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Committee on the Environment, Public Health and Food Safety

2022/0216(COD)

14.3.2023

AMENDMENTS
118 - 327

Draft report
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 118
Mathilde Androuët

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) In accordance with Article 1 of the Charter of Fundamental Rights of the European Union, which states that 'human dignity is inviolable. It must be respected and protected,' and Article 3 of same, the quality and safety standards of SoHOs must respect the physical and mental integrity of the persons concerned, ensure SoHOs are donated with the free and informed consent of those persons and prohibit eugenic principles, financial gain from the human body or its parts and cloning,

Or. fr

Amendment 119
Margarita de la Pisa Carrión

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) In accordance with Article 168(1), first subparagraph, of the Treaty on the Functioning of the European Union (TFEU) and Article 35 of the Charter of Fundamental Rights of the European Union, a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.

Or. es

Amendment 120

Margarita de la Pisa Carrión

Proposal for a regulation
Recital 1 b (new)

Text proposed by the Commission	*Amendment*
	(1b) The scope of this regulation goes beyond the subject matters addressed in previous directives. Reproductive techniques and the use of SoHos as starting materials for medicinal products raise very complex questions that are tackled in a fragmented manner by the Member States in legal and ethical contexts. Both matters require ad hoc legislation that responds effectively to their specific nature.

Or. es

Amendment 121
Margarita de la Pisa Carrión

Proposal for a regulation
Recital 1 c (new)

Text proposed by the Commission	*Amendment*
	(1c) Reproductive techniques, tissue banks and pharmaceutical industries have specific characteristics that make it difficult to establish a common standard to provide the quality, safety and efficacy needed to ensure good practice in these areas.

Or. es

Amendment 122
Margarita de la Pisa Carrión

Proposal for a regulation
Recital 1 d (new)

Text proposed by the Commission	*Amendment*
	(1d) The development of legislation in the areas of reproductive techniques, tissue banks and pharmaceutical industries must reflect the importance of donation and the need for enhanced traceability because of their implications for health-related information and the existence of third parties.

Or. es

Amendment 123
Mathilde Androuët

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) As regards Article 168(4), point (a), TFEU, standards for the safety and quality of organs and SoHOs, blood and blood derivatives should ensure a high level of human health protection. Therefore, this Regulation aims at setting high standards by ensuring, amongst others, the protection of SoHO donors, taking into consideration their fundamental role in the provision of SoHOs and for recipients, as well as measures to monitor and support the sufficiency of the supply of SoHOs that are critical for the health of patients.	(3) As regards Article 168(4), point (a), TFEU, standards for the safety and quality of organs and SoHOs, blood and blood derivatives should ensure a high level of human health protection. Therefore, this Regulation aims at setting high standards by ensuring, amongst others, the protection of SoHO donors, taking into consideration their fundamental role in the provision of SoHOs and for recipients, as well as measures to monitor and support the sufficiency of the supply of SoHOs that are critical for the health of patients. ***In accordance with Article 3 of the Charter of Fundamental Rights of the European Union, these safety standards are based on the fundamental principle that the human body cannot be commercialised, which holds that no SoHO may be sold, as well as on the principle of the unavailability of the human body and the principle that the human body or parts thereof cannot be used for financial gain.***

Or. fr

Amendment 124
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) As regards Article 168(4), point (a), TFEU, standards for the safety and quality of organs and SoHOs, blood and blood derivatives should ensure a high level of human health protection. Therefore, this Regulation aims at setting high standards by ensuring, amongst others, the protection of SoHO donors, taking into consideration their fundamental role in the provision of SoHOs and for recipients, as well as measures to monitor and support the sufficiency of the supply of SoHOs that are critical for the health of patients.	(3) As regards Article 168(4), point (a), TFEU, standards for the safety and quality of organs and SoHOs, blood and blood derivatives should ensure a high level of human health protection. Therefore, this Regulation aims at setting high ***safety*** standards by ensuring, amongst others, the protection of SoHO donors, taking into consideration their fundamental role in the provision of SoHOs and for recipients, as well as measures to monitor and support the sufficiency of the supply of SoHOs that are critical for the health of patients.

Or. en

Amendment 125
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) Directives 2002/98/EC[16]and 2004/23/EC[17]of the European Parliament and of the Council constitute the Union's regulatory framework for blood and for tissues and cells, respectively. Although these Directives have harmonised to a certain degree the rules of Member States in the area of safety and quality of blood, tissues and cells, they include a significant number of options and possibilities for Member States to implement the rules they laid down. This results in divergences between national rules, which can create obstacles to cross-border sharing of these	(4) Directives 2002/98/EC[16]and 2004/23/EC[17]of the European Parliament and of the Council constitute the Union's regulatory framework for blood and for tissues and cells, respectively. Although these Directives have harmonised to a certain degree the rules of Member States in the area of safety and quality of blood, tissues and cells, they include a significant number of options and possibilities for Member States to implement the rules they laid down. This results in divergences between national rules, which can create obstacles to cross-border sharing of these

substances. A fundamental revision of those Directives is needed for a robust, transparent, up-to-date and sustainable regulatory framework for these substances, which achieves safety and quality for all parties involved, enhances legal certainty and supports continuous supply, whilst facilitating innovation for the benefit of public health. In order to achieve a coherent application of the legal framework, it is appropriate to repeal Directives 2002/98/EC and 2004/23/EC and to replace them by a Regulation.

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[16] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).

[17] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).

[16] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).

[17] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).

Or. en

Amendment 126
Mathilde Androuët

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) Directives 2002/98/EC[16]and 2004/23/EC[17]of the European Parliament and of the Council constitute the Union's regulatory framework for blood and for tissues and cells, respectively. Although these Directives have harmonised to a	(4) Directives 2002/98/EC[16]and 2004/23/EC[17]of the European Parliament and of the Council constitute the Union's regulatory framework for blood and for tissues and cells, respectively. Although these

certain degree the rules of Member States in the area of safety and quality of blood, tissues and cells, they include a significant number of options and possibilities for Member States to implement the rules they laid down. This results in divergences between national rules, which can create obstacles to ***cross-border***sharing ***of***these substances. A fundamental revision of those Directives is needed for a robust, transparent, up-to-date and sustainable regulatory framework for these substances, which achieves safety and quality for all parties involved, enhances legal certainty and supports continuous supply, whilst facilitating innovation for the benefit of public health. In order to achieve a coherent application of the legal framework, it is appropriate to repeal Directives 2002/98/EC and 2004/23/EC and to replace them by a Regulation.

Directives have harmonised to a certain degree the rules of Member States in the area of safety and quality of blood, tissues and cells, they include a significant number of options and possibilities for Member States to implement the rules they laid down. This results in divergences between national rules, which can create obstacles to sharing these substances. A fundamental revision of those Directives is needed for a robust, transparent, up-to-date and sustainable regulatory framework for these substances, which achieves safety and quality for all parties involved, enhances legal certainty and supports continuous supply, whilst facilitating innovation for the benefit of public health. In order to achieve a coherent application of the legal framework, it is appropriate to repeal Directives 2002/98/EC and 2004/23/EC and to replace them by a Regulation.

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[16] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).

[17] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).

[16] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).

[17] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).

Or. fr

Amendment 127
Mathilde Androuët

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) Directives 2002/98/EC and 2004/23/EC are highly interconnected and contain very similar provisions for oversight and equivalent principles for safety and quality in the two sectors they regulate. In addition, many authorities and operators work across these sectors. As this Regulation aims to define high level principles that will be common to both the blood and of tissues and cells sectors, it would be appropriate that it replaces these Directives and merges the revised provisions into one legal act.	(5) Directives 2002/98/EC and 2004/23/EC are highly interconnected and contain very similar provisions for oversight and equivalent principles for safety and quality in the two sectors they regulate. In addition, many authorities and operators work across these sectors. As this Regulation aims to define high level principles that will be common to both the blood and of tissues and cells sectors, it would be appropriate that it replaces these Directives and merges the revised provisions into one legal act***, with respect for the special characteristics of each of the substances recognised in the technical guidelines set out in this Regulation***.

Or. fr

Amendment 128
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Radka Maxová, Robert Hajšel

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) Directives 2002/98/EC and 2004/23/EC are highly interconnected and contain very similar provisions for oversight and equivalent principles for safety and quality in the two sectors they regulate. In addition, many authorities and operators work across these sectors. As this Regulation aims to define high level principles that will be common to both the blood and of tissues and cells sectors, it would be appropriate that it replaces these Directives and merges the revised provisions into one legal act.	(5) Directives 2002/98/EC and 2004/23/EC are highly interconnected and contain very similar provisions for oversight and equivalent principles for safety and quality in the two sectors they regulate. In addition, many authorities and operators work across these sectors. As this Regulation aims to define high level principles that will be common to both the blood and of tissues and cells sectors, it would be appropriate that it replaces these Directives and merges the revised provisions into one legal act***, taking into consideration the special characteristics of each type of substance***.

Or. en

Amendment 129
Mathilde Androuët

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) This Regulation should apply to blood and blood components, as regulated by Directive 2002/98/EC, as well as to tissues and cells, including haematopoietic peripheral blood, umbilical-cord blood and bone-marrow stem cells, reproductive cells and tissues, foetal tissues and cells ***and adult and*** embryonic stem cells, as regulated by Directive 2004/23/EC. Since donation and human application of SoHOs other than blood, tissues and cells are increasingly common, it is necessary to extend the scope of this Regulation to any SoHO, regardless of whether it meets the definition of 'blood', 'tissue' or 'cell', to avoid that certain groups of donors or recipients are not protected by an appropriate Union level quality and safety framework. This will, for example, ensure the protection of donors and recipients of human breast milk, intestinal microbiota, blood preparations that are not used for transfusion, and any other SoHO that may be applied to humans in the future.	(6) This Regulation should apply to blood and blood components, as regulated by Directive 2002/98/EC, as well as to tissues and cells, including haematopoietic peripheral blood, umbilical-cord blood and bone-marrow stem cells, reproductive cells and tissues, foetal tissues and cells ***derived solely from postnatal*** embryonic ***remnants and adult*** stem cells, as regulated by Directive 2004/23/EC. Since donation and human application of SoHOs other than blood, tissues and cells are increasingly common, it is necessary to extend the scope of this Regulation to any SoHO, regardless of whether it meets the definition of 'blood', 'tissue' or 'cell', to avoid that certain groups of donors or recipients are not protected by an appropriate Union level quality and safety framework. This will, for example, ensure the protection of donors and recipients of human breast milk, intestinal microbiota, blood preparations that are not used for transfusion, and any other SoHO that may be applied to humans in the future.

Or. fr

Amendment 130
Mathilde Androuët

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) Solid organs are excluded from the definition of SoHOs for the purposes of	(7) Solid organs are excluded from the definition of SoHOs for the purposes of

this Regulation and, thus, from its scope. Their donation and transplantation are significantly different and are regulated in a dedicated legal framework, set out in Directive 2010/53/EU[18]of the European Parliament and of the Council. Shortcomings have not been raised regarding the existing quality and safety provisions for organs. Nonetheless, when organs are removed from a donor for the purposes of separating tissues or cells for human application, for example heart valves from a heart or pancreatic islets from a pancreas, this Regulation should apply.	this Regulation and, thus, from its scope. Their donation and transplantation are significantly different and are regulated in a dedicated legal framework, set out in Directive 2010/53/EU of the European Parliament and of the Council[18]***, with the exception of blood-type conversions for the purposes of organ transplants***. Shortcomings have not been raised regarding the existing quality and safety provisions for organs. Nonetheless, when organs are removed from a donor for the purposes of separating tissues or cells for human application, for example heart valves from a heart or pancreatic islets from a pancreas, this Regulation should apply.
[18] Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p***. 14***).	[18] Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p***.14***).

Or. fr

Justification

With a view to limiting immune rejection reactions of transplanted organs among recipients, it is now possible to safely convert the blood type of organs intended for transplantation into type O - the universal donor type - by injecting enzymes that fight against the antigens that cause rejection, thus reducing the number of organs that go to waste and saving lives.

Amendment 131
Margarita de la Pisa Carrión

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) The EU shall further the development of a European SoHO sovereignty with a view to preventing dependency on third countries with regard to sectors and products of strategical importance for the EU.

Or. es

Amendment 132
Margarita de la Pisa Carrión

Proposal for a regulation
Recital 8 b (new)

Text proposed by the Commission	*Amendment*
	(8b) Every step must be taken to prevent the development or the EU playing a role in the development of a paid cell and tissue donation industry.

