

1. The Commission shall establish, manage and maintain the EU SoHO Platform to facilitate effective and efficient exchange, **registration and storage** of information concerning SoHO activities in the Union, as provided for in this Regulation. **To ensure optimal use of the EU SoHO Platform, the Commission shall:**

Or. en

## **Amendment 841**

**Tilly Metz**

### **Proposal for a regulation**

#### **Article 73 – paragraph 1**

*Text proposed by the Commission*

1. The Commission shall establish, manage and maintain the EU SoHO Platform to facilitate effective and efficient exchange of information concerning SoHO activities in the Union, as provided for in this Regulation.

*Amendment*

1. The Commission shall establish, manage and maintain the EU SoHO Platform to facilitate effective and efficient exchange of information concerning SoHO activities ***and supply of critical SoHOs*** in the Union, as provided for in this Regulation.

Or. en

## **Amendment 842**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

### **Proposal for a regulation**

#### **Article 73 – paragraph 1 – point a (new)**

*Text proposed by the Commission*

*Amendment*

***(a) develop the technical and functional specifications of the EU SoHO Platform, including the data exchange mechanism for the exchange with existing national systems and the format for electronic submission;***

Or. en

## **Amendment 843**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

### **Proposal for a regulation**

#### **Article 73 – paragraph 1 – point b (new)**

*Text proposed by the Commission*

*Amendment*

***(b) verify that the data sent to the EU***

*SoHO Platform are compatible with it;*

Or. en

**Amendment 844**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 73 – paragraph 1 – point c (new)**

*Text proposed by the Commission*

*Amendment*

***(c) develop relevant guidance for reporting through the EU SoHO Platform;***

Or. en

**Amendment 845**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 73 – paragraph 1 – point d (new)**

*Text proposed by the Commission*

*Amendment*

***(d) ensure data interoperability between the EU SoHO Platform, Member States' IT systems and other relevant IT systems and databases, such as the EMA's European Shortages Monitoring Platform or systems defined in the European Health Data Space, without duplication of reporting;***

Or. en

**Amendment 846**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 73 – paragraph 1 – point e (new)**

*Text proposed by the Commission*

*Amendment*

**(e) ensure that the Commission, national authorities and competent authorities, SoHO entities, SCB, ECDC, EMA, EDQM and other relevant bodies have adequate levels of access to the information contained in the EU SoHO Platform to carry out their tasks;**

Or. en

**Amendment 847**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 73 – paragraph 1 – point f (new)**

*Text proposed by the Commission*

*Amendment*

**(f) ensure that confidential information sent to the system is protected from unjustified disclosure;**

Or. en

**Amendment 848**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 73 – paragraph 1 – point g (new)**

*Text proposed by the Commission*

*Amendment*

**(g) ensure that the EU SoHO Platform is fully operational at the latest 2 years after the entry into force of this Regulation, and develop an implementation plan for the Platform.**

Or. en

**Amendment 849**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 73 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1 a. Information collected through the EU SoHO Platform on SoHO shortage alerts, SoHO shortages and demand trends, cross-border SoHO requests and resolutions, or import and export of SoHO to third countries outside the EU will be used for the monitoring, prevention and management of SoHO shortages in the EU, as well as to enhance the EU SoHO autonomy, as part of the plan defined in Article 62 (a).***

Or. en

**Amendment 850**

**Joanna Kopcińska**

**Proposal for a regulation**

**Article 73 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

***4. The Commission shall adopt delegated acts in accordance with Article 77 supplementing this Regulation by laying down technical specifications regarding the establishment, management and maintenance of the EU SoHO Platform.***

***deleted***

Or. pl

*Justification*

*The Commission has not defined the scope of data to be collected by the SoHO platform. The scope of the delegated act is therefore too broad.*

## Amendment 851

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

### Proposal for a regulation

#### Article 74 – paragraph 2

*Text proposed by the Commission*

2. The EU SoHO platform shall also provide a secure environment for the exchange of information between competent authorities **and** the Commission, in particular in relation to SAO and rapid alerts. ***It shall also provide public access to information regarding the registration and authorisation status of SoHO entities and shall indicate the applicable guidelines to be followed to meet the technical standards laid down in Articles 56 and 59.***

*Amendment*

2. The EU SoHO platform shall also provide a secure environment for the exchange of information between competent authorities, the Commission **and the EMA, the ECDC, the SCB and EDQM**, in particular in relation to SAO and rapid alerts.