Or. es

Amendment 133
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Radka Maxová, Robert Hajšel

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(9) All SoHOs that are intended to be applied to humans fall within the scope of this Regulation. SoHOs can be prepared and stored in a variety of ways, becoming SoHO preparations, which can be applied to recipients. In these circumstances, this Regulation should apply to all activities from donor recruitment to human application and outcome monitoring. SoHOs or SoHO preparations can also be used to manufacture products regulated by other Union legislation, or as the starting and raw material thereof, in particular on medical devices, regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council[19], on medicinal products, regulated by Directive 2001/83/EC of the European Parliament and of the Council[20]and by Regulation (EC) No 726/2004 of the European	(9) All SoHOs that are intended to be applied to humans fall within the scope of this Regulation. SoHOs can be prepared and stored in a variety of ways, becoming SoHO preparations, which can be applied to recipients. In these circumstances, this Regulation should apply to all activities from donor recruitment to human application and outcome monitoring. SoHOs or SoHO preparations can also be used to manufacture products regulated by other Union legislation, or as the starting and raw material thereof, in particular on medical devices, regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council[19], on medicinal products, regulated by Directive 2001/83/EC of the European Parliament and of the Council[20]and by Regulation (EC) No 726/2004 of the European

Parliament and of the Council[21], including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007 of the European Parliament and of the Council[22], or on food, regulated by Regulation (EC) No 1925/2006 of the European Parliament and of the Council[23]. The criteria that define when SoHOs or SOHO preparations become products regulated under other Union legislation are not defined in this Regulation but are defined in those other acts. In addition, this Regulation should apply without prejudice to Union legislation on genetically modified organisms.

Parliament and of the Council[21], including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007 of the European Parliament and of the Council[22], or on food, regulated by Regulation (EC) No 1925/2006 of the European Parliament and of the Council[23]. The criteria that define when SoHOs or SOHO preparations become products regulated under other Union legislation are not defined in this Regulation but are defined in those other acts. In ***case of products covered by other legislation of the Union, this Regulation shall only apply to those parts specified on it, without prejudice to other legislation of the Union.In***addition, this Regulation should apply without prejudice to Union legislation on genetically modified organisms.

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[19] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

[20] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

[21] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[22] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p.

[19] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

[20] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

[21] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[22] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p.

121).

[23] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

121).

[23] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

Or. en

Amendment 134
Tudor Ciuhodaru

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(9) All SoHOs that are intended to be applied to humans fall within the scope of this Regulation. SoHOs can be prepared and stored in a variety of ways, becoming SoHO preparations, which can be applied to recipients. In these circumstances, this Regulation should apply to all activities from donor recruitment to human application and outcome monitoring. SoHOs or SoHO preparations can also be used to manufacture products regulated by other Union legislation, or as the starting and raw material thereof, in particular on medical devices, regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council[19], on medicinal products, regulated by Directive 2001/83/EC of the European Parliament and of the Council[20]and by Regulation (EC) No 726/2004 of the European Parliament and of the Council[21], including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007 of the European Parliament and of the Council[22], or on food, regulated by Regulation (EC) No 1925/2006 of the European Parliament and of the Council[23]. The criteria that define when SoHOs or SOHO preparations become products	(9) All SoHOs that are intended to be applied to humans fall within the scope of this Regulation. SoHOs can be prepared and stored in a variety of ways ***in order to preserve all properties that ensure their compatibility with recipients***, becoming SoHO preparations, which can be applied to recipients. In these circumstances, this Regulation should apply to all activities from donor recruitment to human application and outcome monitoring. SoHOs or SoHO preparations can also be used to manufacture products regulated by other Union legislation, or as the starting and raw material thereof, in particular on medical devices, regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council[19], on medicinal products, regulated by Directive 2001/83/EC of the European Parliament and of the Council[20]and by Regulation (EC) No 726/2004 of the European Parliament and of the Council[21], including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007 of the European Parliament and of the Council[22], or on food, regulated by Regulation (EC) No 1925/2006 of the European Parliament and of the Council[23].

regulated under other Union legislation are not defined in this Regulation but are defined in those other acts. In addition, this Regulation should apply without prejudice to Union legislation on genetically modified organisms.

The criteria that define when SoHOs or SOHO preparations become products regulated under other Union legislation are not defined in this Regulation but are defined in those other acts. In addition, this Regulation should apply without prejudice to Union legislation on genetically modified organisms.

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[19] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

[20] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

[21] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[22] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

[23] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

[19] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

[20] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

[21] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[22] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

[23] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

Or. ro

Amendment 135
Ondřej Knotek, Susana Solís Pérez

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(9) All SoHOs that are intended to be applied to humans fall within the scope of this Regulation. SoHOs can be prepared and stored in a variety of ways, becoming SoHO preparations, which can be applied to recipients. In these circumstances, this Regulation should apply to all activities from donor recruitment to human application and outcome monitoring. SoHOs or SoHO preparations can also be used to manufacture products regulated by other Union legislation, or as the starting and raw material thereof, in particular on medical devices, regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council[19], on medicinal products, regulated by Directive 2001/83/EC of the European Parliament and of the Council[20]and by Regulation (EC) No 726/2004 of the European Parliament and of the Council[21], including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007 of the European Parliament and of the Council[22], or on food, regulated by Regulation (EC) No 1925/2006 of the European Parliament and of the Council[23]. The criteria that define when SoHOs or SOHO preparations ***become***products regulated under other Union legislation are not defined in this Regulation but are defined in those other acts. ***In addition, this Regulation should apply without prejudice to Union legislation on genetically modified organisms.***	(9) All SoHOs that are intended to be applied to humans fall within the scope of this Regulation. SoHOs can be prepared and stored in a variety of ways, becoming SoHO preparations, which can be applied to recipients. In these circumstances, this Regulation should apply to all activities from donor recruitment to human application and outcome monitoring. SoHOs or SoHO preparations can also be used to manufacture products regulated by other Union legislation, or as the starting and raw material thereof, in particular on medical devices, regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council[19], on medicinal products, regulated by Directive 2001/83/EC of the European Parliament and of the Council[20]and by Regulation (EC) No 726/2004 of the European Parliament and of the Council[21], including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007 of the European Parliament and of the Council[22], or on food, regulated by Regulation (EC) No 1925/2006 of the European Parliament and of the Council[23]. ***When SoHOs qualify or are used in medicinal products regulated by EU legislations mentioned above, only the provisions of this Regulation related to donor protection should be applicable.***The criteria that define when SoHOs or SOHO preparations ***are***products regulated under other Union legislation are not defined in this Regulation but are defined in those other acts.
[19] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending	[19] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending

Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

[20] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

[21] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[22] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

[23] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

[20] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

[21] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[22] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

[23] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

Or. en

Amendment 136
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) When SoHOs are used in the autologous setting without any manipulation, processing or storage, the	(10) When SoHOs are used in the autologous setting without any manipulation, processing or storage, the

application of this Regulation would not be proportionate to the limited quality and safety risks arising in such a setting. When autologous SoHOs are collected and processed before being re-used in the same person, risks appear that should be mitigated. Thus, there needs to be an assessment and authorisation of the processes applied to ensure that they are demonstrated to be safe and effective for the recipient. When autologous SoHOs are collected to be processed and also stored, risks of cross-contamination, loss of traceability or damage to the biological properties inherent to the substance, and necessary for efficacy in the recipient, also appear. Thus, the requirements for SoHO establishment authorisation should apply.

application of this Regulation would not be proportionate to the limited quality and safety risks arising in such a setting. When autologous SoHOs are collected and processed before being re-used in the same person, risks appear that should be mitigated. Thus, there needs to be an assessment and authorisation of the processes applied to ensure that they are demonstrated to be safe and effective for the recipient. When autologous SoHOs are collected to be processed and also stored, risks of cross-contamination, ***or environmental contamination,*** loss of traceability or damage to the biological properties inherent to the substance, and necessary for efficacy ***and/or functionality*** in the recipient, also appear. Thus, the requirements for SoHO establishment authorisation should apply. ***Furthermore, in case of substances meant for autologous but non-homologous application, this Regulation shall apply without prejudice to Regulation (EC) No 1394/2007 on advanced therapy medicinal products.***

Or. en

(Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004)

Amendment 137
Andreas Glück, Peter Liese, Ondřej Knotek

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) When SoHOs are used in the autologous setting without any manipulation, processing or storage, the application of this Regulation would not be proportionate to the limited quality and safety risks arising in such a setting. When autologous SoHOs are collected and	(10) When SoHOs are used in the autologous setting without any manipulation, processing or storage, the application of this Regulation would not be proportionate to the limited quality and safety risks arising in such a setting***. Furthermore, if minimal processing is***

processed before being re-used in the same person, risks appear that should be mitigated. Thus, there needs to be an assessment and authorisation of the processes applied to ensure that they are demonstrated to be safe and effective for the recipient. When autologous SoHOs are collected to be processed and also stored, risks of cross-contamination, loss of traceability or damage to the biological properties inherent to the substance, and necessary for efficacy in the recipient, also appear. Thus, the requirements for SoHO establishment authorisation should apply.

needed to restore applicability during a surgical procedure or the manipulation is done within a closed system, the Regulation should not apply as well.
When autologous SoHOs are collected and processed before being re-used in the same person, risks appear that should be mitigated. Thus, there needs to be an assessment and authorisation of the processes applied to ensure that they are demonstrated to be safe and effective for the recipient. When autologous SoHOs are collected to be processed and also stored, risks of cross-contamination, loss of traceability or damage to the biological properties inherent to the substance, and necessary for efficacy in the recipient, also appear. Thus, the requirements for SoHO establishment authorisation should apply.

Or. en

Justification

See Article 2 (2) point c respectively. The exemptions are formulated too narrow. For example, during surgeries blood needs to be reprocessed (filtered, washed, etc.) or the edges of skin and cornea need to be cut in order to establish applicability. Moreover, the term minimally processed should include all manipulations which are conducted within a closed system using a medical device.

Amendment 138
Tudor Ciuhodaru

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) When SoHOs are used in the autologous setting without any manipulation, processing or storage, the application of this Regulation would not be proportionate to the limited quality and safety risks arising in such a setting. When autologous SoHOs are collected and processed before being re-used in the same person, risks appear that should be mitigated. Thus, there needs to be an	***10.*** When SoHOs are used in the autologous setting without any manipulation, processing or storage, the application of this Regulation would not be proportionate to the limited quality and safety risks arising in such a setting. When autologous SoHOs are collected and processed before being re-used in the same person, risks appear that should be mitigated. Thus, there needs to be an

assessment and authorisation of the processes applied to ensure that they are demonstrated to be safe and effective for the recipient. When autologous SoHOs are collected to be processed and also stored, risks of cross-contamination, loss of traceability or damage to the biological properties inherent to the substance, and necessary for efficacy in the recipient, also appear. Thus, the requirements for SoHO establishment authorisation should apply.	assessment and authorisation of the processes applied to ensure that they are demonstrated to be safe and effective for the recipient***, especially following transport to other hospital units, including cross-border transport***. When autologous SoHOs are collected to be processed and also stored, risks of cross-contamination, loss of traceability or damage to the biological properties inherent to the substance, and necessary for efficacy in the recipient, also appear. Thus, the requirements for SoHO establishment authorisation should apply.
	Or. ro

Amendment 139
Mathilde Androuët

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) When SoHOs are used in the autologous setting without any manipulation, processing or storage, the application of this Regulation would not be proportionate to the limited quality and safety risks arising in such a setting. When autologous SoHOs are collected and processed before being re-used in the same person, risks appear that should be mitigated. Thus, there needs to be an assessment and authorisation of the processes applied to ensure that they are demonstrated to be safe and effective for the recipient. When autologous SoHOs are collected to be processed and also stored, risks of cross-contamination, loss of traceability or damage to the biological properties inherent to the substance, and necessary for efficacy in the recipient, also appear. Thus, the requirements for SoHO establishment authorisation should apply.	(10) When SoHOs are used in the autologous setting without any manipulation, processing or storage, the application of this Regulation would not be proportionate to the limited quality and safety risks arising in such a setting. When autologous SoHOs are collected and processed before being re-used in the same person, risks appear that should be mitigated. Thus, there needs to be an assessment and authorisation of the processes applied to ensure that they are demonstrated to be safe and effective for the recipient. When autologous SoHOs are collected to be processed and also stored, risks of cross-contamination ***or contamination of caregivers, friends or family***, loss of traceability or damage to the biological properties inherent to the substance, and necessary for efficacy in the recipient, also appear. Thus, the requirements for SoHO establishment

authorisation should apply.

Or. fr

Amendment 140
Susana Solís Pérez, Ondřej Knotek, Véronique Trillet-Lenoir

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(11) When SoHOs are used to manufacture products regulated by other Union legislation, or as the starting and raw material thereof, in order to ensure a high level of protection and contribute to legal clarity and certainty, this Regulation should apply to the extent that the activities to which they are subjected are not regulated by the other Union legislative framework. Without prejudice to other Union legislation, and in particular to Directive 2001/83/EC, Regulations (EC) No 726/2004, (EC) No 1925/2006, (EC) No 1394/2007 ***and*** (EU) 2017/745, this Regulation should at least apply to the recruitment and selection of donors, donation, collection and donor testing as well as to release, distribution, import and export when those activities concern SoHOs up to the point of their transfer to operators regulated by other Union legislation. This means that close interaction between this regulatory framework and other related frameworks is essential to ensure interplay and coherence between relevant legal frameworks, without gaps or overlaps.	(11) When SoHOs are used to manufacture products regulated by other Union legislation, or as the starting and raw material thereof, in order to ensure a high level of protection and contribute to legal clarity and certainty, this Regulation should apply to the extent that the activities to which they are subjected are not regulated by the other Union legislative framework. Without prejudice to other Union legislation, and in particular to Directive 2001/83/EC, Regulations (EC) No 726/2004, (EC) No 1925/2006, (EC) No 1394/2007***,*** (EU) 2017/745 ***and (EU) No 536/2014***, this Regulation should at least apply to the recruitment and selection of donors, donation, collection and donor testing as well as to release, distribution, import and export when those activities concern SoHOs up to the point of their transfer to operators regulated by other Union legislation. This means that close interaction between this regulatory framework and other related frameworks is essential to ensure interplay and coherence between relevant legal frameworks, without gaps or overlaps.

Or. en

Justification

Complementing the listing of existing relevant Union legislation with the addition of the Clinical Trials Regulation.

Amendment 141
Mathilde Androuët

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(11) When SoHOs are used to manufacture products regulated by other Union legislation, or as the starting and raw material thereof, in order to ensure a high level of protection and contribute to legal clarity and certainty, this Regulation should apply to the extent that the activities to which they are subjected are not regulated by the other Union legislative framework. Without prejudice to other Union legislation, and in particular to Directive 2001/83/EC, Regulations (EC) No 726/2004, (EC) No 1925/2006, (EC) No 1394/2007 and (EU) 2017/745, this Regulation should at least apply to the recruitment and selection of donors, donation, collection and donor testing as well as to release, distribution, import and export when those activities concern SoHOs up to the point of their transfer to operators regulated by other Union legislation. This means that close interaction between this regulatory framework and other related frameworks is essential to ensure interplay and coherence between relevant legal frameworks, without gaps or overlaps.	(11) When SoHOs are used to manufacture products regulated by other Union legislation, or as the starting and raw material thereof, in order to ensure a high level of protection and contribute to legal clarity and certainty, this Regulation should apply to the extent that the activities to which they are subjected are not regulated by the other Union legislative framework. Without prejudice to other Union legislation, and in particular to Directive 2001/83/EC, Regulations (EC) No 726/2004, (EC) No 1925/2006, (EC) No 1394/2007 and (EU) 2017/745, this Regulation should at least apply to the recruitment and selection of donors, donation, collection and donor testing as well as to release, distribution, ***dispensing,*** import and export when those activities concern SoHOs up to the point of their transfer to operators regulated by other Union legislation. This means that close interaction between this regulatory framework and other related frameworks is essential to ensure interplay and coherence between relevant legal frameworks, without gaps or overlaps.

Or. fr

Justification

Dispensing is a step that takes place once a product has been released and after or in parallel to distribution. It allocates a blood product to a specific patient, thus making it easier to trace that product until it is used for transfusion.

Amendment 142
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(11) When SoHOs are used to manufacture products regulated by other Union legislation, or as the starting and raw material thereof, in order to ensure a high level of protection and contribute to legal clarity and certainty, this Regulation should apply to the extent that the activities to which they are subjected are not regulated by the other Union legislative framework. Without prejudice to other Union legislation, and in particular to Directive 2001/83/EC, Regulations (EC) No 726/2004, (EC) No 1925/2006, (EC) No 1394/2007 and (EU) 2017/745, this Regulation should at least apply to the recruitment and selection of donors, donation, collection and donor testing as well as to release, distribution, import and export when those activities concern SoHOs up to the point of their transfer to operators regulated by other Union legislation. This means that close interaction between this regulatory framework and other related frameworks is essential to ensure interplay and coherence between relevant legal frameworks, without gaps or overlaps.	(11) When SoHOs are used to manufacture products regulated by other Union legislation, or as the starting and raw material thereof, in order to ensure a high level of protection and contribute to legal clarity and certainty, this Regulation should apply to the extent that the activities to which they are subjected are not regulated by the other Union legislative framework. Without prejudice to other Union legislation, and in particular to Directive 2001/83/EC, Regulations (EC) No 726/2004, (EC) No 1925/2006, (EC) No 1394/2007 and (EU) 2017/745, this Regulation should at least apply to the recruitment and selection of donors, donation, collection and donor testing as well as to release, distribution, ***issuing,*** import and export when those activities concern SoHOs up to the point of their transfer to operators regulated by other Union legislation. This means that close interaction between this regulatory framework and other related frameworks is essential to ensure interplay and coherence between relevant legal frameworks, without gaps or overlaps.

Or. en

Amendment 143
Tudor Ciuhodaru

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) SoHOs can also be combined with other regulated products before human application. In these circumstances, close interaction between this regulatory framework and other related frameworks is	(12) SoHOs can also be combined with other regulated products before human application. In these circumstances, close interaction between this regulatory framework and other related frameworks is

also necessary to ensure a high level of human health protection for all cases where these substances are used.	also necessary to ensure a high level of ***protection when handling these products and hence*** human health protection for all cases where these substances are used.

Or. ro

Amendment 144
Mathilde Androuët

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) SoHOs can also be combined with other regulated products before human application. In these circumstances, close interaction between this regulatory framework and other related frameworks is also necessary to ensure a high level of human health protection for all cases where these substances are used.	(12) SoHOs can also be combined with other regulated products before***, exclusively,*** human application. In these circumstances, close interaction between this regulatory framework and other related frameworks is also necessary to ensure a high level of human health protection for all cases where these substances are used.

Or. fr

Amendment 145
Margarita de la Pisa Carrión

Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission	*Amendment*
	(12a) The scope of this regulation shall have no effect on national assisted reproduction legislation. Sexual and reproductive rights are a national competence.

Or. es

Amendment 146

Alexandr Vondra

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. ***This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly. Donations of oocytes, bone marrow, peripheral blood stem cells and plasma should be considered to imply a significant risk.***	(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk.

Or. en

Amendment 147
Cristian-Silviu Buşoi

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) Given the special nature of SoHOs,	(13) Given the special nature of SoHOs,

resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. ***This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly. Donations of oocytes, bone marrow, peripheral blood stem cells and plasma should be considered to imply a significant risk.***	resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk.

Or. en

Amendment 148
Giuseppe Ferrandino

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs	(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs

should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. ***This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly. Donations of oocytes, bone marrow, peripheral blood stem cells and plasma should be considered to imply a significant risk.***	should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk.

Or. en

Justification

As different types of donations imply different risks for donors, the monitoring of donor health should be proportionate to those levels of risk. The Regulation should refrain from specifically defining the risk level of specific procedures, as this would be determined at a technical level in accordance with Art. 52-56 on SOHO donor protection standards. It is crucial that those standards are based on the latest scientific evidence available, and are regularly updated accordingly.

Amendment 149
Kateřina Konečná

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for	(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for

donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. ***This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly. Donations of oocytes, bone marrow, peripheral blood stem cells and plasma should be considered to imply a significant risk.***	donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk.

Or. en

Justification

As different types of donations imply different risks for donors, the monitoring of donor health should be proportionate to those levels of risk. The Regulation should refrain from specifically defining the risk level of specific procedures, as this would be determined at a technical level in accordance with Art. 52-56 on SOHO donor protection standards. It is crucial that those standards are based on the latest scientific evidence available, and are regularly updated accordingly.

Amendment 150
Sunčana Glavak

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to	(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to

ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. ***This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly. Donations of oocytes, bone marrow, peripheral blood stem cells and plasma should be considered to imply a significant risk.***	ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk.

Or. en

Amendment 151
Andreas Glück, Ondřej Knotek, Susana Solís Pérez, Michal Wiezik

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore ***include*** principles and technical rules to monitor and protect donors. As different	(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore ***address*** principles and technical rules to monitor and protect donors. As different

types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. ***This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly***. ***Donations of oocytes, bone marrow, peripheral blood stem cells and plasma should be considered to imply a significant risk.***	types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. ***The respective risk-classifications shall be defined in the respective guidelines***.

Or. en

Justification

As technologies and risks may change over time, it is better to leave the risk classification out of the proposal and leave it up to the technical guidelines to define them . This is acknowledged already by this Proposal in Recital 33 which, regarding the guidelines, refers to this issues in a similar fashion:"(...).As risks and technologies change, (...)

Amendment 152
Tudor Ciuhodaru

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for	(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection ***when handling these products and hence*** for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors ***from***

donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly. Donations of oocytes, bone marrow, peripheral blood stem cells and plasma should be considered to imply a significant risk.

undesirable short-term and long-term side-effects. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly. Donations of oocytes, bone marrow, peripheral blood stem cells and plasma should be considered to imply a significant risk.

Or. ro

Amendment 153
Sirpa Pietikäinen

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with	(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with

medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly. ***Donations of oocytes, bone marrow, peripheral blood stem cells and plasma should be considered to imply a significant risk.***	medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly.

Or. en

Amendment 154
Pernille Weiss

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly. ***Donations of oocytes, bone marrow, peripheral blood stem cells and plasma should be considered to imply a significant risk.***	(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly.

Or. en

Justification

This recital should not preempt the procedures regarding risk determination laid out in article 52-56 of this proposal.

Amendment 155
Aldo Patriciello, Salvatore De Meo

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. This is particularly important ***when*** donation involves some risk to the donor's health ***due to a*** need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly***. Donations of oocytes, bone marrow, peripheral blood stem cells and plasma should be considered to imply a significant risk.***	(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. This is particularly important ***in case the*** donation involves some risk to the donor's health ***such as the*** need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly

Or. en

Amendment 156
Mathilde Androuët

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that ***no detrimental effects will ensue as a result*** of the ***donation***. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly. Donations of oocytes, bone marrow, peripheral blood stem cells and plasma should be considered to imply a significant risk.	(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that ***the donation will not have any short- or medium-term adverse effects on the health*** of the ***recipient***. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly. Donations of oocytes, bone marrow, peripheral blood stem cells and plasma should be considered to imply a significant risk.

Or. fr

Amendment 157
Mathilde Androuët

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) Given the special nature of SoHOs, resulting from their human origin, and the	(13) Given the special nature of SoHOs, resulting from their human origin, and the

increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly. Donations of oocytes, bone marrow, peripheral blood stem cells and plasma should be considered to imply a significant risk.	increasing demands for these substances for human application or for the manufacture of products ***exclusively for human application*** regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for donors to donate repeatedly. Donations of oocytes, bone marrow, peripheral blood stem cells and plasma should be considered to imply a significant risk.

Or. fr

Amendment 158
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs	(13) Given the special nature of SoHOs, resulting from their human origin, and the increasing demands for these substances for human application or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, it is necessary to ensure a high level of health protection for donors as well as for recipients. SoHOs

should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or ***a need*** for donors to donate repeatedly. Donations of oocytes, bone marrow, peripheral blood stem cells and plasma should be considered to imply a significant risk.

should be obtained from individuals whose health status is such that no detrimental effects will ensue ***on them*** as a result of the donation. This Regulation should therefore include principles and technical rules to monitor and protect donors. As different types of donation imply different risks for donors, with varying levels of significance, the monitoring of donor health should be proportionate to those levels of risk. This is particularly important when donation involves some risk to the donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or ***the possibility*** for donors to donate repeatedly. Donations of oocytes, bone marrow, peripheral blood stem cells and ***frequent donation of*** plasma should be considered to imply a significant risk.

Or. en

Amendment 159
Margarita de la Pisa Carrión

Proposal for a regulation
Recital 13 a (new)

Text proposed by the Commission	*Amendment*
	(13a) This regulation has no bearing on the right of offspring conceived during fertility treatment to know their provenance under the legislation in force in the Member States.