Or. en

## Amendment 852

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

### Proposal for a regulation

#### Article 74 – paragraph 2 a (new)

*Text proposed by the Commission*

*Amendment*

***2 a. The EU SoHO Platform shall also be the main intermediary for reporting SoHO shortages and for cross-border requests of SoHO. National authorities shall issue and receive shortage alerts that cannot be resolved at Member State level, as well as SoHO cross-border requests and shall be able to respond to them. National authorities, aware of the national availability of SoHO, as referred to in Article 34(a), shall use the EU SoHO Platform to report any SoHO shortages that may lead to a public health***



*emergency or severe occurrence.*

Or. en

**Amendment 853**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 74 – paragraph 2 b (new)**

*Text proposed by the Commission*

*Amendment*

***2 b. In the event of a SoHO-related health emergency or for the purpose of preventing potential threats, alerts issued through the EU SoHO Platform shall allow for rapid situational awareness by the Commission, competent authorities and other relevant bodies so that action can be taken as soon as possible as set out in Regulation (EU) 2022/2371 on serious cross-border threats to health.***

Or. en

**Amendment 854**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 74 – paragraph 2 c (new)**

*Text proposed by the Commission*

*Amendment*

***2 c. It shall also provide public access to information regarding the registration and authorisation status of SoHO entities and shall indicate the applicable guidelines to be followed to meet the technical standards laid down in Articles 56 and 59.***

Or. en

**Amendment 855**

**Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation**

**Article 74 – paragraph 2 d (new)**

*Text proposed by the Commission*

*Amendment*

**2 d. The EU SoHO Platform shall contain a record of clinical studies with SoHO and their results, as referred to in Article 36 (a).**

Or. en

**Amendment 856**

**Alexandr Vondra**

**Proposal for a regulation**

**Article 74 – paragraph 3 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

The Commission shall adopt implementing acts laying down technical specifications for the EU SoHO Platform, including its functions, the roles and responsibilities of each of the parties listed in paragraph 1, the retention periods for personal data and the technical and organisational measures to ensure the safety and security of personal data processed.

The Commission shall adopt implementing acts **to ensure uniformity, compatibility and comparability** laying down technical specifications for the EU SoHO Platform, including its functions, the roles and responsibilities of each of the parties listed in paragraph 1, the retention periods for personal data and the technical and organisational measures to ensure the safety and security of personal data processed.

Or. en

**Amendment 857**

**Tilly Metz**

**Proposal for a regulation**

**Article 74 – paragraph 3 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

The Commission shall adopt ***implementing*** acts laying down technical specifications for the EU SoHO Platform, including its functions, the roles and responsibilities of each of the parties listed in paragraph 1, the retention periods for personal data and the technical and organisational measures to ensure the safety and security of personal data processed.

The Commission shall adopt ***delegated*** acts laying down technical specifications for the EU SoHO Platform, including its functions, the roles and responsibilities of each of the parties listed in paragraph 1, the retention periods for personal data and the technical and organisational measures to ensure the safety and security of personal data processed.

Or. en

#### **Amendment 858**

**Tilly Metz**

#### **Proposal for a regulation**

#### **Article 74 – paragraph 3 – subparagraph 2**

*Text proposed by the Commission*

Those ***implementing*** acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

*Amendment*

Those ***delegated*** acts shall be adopted in accordance with the examination procedure referred to in Article 77.

Or. en

#### **Amendment 859**

**Tilly Metz**

#### **Proposal for a regulation**

#### **Article 75 – paragraph 1 – introductory part**

*Text proposed by the Commission*

1. Unless otherwise provided for in this Regulation ***or in national legislation on confidentiality***, and without prejudice to Regulation (EC) No 1049/2001 of the European Parliament and of the Council<sup>33</sup>, each party involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:

*Amendment*

1. Unless otherwise provided for in this Regulation, and without prejudice to Regulation (EC) No 1049/2001 of the European Parliament and of the Council<sup>33</sup>, each party involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:

<sup>33</sup> Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

<sup>33</sup> Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

Or. en

**Amendment 860**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 75 – paragraph 1 – point a**

*Text proposed by the Commission*

(a) personal data in accordance with Article 76;

*Amendment*

(a) ***natural persons with regard to the processing of*** personal data in accordance with Article 76;

Or. en

*Justification*

*Data Protection does not protect the data, but “natural persons with regard to the processing of personal data” - as copied from the title of the GDPR.*

**Amendment 861**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 75 – paragraph 3**

*Text proposed by the Commission*

3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and competent authorities with regard to the exchange of information and the dissemination of alerts, nor the obligations of persons to provide information under national criminal law.