Or. es

Amendment 160
Mathilde Androuët

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) When a harmful genetic condition is detected in the ***offspring*** resulting from medically assisted reproduction with third party donation, the transmission of that information enables the prevention of further use of donations affected by that genetic risk. It is thus important that relevant information in such cases is effectively communicated between SoHO entities and acted upon appropriately.	(14) When a harmful genetic condition is detected in the ***children*** resulting from medically assisted reproduction with third party donation, the transmission of that information enables the prevention of further use of donations affected by that genetic risk. It is thus important that relevant information in such cases is effectively communicated between SoHO entities and acted upon appropriately.

Or. fr

Amendment 161
Nathalie Colin-Oesterlé

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) This Regulation does not prevent Member States from maintaining or introducing more stringent protective measures that are compatible with Union law. Member States should notify the Commission of any such measures. More stringent protective measures put in place by Member States should be evidence-based and proportionate to the risk to human health, for example based on overall safety concerns and corresponding risks in a Member State or specific local risks. They should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation, unless that measure or its application is objectively justified by a legitimate aim, and the means of achieving that aim are appropriate and necessary.	(15) This Regulation does not prevent Member States from maintaining or introducing more stringent protective measures that are compatible with Union law ***and founded on the principle of voluntary and unpaid SoHO donation***. Member States should notify the Commission ***via the SoHO platform set up by this Regulation*** of any such measures. More stringent protective measures put in place by Member States should be evidence-based and proportionate to the risk to human health, for example based on overall safety concerns and corresponding risks in a Member State or specific local risks. They should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation, unless that measure or its application is objectively justified by a legitimate aim, and the means of achieving that aim are appropriate and necessary.

Or. fr

Amendment 162
Mathilde Androuët

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) This Regulation does not prevent Member States from maintaining or introducing more stringent protective measures that are compatible with Union law. Member States should notify the Commission of any such measures. More stringent protective measures put in place by Member States should be evidence-based and proportionate to the risk to human health, for example based on overall safety concerns and corresponding risks in a Member State or specific local risks. They should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation, unless that measure or its application is objectively justified by a legitimate aim, and the means of achieving that aim are appropriate and necessary.	(15) This Regulation does not prevent Member States from maintaining or introducing more stringent protective measures that are compatible with Union law ***and founded on respect for human dignity, voluntary donation, and the principle that SoHOs cannot be used for financial gain***. Member States should notify the Commission of any such measures. More stringent protective measures put in place by Member States should be evidence-based and proportionate to the risk to human health, for example based on overall safety concerns and corresponding risks in a Member State or specific local risks. They should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation, unless that measure or its application is objectively justified by a legitimate aim, and the means of achieving that aim are appropriate and necessary.

Or. fr

Amendment 163
Tudor Ciuhodaru

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) This Regulation does not prevent Member States from maintaining or introducing more stringent protective measures that are compatible with Union	(15) This Regulation does not prevent Member States from maintaining or introducing more stringent protective measures that are compatible with Union

law. Member States should notify the Commission of any such measures. More stringent protective measures put in place by Member States should be evidence-based and proportionate to the risk to human health, for example based on overall safety concerns and corresponding risks in a Member State or specific local risks. They should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation, unless that measure or its application is objectively justified by a legitimate aim, and the means of achieving that aim are appropriate and necessary.

law. Member States should notify the Commission of any such measures ***as soon as possible after their introduction so that the other Member States can be informed accordingly***. More stringent protective measures put in place by Member States should be evidence-based and proportionate to the risk to human health, for example based on overall safety concerns and corresponding risks in a Member State or specific local risks. They should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation, unless that measure or its application is objectively justified by a legitimate aim, and the means of achieving that aim are appropriate and necessary.

Or. ro

Amendment 164
Margarita de la Pisa Carrión

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) This Regulation does not prevent Member States from maintaining or introducing more stringent protective measures that are compatible with Union law. Member States should notify the Commission of any such measures. More stringent protective measures put in place by Member States should be evidence-based and proportionate to the risk to human health, for example based on overall safety concerns and corresponding risks in a Member State or specific local risks. They should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation, unless that measure or its application is objectively justified by a legitimate aim, and the means of achieving	(15) This Regulation does not prevent Member States from maintaining or introducing more stringent protective measures that are compatible with Union law***, particularly in the area of conception by means of fertility treatment***. Member States should notify the Commission of any such measures. More stringent protective measures put in place by Member States should be evidence-based and proportionate to the risk to human health, for example based on overall safety concerns and corresponding risks in a Member State or specific local risks. They should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation, unless that measure or its application is objectively justified by a

that aim are appropriate and necessary.	legitimate aim, and the means of achieving that aim are appropriate and necessary.

Or. es

Amendment 165
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) This Regulation does not prevent Member States from maintaining or introducing more stringent protective measures that are compatible with Union law. Member States should notify the Commission of any such measures. More stringent protective measures put in place by Member States should be evidence-based and proportionate to the risk to human health, for example based on overall safety concerns and corresponding risks in a Member State or specific local risks. They should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation, unless that measure or its application is objectively justified by a legitimate aim, and the means of achieving that aim are appropriate and necessary.	(15) This Regulation does not prevent Member States from maintaining or introducing more stringent protective measures that are compatible with Union law. Member States should notify the Commission of any such measures. More stringent protective measures put in place by Member States should be evidence-based and proportionate to the risk to human health, for example based on overall safety concerns and corresponding risks in a Member State or specific local risks. They should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation, unless that measure or its application is objectively justified by a legitimate aim, and ***where necessary supported by scientific evidence, and*** the means of achieving that aim are appropriate and necessary.

Or. en

Amendment 166
Tilly Metz

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*

(15) This Regulation does not prevent Member States from maintaining or introducing more stringent protective measures that are compatible with Union law. Member States should notify the Commission of any such measures. More stringent protective measures put in place by Member States should be evidence-based and proportionate to the risk to human health, for example based on overall safety concerns and corresponding risks in a Member State or specific local risks. They should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation***, unless that measure or its application is objectively justified by a legitimate aim, and the means of achieving that aim are appropriate and necessary***.	(15) This Regulation does not prevent Member States from maintaining or introducing more stringent protective measures that are compatible with Union law. Member States should notify the Commission of any such measures. More stringent protective measures put in place by Member States should be evidence-based and proportionate to the risk to human health, for example based on overall safety concerns and corresponding risks in a Member State or specific local risks. They should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation***. In that regard, when selecting SoHO donors, Member States should use individual risk-based questions***.

Or. en

Amendment 167
Jan Huitema, Catharina Rinzema, Véronique Trillet-Lenoir, Michal Wiezik, Martin Hojsík, Susana Solís Pérez

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) This Regulation does not prevent Member States from maintaining or introducing more stringent protective measures that are compatible with Union law. Member States should notify the Commission of any such measures. More stringent protective measures put in place by Member States should be evidence-based and proportionate to the risk to human health, for example based on overall safety concerns and corresponding risks in a Member State or specific local risks. They should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation, unless that measure or	(15) This Regulation does not prevent Member States from maintaining or introducing more stringent protective measures that are compatible with Union law. Member States should notify the Commission of any such measures. More stringent protective measures put in place by Member States should be evidence-based and proportionate to the risk to human health, for example based on overall safety concerns and corresponding risks in a Member State or specific local risks. They should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation, unless that measure or

its application is objectively justified by a legitimate aim, and the means of achieving that aim are appropriate and necessary.	its application is objectively justified by a legitimate aim, and the means of achieving that aim are ***science-based,*** appropriate and necessary.

Or. en

Amendment 168
Jan Huitema, Catharina Rinzema, Véronique Trillet-Lenoir, Michal Wiezik, Martin Hojsík, Susana Solís Pérez

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15 a) This Regulation should ensure a science-based and non-discriminatory approach to SoHO donations. Men having sex with men (MSM), in particular, have been discriminated against in blood donation procedures following the HIV epidemic. To ensure the highest level of safety of SoHO donations, various Member States have enacted legislative or administrative bans on SoHOs donations from MSM, or have installed time deferral periods, based on a person's sexual orientation or gender identity. This could have been justified at the beginning of the HIV epidemic when medical solutions were absent, but at present several medical evolutions have materialised, such as more reliable blood testing and screening technology, antiretroviral therapy and the rising use of pre-exposure prophylaxis (PrEP) in MSM communities. National donation policies introducing bans and other obstacles for MSM to donate SoHOs are therefore unnecessary and discriminatory. This Regulation should ensure that Member States replace donor eligibility criteria based on sexual orientation or gender identity with sexual behaviour-based screening criteria for all donors, regardless of their gender or sexual

orientation.

Or. en

Justification

National eligibility criteria in various member states are disabling MSM to donate SoHO material, in particular blood. This is based on - and continues the narrative of - stigmatization of the MSM community. By requiring Member States to have sexual-behavior based screening criteria, this Regulation ensures a non-discriminatory, science-based and risk-based approach.

Amendment 169
Margarita de la Pisa Carrión

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) Human embryos and foetuses and their cells, tissues and organs must not be used for diagnostic, therapeutic, research or experimental purposes.

Or. es

Amendment 170
Mathilde Androuët

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(16) This Regulation should not interfere with national legislation in the health area with objectives other than quality and safety of SoHOs that is compatible with Union law, in particular legislation concerning ethical aspects. Such aspects arise due to the human origin of the substances, which touches upon various sensitive and ethical concerns for Member States and citizens, such as access to particular services that use SoHOs. This	(16) This Regulation should not interfere with national legislation in the health area with objectives other than quality and safety of SoHOs that is compatible with Union law, in particular legislation concerning ethical aspects. Such aspects arise due to the human origin of the substances, which touches upon various sensitive and ethical concerns for Member States and citizens, such as access to particular services that use SoHOs. This

Regulation should also not interfere with decisions of an ethical nature made by Member States. Such ethical decisions might concern ***the use, or limitation of the use, of specific types of*** SoHOs or specific uses of SoHOs, including reproductive cells and embryonic stem cells. When a Member State allows the use of such cells, this Regulation should apply in full with a view to ensuring safety and quality and to protecting human health.	Regulation should also not interfere with decisions of an ethical nature made by Member States. Such ethical decisions might concern SoHOs or specific uses of SoHOs, including reproductive cells and embryonic stem cells. When a Member State allows the use of such cells, this Regulation should apply in full with a view to ensuring safety and quality and to protecting human health. ***The authorisation of the use of such SoHOs in one Member State in no way obliges another Member State to adopt the same provisions or to transpose them into its own legislation. Indeed, some Member States prohibit all use of embryos for scientific and medical purposes, including for research.***
	Or. fr

Amendment 171
Joanna Kopcińska

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(16) ***This Regulation should not interfere with*** national legislation in the health area with objectives other than quality and safety of SoHOs ***that is compatible with Union law, in particular legislation concerning ethical aspects***. Such aspects arise due to the human origin of the substances, which touches upon various sensitive and ethical concerns for Member States and citizens, such as access to particular services that use SoHOs. This Regulation ***should*** also not interfere with decisions of an ethical nature made by Member States***. Such ethical decisions might concern*** the use, or limitation of the use, of specific types of SoHOs or specific uses of SoHOs, including reproductive cells and embryonic stem cells. When a Member State allows the use of such cells,	(16) National legislation in the health area with objectives other than quality and safety of SoHOs***, in particular legislation concerning ethical aspects, shall take precedence over the provisions of this Regulation***. Such aspects arise due to the human origin of the substances, which touches upon various sensitive and ethical concerns for Member States and citizens, such as access to particular services that use SoHOs. This Regulation ***shall*** also not interfere with decisions of an ethical nature made by Member States***, and, in particular, no provision of this Regulation may be construed as imposing an obligation on Member States to use types of SoHOs that are legally prohibited in that Member State. Decisions concerning*** the use, or limitation of the use, of specific

this Regulation should apply in full with a view to ensuring safety and quality and to protecting human health.

types of SoHOs or specific uses of SoHOs, including reproductive cells and embryonic stem cells***, are an exclusive competence of the Member States***. When a Member State allows the use of such cells, this Regulation should apply in full with a view to ensuring safety and quality and to protecting human health.

Or. pl

Amendment 172
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(16) This Regulation should not interfere with national legislation in the health area with objectives other than quality and safety of SoHOs that is compatible with Union law, in particular legislation concerning ethical aspects. Such aspects arise due to the human origin of the substances, which touches upon various sensitive and ethical concerns for Member States and citizens, such as access to particular services that use SoHOs. This Regulation should also not interfere with decisions of an ethical nature made by Member States. Such ethical decisions might concern the use, or limitation of the use, of specific types of SoHOs or specific uses of SoHOs, including reproductive cells and embryonic stem cells. When a Member State allows the use of such cells, this Regulation should apply in full with a view to ensuring safety and quality and to protecting human health.	(16) This Regulation should not interfere with national legislation in the health area with objectives other than quality and safety of SoHOs that is compatible with Union law, in particular legislation concerning ethical aspects. Such aspects arise due to the human origin of the substances, which touches upon various sensitive and ethical concerns for Member States and citizens, such as access to particular services that use SoHOs. This Regulation should also not interfere with decisions of an ethical nature made by Member States***, provided that they adhere to the Charter of Fundamental Rights of the European Union***. Such ethical decisions might concern the use, or limitation of the use, of specific types of SoHOs or specific uses of SoHOs, including reproductive cells and embryonic stem cells. When a Member State allows the use of such cells, this Regulation should apply in full with a view to ensuring safety and quality and to protecting human health.

Or. en

Amendment 173
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) This Regulation is not meant to cover research using SoHOs when that research does not involve application to the human body, for example in vitro research or research in animals. However, human substances used in research involving studies where they are applied to the human body should comply with the rules laid down in this Regulation.	(17) This Regulation is not meant to cover research using SoHOs when that research does not involve application to the human body, for example in vitro research or research in animals. However, human substances used in research involving studies where they are applied to the human body should comply with the rules laid down in this Regulation***, regarding clinical studies with SoHO***.

Or. en

Amendment 174
Kateřina Konečná

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. ***Voluntary and unpaid SoHO*** donation ***is also a factor which can*** contribute ***to high safety standards for SoHOs and therefore to the protection of human health***. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove	(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. ***This solidarity should be built from the local and regional levels up to the national and EU self-sufficiency spreading the burden of*** donation ***evenly across the EU population and ensuring that donors gain an adequate public recognition. Each Member State shall pay the attention to its own self-sufficiency and*** contribute ***accordingly***. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that

any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.

[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives. ***SoHOs donation advertisements play an important role in getting people to donate.The significant amount of information that provides people with an idea and reasons for SOHOs donations plays an important role in how people view donation and the out coming results.Member States shall allow and regulate the advertisement for SOHOs collection.However, 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 to avoid above mentioned risks and negative social impact.***

[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

Or. en

Justification

The reference to voluntary and unpaid donation (VUD) as a factor that can contribute to high safety standards could contribute to a negative perception of the safety of SoHOs from donors who received compensation to make good the expenses and inconveniences of donating. This VUD statement in the recital is not supported by any scientific evidence. The EMA has found

that plasma-derived medicinal products (PDMPs) derived from donors compensated for expenses and inconveniences have the same safety profile as PDMPs from non-compensated donors (EMEA/CPMP/BWP/1818/02/Final).

Amendment 175
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) ***As a matter of principle,*** programmes promoting the donation of SoHOs ***should*** be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. Voluntary and unpaid SoHO donation is also a factor which ***can contribute*** to high safety standards for SoHOs and therefore to the protection of human health. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate ***more frequently than is allowed, posing***risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.	(18) ***Article 3 of the Charter of Fundamental Rights of the European Union prohibits the human body or parts of it from becoming a source of financial gain.*** Programmes promoting the donation of SoHOs ***must*** be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. Voluntary and unpaid SoHO donation is also a factor which ***contributes*** to high safety standards for SoHOs and therefore to the protection of human health***, and increases public trust in donation systems***. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, ***financially neutral***compensation to remove any such risk is acceptable but should never ***produce a financial gain for the donor or***constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate ***in any way that could pose***risks to their own health and to that of prospective recipients***.Compensation and reimbursements should under no circumstances be an incentive or a claim to recruit donors, should not expose vulnerable persons in society to exploitation and should not promote competition among SoHO entities for the***

recruitment of donors. Such compensation should, therefore, be set by national authorities, at a level ***justified and***appropriate in their Member State to reach such objectives.

[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

Or. en

Amendment 176
Tilly Metz

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) ***As a matter of principle,*** programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. Voluntary and unpaid SoHO donation is also a factor which can contribute to high safety standards for SoHOs and therefore to the protection of human health. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be ***necessary***to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that	(18) Programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient***. Donor recruitment campaigns should never refer to compensation to avoid risk of incentivising donations***. Voluntary and unpaid SoHO donation is also a factor which can contribute to high safety standards for SoHOs and therefore to the protection of human health. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be ***acceptable***to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history

of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach ***such objectives***.	or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be ***based on quantifiable and transparent criteria***set by national authorities, at a level appropriate in their Member State to reach ***the principle of financial neutrality***. ***Any compensation regime should not serve as an inducement to donate nor lead to inappropriate financially-driven competition, including cross-border competition, between SoHO establishments and entities over donor recruitment.***
[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.	[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

Or. en

Amendment 177
Stanislav Polčák

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. ***Voluntary and unpaid SoHO donation is also a factor which can contribute to high safety standards for SoHOs and therefore to the protection of human health.*** It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while	(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. It is also recognised, including by the Council of Europe Committee on Bioethics, that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove

financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.

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[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

Or. en

Amendment 178
Aldo Patriciello, Salvatore De Meo

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. ***Voluntary and unpaid SoHO donation is also a factor which can contribute to high safety standards for SoHOs and therefore to the protection of human health.*** It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.	(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. It is also recognised, including by the Council of Europe Committee on Bioethics, that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove

financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.

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[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

Or. en

Amendment 179
Radka Maxová

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. ***Voluntary and unpaid SoHO donation is also a factor which can contribute to high safety standards for SoHOs and therefore to the protection of human health.*** It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while	(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. It is also recognised, including by the Council of Europe Committee on Bioethics, that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove

financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.

any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives. **.**

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[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

Or. en

Amendment 180
Cristian-Silviu Buşoi

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient***. *Voluntary and unpaid SoHO donation is also a factor which can contribute to high safety standards for SoHOs and therefore to the protection of human health***. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.	(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove

financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.

[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.

[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

Or. en

Amendment 181
Andreas Glück, Ondřej Knotek, Susana Solís Pérez, Jan Huitema, Michal Wiezik

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient***. Voluntary and unpaid SoHO donation is also a factor which can contribute to high safety standards for SoHOs and therefore to the protection of human health***. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.	(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove

financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.	any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.
[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.	[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

Or. en

Justification

The deleted sentence is ambiguous and could cause misunderstanding regarding the role of VUD on the safety of SoHO donation.

Amendment 182
Giuseppe Ferrandino

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient***. *Voluntary and unpaid SoHO donation is also a factor which can***	(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. It is also recognised, including by the Council of Europe

contribute to high safety standards for SoHOs and therefore to the protection of human health. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.

[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.

[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

Or. en

Justification

The reference to voluntary and unpaid donation (VUD) as a factor that can contribute to high safety standards could contribute to a negative perception of the safety of SoHOs from donors who received compensation to make good the expenses and inconveniences of donating. Even article 54 clarifies that compensation is compatible with the VUD principle.

This VUD statement in the recital is not supported by any scientific evidence.

Amendment 183
Stelios Kympouropoulos, Tomislav Sokol

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient***. Voluntary and unpaid SoHO donation is also a factor which can contribute to high safety standards for SoHOs and therefore to the protection of human health***. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.	(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.
[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.	[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

Or. en

Justification

The EMA has found that plasma-derived medicinal products (PDMPs) derived from donors compensated for expenses and inconveniences have the same safety profile as PDMPs from non-compensated donors (EMEA/CPMP/BWP/1818/02/Final). The reference to voluntary and unpaid donation (VUD) as a factor that can contribute to high safety standards could falsely lead to a negative perception of the safety of SoHOs from donors who received compensation to make good the expenses and inconveniences of donating, which is

scientifically invalid.

Amendment 184
Sunčana Glavak

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient***. Voluntary and unpaid SoHO donation is also a factor which can contribute to high safety standards for SoHOs and therefore to the protection of human health***. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.	(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.
[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.	[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

Or. en

Amendment 185
Alexandr Vondra

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient***. *Voluntary and unpaid SoHO donation is also a factor which can contribute to high safety standards for SoHOs and therefore to the protection of human health***. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.	(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.
[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.	[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

Or. en

Amendment 186
Margarita de la Pisa Carrión

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. Voluntary and unpaid SoHO donation is also a factor which can contribute to high safety standards for SoHOs and therefore to the protection of human health. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.	(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient ***and may help to ensure the traceability of the donor***. Voluntary and unpaid SoHO donation is also a factor which can contribute to ***ensuring the traceability of the donor and*** high safety standards for SoHOs and therefore to the protection of human health. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.
[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-	[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-

gain/16807bfc9a.

gain/16807bfc9a.

Or. es

Amendment 187
Mathilde Androuët

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) ***As a matter of principle,*** programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. Voluntary and unpaid SoHO donation is also a factor which ***can contribute*** to high safety standards for SoHOs and therefore to the protection of human health. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be ***necessary***to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.	(18) Programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. Voluntary and unpaid SoHO donation is also a factor which ***contributes*** to high safety standards for SoHOs and therefore to the protection of human health. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be ***acceptable***to ensure that donors are not financially disadvantaged by their donation. Thus, ***financially neutral***compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.
[24] 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 ***(***March 2018***)***. Available at https://rm.coe.int/guide-financial-	[24] Council of Europe Committee on Bioethics 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**,** March 2018. Available at***:*** https://rm.coe.int/guide-financial-

Amendment 188
Adam Jarubas, Ewa Kopacz, Bartosz Arłukowicz

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. Voluntary ***and*** unpaid SoHO donation ***is also a factor which can contribute to*** high safety standards for SoHOs and therefore to the protection of human health. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.	(18) As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. ***All donations, including*** voluntary***,*** unpaid SoHO donation***, must meet*** high safety standards for SoHOs and therefore to the protection of human health. It is also recognised, including by the Council of Europe Committee on Bioethics[24], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.
[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-	[24] 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 (March 2018). Available at https://rm.coe.int/guide-financial-

gain/16807bfc9a. gain/16807bfc9a.

Or. en

Amendment 189
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) In order to maintain public trust in SoHO donation and use programmes, information that is given to prospective donors, recipients or physicians regarding the likely use and benefits of particular SoHOs or SoHO preparations when applied to recipients should accurately reflect reliable scientific evidence. This should ensure that donors, or their families, are not coerced to donate by exaggerated descriptions of benefits and prospective ***patients*** are not given false hopes when making decisions on their options for treatment. The verification of compliance with this Regulation through supervisory activities is of fundamental importance to ensure that, across the Union, the objectives of the Regulation are effectively achieved. The responsibility to enforce this Regulation lies with the Member States, whose competent authorities should monitor and verify, through the organisation of supervisory activities, that relevant Union requirements are effectively complied with and enforced.	(19) In order to maintain public trust in SoHO donation and use programmes, information that is given to prospective donors, recipients or physicians regarding the likely use and benefits of particular SoHOs or SoHO preparations when applied to recipients should accurately reflect reliable scientific evidence ***and under no circumstances attribute or imply levels of safety or efficacy not supported by scientific methods***. This should ensure that donors, or their families, are not coerced to donate by exaggerated descriptions of benefits and prospective ***recipients*** are not given false hopes when making decisions on their options for treatment. The verification of compliance with this Regulation through supervisory activities is of fundamental importance to ensure that, across the Union, the objectives of the Regulation are effectively achieved. The responsibility to enforce this Regulation lies with the Member States, whose competent authorities should monitor and verify, through the organisation of supervisory activities, that relevant Union requirements are effectively complied with and enforced.

Or. en

Amendment 190
Tilly Metz

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) Competent authorities should be designated by the Member States for all the areas that fall within the scope of this Regulation. While Member States are best placed to identify the competent authority or authorities for each area, for example by geography, topic or substance, they should also be required to designate a single national authority that ensures appropriately coordinated communication with other Member States' competent authorities and with the Commission. The SoHO National Authority should be considered the same as the designated competent authority in Member States where only one competent authority is designated.	(20) Competent authorities should be designated by the Member States for all the areas that fall within the scope of this Regulation. While Member States are best placed to identify the competent authority or authorities for each area, for example by geography, topic or substance, they should also be required to designate a single national authority that ensures appropriately coordinated communication with other Member States' competent authorities and with the Commission. The SoHO National Authority should be considered the same as the designated competent authority in Member States where only one competent authority is designated. ***The list of all SoHO competent national authorities should be made publicly available.***

Or. en

Amendment 191
Mathilde Androuët

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) Competent authorities should be designated by the Member States for all the areas that fall within the scope of this Regulation. While Member States are best placed to identify the competent authority or authorities for each area, for example by geography, topic or substance, they ***should*** also be required to designate a single national authority that ensures appropriately coordinated communication with other Member States' competent authorities and with the Commission. The	(20) Competent authorities should be designated by the Member States for all the areas that fall within the scope of this Regulation. While Member States are best placed to identify the competent authority or authorities for each area, for example by geography, topic or substance, they ***shall*** also be required to designate a single ***independent*** national authority that ensures appropriately coordinated communication with other Member States' competent authorities and with the Commission. The

SoHO National Authority should be considered the same as the designated competent authority in Member States where only one competent authority is designated.	SoHO National Authority should be considered the same as the designated competent authority in Member States where only one competent authority is designated.