*Amendment*

3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and competent authorities with regard to the exchange of information and the dissemination of alerts, nor the obligations of persons to provide information under national criminal law ***or other applicable law, including on access to information.***

*Justification*

*It could also be administrative law, or EU legislation like the Data Act (still in the making).*

**Amendment 862**

**Tilly Metz**

**Proposal for a regulation**

**Article 75 – paragraph 5 – introductory part**

*Text proposed by the Commission*

5. Competent authorities **may** publish or make otherwise available to the public the outcome of SoHO supervisory activities regarding individual SoHO entities provided that the following conditions are met:

*Amendment*

5. Competent authorities **shall** publish or make otherwise available to the public the outcome of SoHO supervisory activities regarding individual SoHO entities provided that the following conditions are met:

Or. en

**Amendment 863**

**Tilly Metz**

**Proposal for a regulation**

**Article 75 – paragraph 6 – point b**

*Text proposed by the Commission*

(b) the information or data made available to the public does not **unnecessarily** undermine the protection of commercial interests of a SoHO entity **or any other natural or legal person**;

*Amendment*

(b) the information or data made available to the public does not **disproportionately** undermine the protection of commercial interests of a SoHO entity;

Or. en

**Amendment 864**

**Tilly Metz**

**Proposal for a regulation**

**Article 76 – paragraph 3**

*Text proposed by the Commission*

3. Personal data, including data concerning health, required for the application of Articles 35, 36, 41 and 47, Article 53(1), points (f) and (g), Article 53(3), and Article 58(11), (13) and (14), shall only be processed for the purpose of ensuring safety and quality of SoHOs and protecting the concerned SoHO donors, SoHO recipients and offspring from medically assisted reproduction. Those data shall be directly related to the performance of the supervisory activities and SoHO activities concerned and be limited to the extent necessary and proportionate for that purpose.

*Amendment*

3. Personal data, including data concerning health, required for the application of Articles 35, 36, 41 and 47, Article 53(1), points (f) and (g), Article 53(3), and Article 58(11), (13) and (14), shall only be processed for the purpose of ensuring safety and quality of SoHOs and protecting the concerned SoHO donors, SoHO recipients and offspring from medically assisted reproduction. Those data shall be directly related to the performance of the supervisory activities and SoHO activities concerned and be limited to the extent necessary and proportionate for that purpose. ***The Commission shall adopt implementing acts laying down categories of personal data necessary to fulfilling the above listed obligations.***

***Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).***

Or. en

**Amendment 865**

**Tilly Metz**

**Proposal for a regulation**

**Article 76 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***3 a. Any re-use of personal data of SoHO donors, recipients and offspring born from medically assisted reproduction shall be provided in an anonymised format. Where, in duly justified cases, the purpose of the data processing cannot be achieved with anonymised data, pseudonymised data format may be used.***

Or. en

## Amendment 866

Tilly Metz

### Proposal for a regulation

#### Article 76 – paragraph 6

*Text proposed by the Commission*

6. In relation to their responsibilities to process personal data to comply with the obligations of this Regulation, the SoHO entities and competent authorities of the Member States shall be regarded as controllers as defined in Article 4, point (7), of Regulation (EU) 2016/679 and they are bound by the rules of that Regulation.

*Amendment*

6. In relation to their responsibilities to process personal data to comply with the obligations of this Regulation, the SoHO entities and competent authorities of the Member States shall be regarded as controllers as defined in Article 4, point (7), of Regulation (EU) 2016/679 and they are bound by the rules of that Regulation. ***The same provisions shall apply to any third party contracted by a SoHO entity for the processing of personal data, who shall be considered a processor as defined in Article 4, point (8) of the GDPR.***

Or. en

## Amendment 867

Tilly Metz

### Proposal for a regulation

#### Article 77 – paragraph 2

*Text proposed by the Commission*

2. The power to adopt delegated acts referred to in Articles 28(10), 42(3), 53(6), **58(15)**, 69(6), 73(4), and 76(8) shall be conferred on the Commission for an indeterminate period of time from ... [OP please insert the date = date of entry into force of this Regulation].

*Amendment*

2. The power to adopt delegated acts referred to in Articles **14(7)**, 28(10), 42(3), 53(6), **56(1)**, **58(15)**, **62(7)**, **62a(4)**, **67(7)**, 69(6), 73(4), **74(3)** and 76(8) shall be conferred on the Commission for an indeterminate period of time from ... [OP please insert the date = date of entry into force of this Regulation].