Or. fr

Amendment 192
Tudor Ciuhodaru

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) For the performance of supervisory activities aimed at verifying the correct application of SoHO legislation, Member States should designate competent authorities that act independently and impartially. It is therefore important that their function of oversight is separate and independent from the performance of SoHO activities. In particular, competent authorities should be free from undue political influence and from industry interference that might affect their operational impartiality.	(21) For the performance of supervisory activities aimed at verifying the correct application of SoHO legislation, Member States should designate competent authorities that act independently and impartially. It is therefore important that their function of oversight is separate and independent from the performance of SoHO activities. In particular, competent authorities should be free from undue political influence and from industry interference that might affect their operational impartiality. ***In order to prevent such interference, it is advisable to make any appointment within these authorities incompatible with decision-making or management positions in the industry.***

Or. ro

Amendment 193
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*

(21) For the performance of supervisory activities aimed at verifying the correct application of SoHO legislation, Member States should designate competent authorities that act independently and impartially. It is therefore important that their function of oversight is separate and independent from the performance of SoHO activities. In particular, competent authorities should be free from undue political influence and from industry interference that might affect their operational impartiality.	(21) For the performance of supervisory activities aimed at verifying the correct application of SoHO legislation, Member States should designate competent authorities that act independently and impartially. It is therefore important that their function of oversight is separate and independent from the performance of SoHO activities. In particular, competent authorities should be free from undue political influence and from industry ***or other actors'*** interference that might affect their operational impartiality.

Or. en

Amendment 194
Joanna Kopcińska

Proposal for a regulation
Recital 22

Text proposed by the Commission	*Amendment*
(22) For the performance of supervisory activities aimed at verifying the correct application of SoHO legislation, Member States should designate competent authorities that act in the public interest, are appropriately resourced and equipped, and offer guarantees of impartiality, professionalism and transparency. When infringements relate to direct health risks, and the publication of information regarding those infringements can contribute to risk mitigation and the protection of donors, recipients or offspring from medically assisted reproduction, competent authorities should, where necessary, be able to prioritise transparency of their enforcement activities over the protection of confidentiality of the party that has infringed the Regulation.	(22) For the performance of supervisory activities aimed at verifying the correct application of SoHO legislation, Member States should designate competent authorities that act in the public interest, are appropriately resourced and equipped, and offer guarantees of impartiality, professionalism and transparency. When infringements relate to direct health risks, and the publication of information regarding those infringements can contribute to risk mitigation and the protection of donors, recipients or offspring from medically assisted reproduction, competent authorities should, where necessary, be able to prioritise transparency of their enforcement activities over the protection of confidentiality of the party that has infringed the Regulation. ***Matters covered by trade secrecy or infringements of the law until such time as the competent court has issued a ruling may not be the subject of such public***

information.

Or. pl

Amendment 195
Mathilde Androuët

Proposal for a regulation
Recital 22

Text proposed by the Commission	*Amendment*
(22) For the performance of supervisory activities aimed at verifying the correct application of SoHO legislation, Member States should designate competent authorities that act in the public interest, are appropriately resourced and equipped, and offer guarantees of impartiality, professionalism and transparency. When infringements relate to direct health risks, and the publication of information regarding those infringements can contribute to risk mitigation and the protection of donors, recipients or ***offspring*** from medically assisted reproduction, competent authorities should, where necessary, be able to prioritise transparency of their enforcement activities over the protection of confidentiality of the party that has infringed the Regulation.	(22) For the performance of supervisory activities aimed at verifying the correct application of SoHO legislation, Member States should designate competent authorities ***– whose induction training they shall ensure –*** that act in the public interest, are appropriately resourced and equipped, and offer guarantees of impartiality, professionalism and transparency. When infringements relate to direct health risks, and the publication of information regarding those infringements can contribute to risk mitigation and the protection of donors, recipients or ***child*** from medically assisted reproduction, competent authorities should, where necessary, be able to prioritise transparency of their enforcement activities over the protection of confidentiality of the party that has infringed the Regulation.

Or. fr

Amendment 196
Nathalie Colin-Oesterlé

Proposal for a regulation
Recital 22 a (new)

Text proposed by the Commission	*Amendment*
	(22a) For the performance of supervisory activities, competent authorities should ensure the impartiality

	and independence of the inspectors and provide them with training.

Or. fr

Amendment 197
Tudor Ciuhodaru

Proposal for a regulation
Recital 23

Text proposed by the Commission	*Amendment*
(23) The correct application and enforcement of the rules falling within the scope of this Regulation require an appropriate knowledge of those rules. It is therefore important that the staff performing supervisory activities have an appropriate professional background and are regularly trained, in accordance with their area of competence, on the obligations resulting from this Regulation.	(23) The correct application and enforcement of the rules falling within the scope of this Regulation require an appropriate knowledge of those rules. It is therefore important that the staff performing supervisory activities have an appropriate professional background and are regularly trained, in accordance with their area of competence, on the obligations resulting from this Regulation***, in order to make informed decisions and to be able to provide the target public with the correct information***.

Or. ro

Amendment 198
Ondřej Knotek, Susana Solís Pérez

Proposal for a regulation
Recital 24

Text proposed by the Commission	*Amendment*
(24) When there is doubt about the regulatory status of a particular substance, product or activity under this Regulation, competent authorities should consult with the relevant authorities responsible for other relevant regulatory frameworks, namely medicinal products, medical devices, organs or food, with the aim of ensuring coherent procedures for the	(24) When there is doubt about the regulatory status of a particular substance, product or activity under this Regulation, competent authorities should consult with the relevant authorities responsible for other relevant regulatory frameworks, namely medicinal products, medical devices, organs or food, with the aim of ensuring coherent procedures for the

application of this Regulation***. Competent authorities*** should inform the SoHO Coordination Board of the outcome of their consultations. When SoHOs or SoHO preparations are used to manufacture products regulated under other Union legislation, or as the starting and raw material thereof, competent authorities should cooperate with the relevant authorities on their territory. This cooperation should aim to reach an agreed approach for any subsequent communications between the authorities responsible for SoHO and for the other relevant sectors, as needed, regarding authorisation and monitoring of the SoHOs or the product manufactured from SoHOs. It should in principle be the responsibility of the Member States to decide on a case-by-case basis on the regulatory status of a substance, product or activity. However, in order to ensure consistent decisions across all Member States with regard to borderline cases, the Commission should be empowered to, on its own initiative or at the duly substantiated request of a Member State, decide on the regulatory status of a particular substance, product or activity under this Regulation.

application of this Regulation ***and other relevant EU legislations. When SoHOs or SoHO preparations meet the criteria to be defined as a medicinal products or an advanced therapy medicinal product, the classification as medicinal product or as advanced therapy medicinal product should prevail. National authority*** should inform the SoHO Coordination Board of the outcome of their consultations. When SoHOs or SoHO preparations are used to manufacture products regulated under other Union legislation, or as the starting and raw material thereof, competent authorities should cooperate with the relevant authorities on their territory. This cooperation should aim to reach an agreed approach for any subsequent communications between the authorities responsible for SoHO and for the other relevant sectors, as needed, regarding authorisation and monitoring of the SoHOs or the product manufactured from SoHOs. It should in principle be the responsibility of the Member States to decide on a case-by-case basis on the regulatory status of a substance, product or activity. However, in order to ensure consistent decisions across all Member States with regard to borderline cases, the Commission should be empowered to, on its own initiative or at the duly substantiated request of a Member State, decide on the regulatory status of a particular substance, product or activity under this Regulation. ***In case of doubt on the classification of a substance, product or activity as medicinal product, the Commission should consult the permanent panel composed of representatives of the European Medicine Agency and the SoHO Coordination Board (SCB) for advice and to implement the classification decision taken by the panel across all EU Member States.***

Or. en

Amendment 199

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

Proposal for a regulation
Recital 24

Text proposed by the Commission	*Amendment*
(24) When there is doubt about the regulatory status of a particular substance, product or activity under this Regulation, competent authorities should consult ***with*** the relevant authorities responsible for other relevant regulatory frameworks, namely medicinal products, medical devices***, organs or food***, with the aim of ensuring coherent procedures for the application of this Regulation***. Competent authorities should inform the SoHO Coordination Board of the outcome of their consultations***. When SoHOs or SoHO preparations are used to manufacture products regulated under other Union legislation, or as the starting and raw material thereof, competent authorities should cooperate with the relevant authorities on their territory. This cooperation should aim to reach an agreed approach for any subsequent communications between the authorities responsible for SoHO and for the other relevant sectors, as needed, regarding authorisation and monitoring of the SoHOs or the product manufactured from SoHOs. It should in principle be the responsibility of the Member States to decide on a case-by-case basis on the regulatory status of a substance, product or activity. However, in order to ensure consistent decisions across all Member States with regard to borderline cases, the Commission should be empowered to, ***on its own initiative or*** at the duly substantiated request of a Member State, decide on the regulatory status of a particular substance, product or activity under this Regulation.	(24) When there is doubt about the regulatory status of a particular substance, product or activity under this Regulation, competent authorities should consult ***the Clasification Advisory Council, defined in this Regulation and composed by representatives of*** the relevant authorities responsible for other relevant regulatory frameworks, namely medicinal products, ***advanced therapies,*** medical devices ***and the SoHO Coordination Board***, with the aim of ensuring coherent procedures for the application of this Regulation. When SoHOs or SoHO preparations are used to manufacture products regulated under other Union legislation, or as the starting and raw material thereof, competent authorities should cooperate with the relevant authorities on their territory. This cooperation should aim to reach an agreed approach for any subsequent communications between the authorities responsible for SoHO and for the other relevant sectors, as needed, regarding authorisation and monitoring of the SoHOs or the product manufactured from SoHOs. It should in principle be the responsibility of the Member States to decide on a case-by-case basis on the regulatory status of a substance, product or activity. However, in order to ensure consistent decisions across all Member States with regard to borderline cases, the Commission should be empowered to, at the duly substantiated request of a Member State ***or the Classification Advisory Council***, decide on the regulatory status of a particular substance, product or activity under this Regulation.

Or. en

Justification

Regarding borderline products, the proposed Classification Advisory Board would sit experts from the EMA, the SCB and the Medical Devices Coordination Group at the same table so that they can discuss and reach a consensus

Amendment 200
Tudor Ciuhodaru

Proposal for a regulation
Recital 24

Text proposed by the Commission	*Amendment*
(24) When there is doubt about the regulatory status of a particular substance, product or activity under this Regulation, competent authorities should consult with the relevant authorities responsible for other relevant regulatory frameworks, namely medicinal products, medical devices, organs or food, with the aim of ensuring coherent procedures for the application of this Regulation. Competent authorities should inform the SoHO Coordination Board of the outcome of their consultations. When SoHOs or SoHO preparations are used to manufacture products regulated under other Union legislation, or as the starting and raw material thereof, competent authorities should cooperate with the relevant authorities on their territory. This cooperation should aim to reach an agreed approach for any subsequent communications between the authorities responsible for SoHO and for the other relevant sectors, as needed, regarding authorisation and monitoring of the SoHOs or the product manufactured from SoHOs. It should in principle be the responsibility of the Member States to decide on a case-by-case basis on the regulatory status of a substance, product or activity. However, in order to ensure consistent decisions across all Member States with regard to borderline cases, the Commission should be ***empowered to***, on its own initiative or at	(24) When there is doubt about the regulatory status of a particular substance, product or activity under this Regulation, competent authorities should consult with the relevant authorities responsible for other relevant regulatory frameworks, namely medicinal products, medical devices, organs or food, with the aim of ensuring coherent procedures for the application of this Regulation. Competent authorities should inform the SoHO Coordination Board of the outcome of their consultations. When SoHOs or SoHO preparations are used to manufacture products regulated under other Union legislation, or as the starting and raw material thereof, competent authorities should cooperate with the relevant authorities on their territory. This cooperation should aim to reach an agreed approach for any subsequent communications between the authorities responsible for SoHO and for the other relevant sectors, as needed, regarding authorisation and monitoring of the SoHOs or the product manufactured from SoHOs. It should in principle be the responsibility of the Member States to decide on a case-by-case basis on the regulatory status of a substance, product or activity. However, in order to ensure consistent decisions across all Member States with regard to borderline cases, the Commission should be ***informed sufficiently early to be able to***

the duly substantiated request of a Member State, ***decide*** on the regulatory status of a particular substance, product or activity under this Regulation.

decide, on its own initiative or at the duly substantiated request of a Member State, on the regulatory status of a particular substance, product or activity under this Regulation.

Or. ro

Amendment 201
Mathilde Androuët

Proposal for a regulation
Recital 24

Text proposed by the Commission	*Amendment*
(24) When there is doubt about the regulatory status of a particular substance, product or activity under this Regulation, competent authorities should consult with the relevant authorities responsible for other relevant regulatory frameworks, namely medicinal products, medical devices, organs or food, with the aim of ensuring coherent procedures for the application of this Regulation. Competent authorities should inform the SoHO Coordination Board of the outcome of their consultations. When SoHOs or SoHO preparations are used to manufacture products regulated under other Union legislation, or as the starting and raw material thereof, competent authorities should cooperate with the relevant authorities on their territory. This cooperation should aim to reach an agreed approach for any subsequent communications between the authorities responsible for SoHO and for the other relevant sectors, as needed, regarding authorisation and monitoring of the SoHOs or the product manufactured from SoHOs. It should in principle be the responsibility of the Member States to decide on a case-by-case basis on the regulatory status of a substance, product or activity. However, in order to ensure consistent decisions across all Member States with regard to	(24) When there is doubt about the regulatory status of a particular substance, product or activity under this Regulation, competent authorities should consult with the relevant authorities responsible for other relevant regulatory frameworks, namely medicinal products, medical devices, organs or food, with the aim of ensuring coherent procedures for the application of this Regulation. Competent authorities should inform the SoHO Coordination Board of the outcome of their consultations. When SoHOs or SoHO preparations are used to manufacture products regulated under other Union legislation, or as the starting and raw material thereof, competent authorities should cooperate with the relevant authorities on their territory. This cooperation should aim to reach an agreed approach for any subsequent communications between the authorities responsible for SoHO and for the other relevant sectors, as needed, regarding authorisation and monitoring of the SoHOs or the product manufactured from SoHOs. It should in principle be the responsibility of the Member States to decide on a case-by-case basis on the regulatory status of a substance, product or activity. However, in order to ensure consistent decisions across all Member States with regard to

borderline cases, the Commission should be empowered to, ***on its own initiative or*** at the duly substantiated request of a Member State, decide on the regulatory status of a particular substance, product or activity under this Regulation.	borderline cases, the Commission should be empowered to, at the duly substantiated request of a Member State, decide on the regulatory status of a particular substance, product or activity under this Regulation.

Or. fr

Amendment 202
Kateřina Konečná

Proposal for a regulation
Recital 24 a (new)

Text proposed by the Commission	*Amendment*
	(24 a) Education in current science concerning SoHO application and transfusion as well as the whole process of SoHO procurement must receive more attention during formal mandatory medical training. Member States are encouraged to establish certain areas such as transfusion medicine as an independent medical subject with structured training, including medical speciality schools and programmes for continuous medical education for all medical staff. Training and better information of the prescribers would reduce the risk of unnecessary application of SoHO.

Or. en

Justification

There is currently a shortage of qualified medical staff on certain SoHO sectors, such as blood. Member States should be encouraged to address this issue to ensure a resilient SoHO supply system. Also, more and better training also means a more efficient application of scarce SoHO.

Amendment 203
Nathalie Colin-Oesterlé

Proposal for a regulation
Recital 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) Health-care personnel should be informed about, and trained in, the functioning of the entire SoHO supply chain, in particular patient blood management, as recommended by the World Health Organization. Awareness-raising and continuous training for prescribers could avoid the application of SoHOs where therapeutic alternatives are available, in particular by ensuring the best possible use is made of SoHOs.

Or. fr

Amendment 204
Mathilde Androuët

Proposal for a regulation
Recital 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) Given the World Health Organization's[1 a] recommendation that health-care personnel should be informed about, and trained in, patient blood management, prescribers should be made more aware of therapeutic alternatives to the application of this SoHO Regulation. This practice is also liable to limit the flow of SoHOs and ensure security of supply.
	[1 a] World Health Organization Resolution WHA 63.12, 'Availability, safety and quality of blood products', 21.5.2010.

Or. fr

Justification

Patient blood management has at least two advantages: it makes it possible to offer patients therapeutic alternatives that are less invasive than transfusions and ensures better

management of the available blood supply.

Amendment 205
Tudor Ciuhodaru

Proposal for a regulation
Recital 26

Text proposed by the Commission	*Amendment*
(26) Commission experts should be able to perform controls, including audits, in Member States to verify the effective application of the relevant requirements of competent authorities and of the supervisory activity systems. Commission controls should also serve to investigate and collect information on enforcement practices or problems, emergencies and new developments in Member States. Official controls should be performed by personnel who are independent, free from any conflict of interest and in particular who are not in a situation which, directly or indirectly, could affect their ability to carry out their professional duties in an impartial manner.	(26) Commission experts should ***have the necessary medical experience and knowledge to*** be able to perform controls, including audits, in Member States to verify the effective application of the relevant requirements of competent authorities and of the supervisory activity systems. Commission controls should also serve to investigate and collect information on enforcement practices or problems, emergencies and new developments in Member States. Official controls should be performed by personnel who are independent, free from any conflict of interest and in particular who are not in a situation which, directly or indirectly, could affect their ability to carry out their professional duties in an impartial manner.

Or. ro

Amendment 206
Joanna Kopcińska

Proposal for a regulation
Recital 26

Text proposed by the Commission	*Amendment*
(26) Commission experts should be able to perform controls, including audits, in Member States to verify the effective application of the relevant requirements of competent authorities and of the supervisory activity systems. ***Commission***	(26) Commission experts should be able to perform controls, including audits, in Member States to verify the effective application of the relevant requirements of competent authorities and of the supervisory activity systems. ***Official***

controls ***should also serve to investigate and collect information on enforcement practices or problems, emergencies and new developments in Member States***. Official controls should be performed by personnel who are independent, free from any conflict of interest and in particular who are not in a situation which, directly or indirectly, could affect their ability to carry out their professional duties in an impartial manner.	controls ***may only be carried out with the agreement of the Member State, in compliance with the organisational rules, functioning and powers of the national supervisory authorities***. Official controls should be performed by personnel who are independent, free from any conflict of interest and in particular who are not in a situation which, directly or indirectly, could affect their ability to carry out their professional duties in an impartial manner.

Or. pl

Amendment 207
Mathilde Androuët

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*
(27) Since SoHO preparations are subjected to a series of SoHO activities prior to their release and distribution, competent authorities should assess and authorise SoHO preparations to verify that a high level of safety, quality and efficacy is achieved consistently by the application of that specific series of activities, performed in that specific manner. When SoHOs are prepared with newly developed and validated collection, testing or processing methods, consideration should be given to the demonstration of safety and efficacy in recipients by means of requirements for clinical outcome data collection and review. The extent of such required clinical outcome data should correlate with the level of risk associated with the activities performed for that SoHO preparation and use. Where a new or modified SoHO preparation poses negligible risks for recipients (or ***offspring*** in the case of medically assisted reproduction), the vigilance reporting requirements provided for in this	(27) Since SoHO preparations are subjected to a series of SoHO activities prior to their release and distribution, competent authorities should assess and authorise SoHO preparations to verify that a high level of safety, quality and efficacy is achieved consistently by the application of that specific series of activities, performed in that specific manner. When SoHOs are prepared with newly developed and validated collection, testing or processing methods, consideration should be given to the demonstration of safety and efficacy in recipients by means of requirements for clinical outcome data collection and review. The extent of such required clinical outcome data should correlate with the level of risk associated with the activities performed for that SoHO preparation and use. Where a new or modified SoHO preparation poses negligible risks for recipients (or ***foetuses, newborns or children*** in the case of medically assisted reproduction), the vigilance reporting requirements provided

Regulation should be adequate to demonstrate safety and quality. This should apply for well-established SoHO preparations that are introduced in a new SoHO entity but have been robustly demonstrated as safe and effective by their use in other entities.

for in this Regulation should be adequate to demonstrate safety and quality. This should apply for well-established SoHO preparations that are introduced in a new SoHO entity but have been robustly demonstrated as safe and effective by their use in other entities.

Or. fr

Amendment 208
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*
(27) Since SoHO preparations are subjected to a series of SoHO activities prior to their release ***and*** distribution, competent authorities should assess and authorise SoHO preparations to verify that a high level of safety, quality and efficacy is achieved consistently by the application of that specific series of activities, performed in that specific manner. When SoHOs are prepared with newly developed and validated collection, testing or processing methods, consideration should be given to the demonstration of safety and efficacy in recipients by means of requirements for clinical outcome data collection and review. The extent of such required clinical outcome data should correlate with the level of risk associated with the activities performed for that SoHO preparation and use. Where a new or modified SoHO preparation poses negligible risks for recipients (or offspring in the case of medically assisted reproduction), the vigilance reporting requirements provided for in this Regulation should be adequate to demonstrate safety and quality. This should apply for well-established SoHO preparations that are introduced in a new	(27) Since SoHO preparations are subjected to a series of SoHO activities prior to their release***,*** distribution ***and issuing***, competent authorities should assess and authorise SoHO preparations to verify that a high level of safety, quality and efficacy is achieved consistently by the application of that specific series of activities, performed in that specific manner. When SoHOs are prepared with newly developed and validated collection, testing or processing methods, consideration should be given to the demonstration of safety and efficacy in recipients by means of requirements for clinical outcome data collection and review. The extent of such required clinical outcome data should correlate with the level of risk associated with the activities performed for that SoHO preparation and use. Where a new or modified SoHO preparation poses negligible risks for recipients (or offspring in the case of medically assisted reproduction), the vigilance reporting requirements provided for in this Regulation should be adequate to demonstrate safety and quality. This should apply for well-established SoHO preparations that are introduced in a new

SoHO entity but have been robustly demonstrated as safe and effective by their use in other entities.

SoHO entity but have been robustly demonstrated as safe and effective by their use in other entities.

Or. en

Amendment 209
Tilly Metz

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) With regard to SoHO preparations that pose a certain level of risk (low, moderate or high), the applicant should propose a plan for clinical outcome monitoring that should fulfil different requirements appropriate to the risk indicated. The most up-to-date guidance of the European Directorate for the Quality of Medicines & HealthCare (EDQM, a Directorate of the Council of Europe) should be considered relevant in the design of clinical follow-up studies proportionate in extent and complexity to the identified level of risk of the SoHO preparation. In the case of low risk, in addition to the mandatory continuous vigilance reporting, the applicant should organise proactive clinical follow-up for a defined number of patients. For moderate and high risk, in addition to the mandatory vigilance reporting and the clinical follow-up, the applicant should propose clinical investigation studies with monitoring of pre-defined clinical end-points. In case of high risk, these should include a comparison with standard treatments, ideally in a study with subjects allocated to test and control groups in a randomised manner. The competent authority should approve the plans before they are implemented and should assess the outcome data as part of a SoHO preparation authorisation.	(28) ***Applicants requesting an authorisation of SoHO preparation should use the Euro GTP II methodologies or equivalent tools to assess the risk level of their SoHO preparation. Applicants should share the results of the risk assessments with competent authorities when requesting authorisation.*** With regard to SoHO preparations that pose a certain level of risk (low, moderate or high), the applicant should propose a plan for clinical outcome monitoring that should fulfil different requirements appropriate to the risk indicated. The most up-to-date guidance of the European Directorate for the Quality of Medicines & HealthCare (EDQM, a Directorate of the Council of Europe) should be considered relevant in the design of clinical follow-up studies proportionate in extent and complexity to the identified level of risk of the SoHO preparation. In the case of low risk, in addition to the mandatory continuous vigilance reporting, the applicant should organise proactive clinical follow-up for a defined number of patients. For moderate and high risk, in addition to the mandatory vigilance reporting and the clinical follow-up, the applicant should propose clinical investigation studies with monitoring of pre-defined clinical end-points. In case of high risk, these should include a comparison with standard treatments,

ideally in a study with subjects allocated to test and control groups in a randomised manner. The competent authority should approve the plans before they are implemented and should assess the outcome data as part of a SoHO preparation authorisation.