Or. en

## Amendment 868

Joanna Kopcińska

**Proposal for a regulation**  
**Article 77 – paragraph 2**

*Text proposed by the Commission*

2. The power to adopt delegated acts referred to in Articles 28(10), 42(3), **53(6)**, **58(15)**, **69(6)**, **73(4)**, and 76(8) shall be conferred on the Commission for an indeterminate period of time from ... [OP please insert the date = date of entry into force of this Regulation].

*Amendment*

2. The power to adopt delegated acts referred to in Articles 28(10), 42(3), **69(6)** and 76(8) shall be conferred on the Commission for an indeterminate period of time from ... [OP please insert the date = date of entry into force of this Regulation].

Or. pl

**Amendment 869**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 77 – paragraph 3**

*Text proposed by the Commission*

3. The delegation of power referred to in Articles 28(10), 42(3), 53(6), **58(15)**, 69(6), 73(4), and 76(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

*Amendment*

3. The delegation of power referred to in Articles **14(7)**, 28(10), 42(3), 53(6), **56(1)**, **58(15)**, **62(7)**, **62a(4)**, **67(7)**, 69(6), 73(4), **74(3)** and 76(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Or. en

**Amendment 870**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 80 – paragraph 1**



*Text proposed by the Commission*

Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, by ... [OP please insert the date = 3 years after the date of entry into force of this Regulation], notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

*Amendment*

Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, by ... [OP please insert the date = 2 years after the date of entry into force of this Regulation], notify the Commission **and the SCB** of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them. ***The Commissions shall make those provisions on penalties and their use publicly available on the EU SoHO Platform.***

Or. en

**Amendment 871**  
**Tilly Metz**

**Proposal for a regulation**  
**Article 84 – paragraph 1**

*Text proposed by the Commission*

Without prejudice to the dates of application referred to in Article 87 and the transitional provisions provided for in this Chapter, the Commission is empowered to adopt the delegated acts referred to in Articles 42(3) and 73(4) and the implementing acts referred to in Articles 26(4), 43(6), 44(3), 46(3), **67(7)** and 74(3) as from ... [OP please insert the date = one day after the date of entry into force of this Regulation]. Such acts shall apply from the date of application in accordance with Article 87(1), second subparagraph, without prejudice to any transitional rules provided for in this Chapter.

*Amendment*

Without prejudice to the dates of application referred to in Article 87 and the transitional provisions provided for in this Chapter, the Commission is empowered to adopt the delegated acts referred to in Articles 42(3), **67(7)** and 73(4) and the implementing acts referred to in Articles 26(4), 43(6), 44(3), 46(3) and 74(3) as from ... [OP please insert the date = one day after the date of entry into force of this Regulation]. Such acts shall apply from the date of application in accordance with Article 87(1), second subparagraph, without prejudice to any transitional rules provided for in this Chapter.

Or. en

**Amendment 872**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Article 86 – paragraph 1**

*Text proposed by the Commission*

The Commission shall, by ... [OP please insert the date = five years after the date of application of this Regulation] assess the application of this Regulation, produce an evaluation report on the progress towards achievement of the objectives of this Regulation and present the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.

*Amendment*

The Commission shall, by ... [OP please insert the date = five years after the date of application of this Regulation] assess the application of this Regulation, produce an evaluation report on the progress towards achievement of the objectives of this Regulation and present the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions. ***The Commission should publish every two years, starting with the date of the application of this Regulation, a progress report on the status of plasma collection in the EU, in order to evaluate the progress made on plasma collection as a critical SoHO at the EU level, to promote the exchange of best practices and relevant evidence and experience across Member States.***

Or. en

**Amendment 873**  
**Joanna Kopcińska**

**Proposal for a regulation**  
**Article 87 – paragraph 1 – subparagraph 2**

*Text proposed by the Commission*

Unless otherwise provided for in paragraph 2, it shall apply from ... [OP please insert the date = **two** years after the date of entry into force of this Regulation].

*Amendment*

Unless otherwise provided for in paragraph 2, it shall apply from ... [OP please insert the date = **three** years after the date of entry into force of this Regulation].

Or. pl

**Amendment 874**  
**Joanna Kopcińska**

**Proposal for a regulation**  
**Article 87 – paragraph 2 – subparagraph 1**

*Text proposed by the Commission*

Article 81(3) to (6) and Article 82(3) shall apply from ... [OP please insert the date = **three** years after the date of entry into force of this Regulation].

*Amendment*

Article 81(3) to (6) and Article 82(3) shall apply from ... [OP please insert the date = **four** years after the date of entry into force of this Regulation].

Or. pl