Or. en

Amendment 210
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) With regard to SoHO preparations that pose a certain level of risk (low, moderate or high), the applicant should propose a plan for clinical outcome monitoring that should fulfil different requirements appropriate to the risk indicated. The most up-to-date guidance of the European Directorate for the Quality of Medicines & HealthCare (EDQM, a Directorate of the Council of Europe) should be considered relevant in the design of clinical follow-up studies proportionate in extent and complexity to the identified level of risk of the SoHO preparation. In the case of low risk, in addition to the mandatory continuous vigilance reporting, the applicant should organise proactive clinical follow-up for a defined number of patients. For moderate and high risk, in addition to the mandatory vigilance reporting and the clinical follow-up, the applicant should propose clinical investigation studies with monitoring of pre-defined clinical end-points. In case of high risk, these should include a comparison with standard treatments, ideally in a study with subjects allocated to test and control groups in a randomised manner. The competent authority should	(28) With regard to SoHO preparations that pose a certain level of risk (low, moderate or high), the applicant should propose a plan for clinical outcome monitoring that should fulfil different requirements appropriate to the risk indicated***, following the guidelines specified in this Regulation***. The most up-to-date guidance of the European Directorate for the Quality of Medicines & HealthCare (EDQM, a Directorate of the Council of Europe) should be considered relevant in the design of clinical follow-up studies proportionate in extent and complexity to the identified level of risk of the SoHO preparation. In the case of low risk, in addition to the mandatory continuous vigilance reporting, the applicant should organise proactive clinical follow-up for a defined number of patients. For moderate and high risk, in addition to the mandatory vigilance reporting and the clinical follow-up, the applicant should propose clinical investigation studies with monitoring of pre-defined clinical end-points. In case of high risk, these should include a comparison with standard treatments, ideally in a study with subjects allocated to test and control groups in a

approve the plans before they are implemented and should assess the outcome data as part of a SoHO preparation authorisation.	randomised manner. The competent authority should approve the plans before they are implemented and should assess the outcome data as part of a SoHO preparation authorisation. ***If a conventional treatment or a control group is based on a medicinal product for human use, these studies shall be considered clinical trials that are covered by Regulation 536/2014.***

Or. en

(Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC)

Amendment 211
Susana Solís Pérez, Ondřej Knotek, Véronique Trillet-Lenoir

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) With regard to SoHO preparations that pose a certain level of risk (low, moderate or high), the applicant should propose a plan for clinical outcome monitoring that should fulfil different requirements appropriate to the risk indicated. The most up-to-date guidance of the European Directorate for the Quality of Medicines & HealthCare (EDQM, a Directorate of the Council of Europe) should be considered relevant in the design of clinical follow-up studies proportionate in extent and complexity to the identified level of risk of the SoHO preparation. In the case of low risk, in addition to the mandatory continuous vigilance reporting, the applicant should organise proactive clinical follow-up for a defined number of patients. For moderate and high risk, in addition to the mandatory vigilance reporting and the clinical follow-up, the applicant should propose clinical investigation studies with monitoring of	(28) With regard to SoHO preparations that pose a certain level of risk (low, moderate or high), the applicant should propose a plan for clinical outcome monitoring that should fulfil different requirements appropriate to the risk indicated. The most up-to-date guidance of the European Directorate for the Quality of Medicines & HealthCare (EDQM, a Directorate of the Council of Europe) should be considered relevant in the design of clinical follow-up studies proportionate in extent and complexity to the identified level of risk of the SoHO preparation. In the case of low risk, in addition to the mandatory continuous vigilance reporting, the applicant should organise proactive clinical follow-up for a defined number of patients. For moderate and high risk, in addition to the mandatory vigilance reporting and the clinical follow-up, the applicant should propose clinical investigation studies with monitoring of

pre-defined clinical end-points. In case of high risk, these should include a comparison with standard treatments, ideally in a study with subjects allocated to test and control groups in a randomised manner. The competent authority should approve the plans before they are implemented and should assess the outcome data as part of a SoHO preparation authorisation.	pre-defined clinical end-points. In case of high risk, these should include a comparison with standard treatments, ideally in a study with subjects allocated to test and control groups in a randomised manner. ***In case the standard treatment or control group is based on medcinal products, the studies are considered as clinical trials as defined and regulated by Regulation 536/2014.*** The competent authority should approve the plans before they are implemented and should assess the outcome data as part of a SoHO preparation authorisation.

Or. en

Justification

Clarification on the application case of existing relevant Union legislation, namely the Clinical Trials Regulation.

Amendment 212
Tudor Ciuhodaru

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) With regard to SoHO preparations that pose a certain level of risk (low, moderate or high), the applicant should propose a plan for clinical outcome monitoring that should fulfil different requirements appropriate to the risk indicated. The most up-to-date guidance of the European Directorate for the Quality of Medicines & HealthCare (EDQM, a Directorate of the Council of Europe) should be considered relevant in the design of clinical follow-up studies proportionate in extent and complexity to the identified level of risk of the SoHO preparation. In the case of low risk, in addition to the mandatory continuous vigilance reporting, the applicant should organise proactive clinical follow-up for a defined number of	(28) With regard to SoHO preparations that pose a certain level of risk (low, moderate or high), the applicant should propose a plan for ***medium-term and long-term*** clinical outcome monitoring that should fulfil different requirements appropriate to the risk indicated. The most up-to-date guidance of the European Directorate for the Quality of Medicines & HealthCare (EDQM, a Directorate of the Council of Europe) should be considered relevant in the design of clinical follow-up studies proportionate in extent and complexity to the identified level of risk of the SoHO preparation. In the case of low risk, in addition to the mandatory continuous vigilance reporting, the applicant should organise proactive

patients. For moderate and high risk, in addition to the mandatory vigilance reporting and the clinical follow-up, the applicant should propose clinical investigation studies with monitoring of pre-defined clinical end-points. In case of high risk, these should include a comparison with standard treatments, ideally in a study with subjects allocated to test and control groups in a randomised manner. The competent authority should approve the plans before they are implemented and should assess the outcome data as part of a SoHO preparation authorisation.	***medium-term and long-term*** clinical follow-up for a defined number of patients. For moderate and high risk, in addition to the mandatory vigilance reporting and the clinical follow-up, the applicant should propose clinical investigation studies with ***medium-term and long-term*** monitoring of pre-defined clinical end-points. In case of high risk, these should include a comparison with standard treatments, ideally in a study with subjects allocated to test and control groups in a randomised manner. The competent authority should approve the plans before they are implemented and should assess the outcome data as part of a SoHO preparation authorisation.

Or. ro

Amendment 213
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 28 a (new)

Text proposed by the Commission	*Amendment*
	(28 a) With the aim of evaluating or improving SoHO treatments, it is common practice to conduct clinical studies with SoHO, in the context of the authorisation of a new SoHO preparation or beyong it. While these clinical studies with SoHO are not covered by Regulation (EU) No 536/2014 on clinical trials, it is necessary to extend the technical guarantees and ethical principles of that Regulation to clinical studies with SoHO. In clinical studies with SoHO, patients' rights, safety, dignity and well-being must always be the priority and the study should be designed in a way that leads to reliable and robust data and conclusions. The evaluation by a Research Ethics Committee (REC) should ensure the protection of the rights, safety and well-

being of recipients and donors and the ethical and scientific quality of the study. Such committees should take into account new forms of scientific evidence, such as the incorporation of real-world data or the use of artificial intelligence.

Or. en

(Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC)

Amendment 214
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 28 b (new)

Text proposed by the Commission	*Amendment*
	(28 b) The commitment to publish the clinical results obtained should be a mandatory requirement for clinical studies with SoHO. The existence of a registry of SoHO clinical studies at EU level is critical to facilitate patient participation in clinical studies, to boost multi-centre studies and to foster collaboration to generate more robust results and conclusions, and to make the generated knowledge available to other researchers, healthcare professionals, participants themselves and the general public.

Or. en

Amendment 215
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 29

Text proposed by the Commission	*Amendment*
(29) In the interests of efficiency, it should be permitted to conduct clinical outcome studies using the established framework in the pharmaceutical sector for clinical trials, as set out in Regulation (EU) No 536/2014 of the European Parliament and of the Council[25], when operators wish to do so. ***Whilst applicants can choose to record the clinical data generated during the clinical outcome monitoring themselves, they should also be permitted to use existing clinical data registries as a means of such recording when those registries have been verified by the competent authority, or are certified by an external institution, in terms of the reliability of their data management procedures.***	(29) In the interests of efficiency, it should be permitted to conduct clinical outcome studies using the established framework in the pharmaceutical sector for clinical trials, as set out in Regulation (EU) No 536/2014 of the European Parliament and of the Council[25], when operators wish to do so.
[25] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).	[25] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

Or. en

Justification

The registration of a clinical study should be mandatory.

Amendment 216
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(30) In order to facilitate innovation and reduce administrative burden, competent authorities should share with each other information on the authorisation of new	(30) In order to facilitate innovation and reduce administrative burden, competent authorities should share with each other information on the authorisation of new

SoHO preparations and the evidence used for such authorisations, including for the validation of certified medical devices used for SoHO collection, processing, storage or application to patients. Such sharing could allow authorities to accept previous authorisations granted to other entities, including in other Member States and to thus significantly reduce the requirements to generate evidence.	SoHO preparations and the evidence used for such authorisations***, through the EU SoHO platform***, including for the validation of certified medical devices used for SoHO collection, processing, storage or application to patients. Such sharing could allow authorities to accept previous authorisations granted to other entities, including in other Member States and to thus significantly reduce the requirements to generate evidence. ***Competent authorities should also share with each other information on clinical studies with SoHO, via the EU SoHO Platform.***

Or. en

Amendment 217
Tudor Ciuhodaru

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(30) In order to facilitate innovation and reduce administrative burden, competent authorities should share with each other information on the authorisation of new SoHO preparations and the evidence used for such authorisations, including for the validation of certified medical devices used for SoHO collection, processing, storage or application to patients. Such sharing could allow authorities to accept previous authorisations granted to other entities, including in other Member States and to thus significantly reduce the requirements to generate evidence.	(30) In order to facilitate innovation***, identify the best solutions and preparations*** and reduce administrative burden, competent authorities should share with each other information on the authorisation of new SoHO preparations and the evidence used for such authorisations, including for the validation of certified medical devices used for SoHO collection, processing, storage or application to patients. Such sharing could allow authorities to accept previous authorisations granted to other entities, including in other Member States***, to use these solutions and products for the benefit of recipients*** and to thus significantly reduce the requirements to generate evidence.

Or. ro

Amendment 218
Andreas Glück, Véronique Trillet-Lenoir, Peter Liese, Susana Solís Pérez

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(30) In order to facilitate innovation and reduce administrative burden, competent authorities ***should*** share with each other information on the authorisation of new SoHO preparations and the evidence used for such authorisations, including for the validation of certified medical devices used for SoHO collection, processing, storage or application to patients. Such sharing could allow authorities to accept previous authorisations granted to other entities, including in other Member States and to thus significantly reduce the requirements to generate evidence.	(30) In order to facilitate innovation and reduce administrative burden, competent authorities ***must*** share with each other information on the authorisation of new SoHO preparations and the evidence used for such authorisations, including for the validation of certified medical devices used for SoHO collection, processing, storage or application to patients. Such sharing could allow authorities to accept previous authorisations granted to other entities, including in other Member States and to thus significantly reduce the requirements to generate evidence.

Or. en

Justification

In order to avoid the duplication of work, e.g. preparation authorisations, competent authorities must share information.

Amendment 219
Tudor Ciuhodaru

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(31) A broad range of public and private organisations influence the safety, quality and efficacy of SoHOs, even if they do not maintain banks of those SoHOs. Many organisations carry out a single SoHO activity, such as collection or donor testing on behalf of one or many organisations that maintain banks of SoHOs. The SoHO entity concept includes this broad range of organisations, from donor registries to	(31) A broad range of public and private organisations influence the safety, quality and efficacy of SoHOs, even if they do not maintain banks of those SoHOs. Many organisations carry out a single SoHO activity, such as collection or donor testing on behalf of one or many organisations that maintain banks of SoHOs. The SoHO entity concept includes this broad range of organisations, from donor

physicians that apply SoHOs to recipients or use SoHO processing devices at the recipient's bedside. The registration of all such SoHO entities should ensure that competent authorities have a clear overview of the field and its scale and can take enforcement action when deemed necessary. A SoHO entity registration should refer to the legal entity, regardless of the number of physical sites associated with the entity.	registries to physicians that apply SoHOs to recipients or use SoHO processing devices at the recipient's bedside. The registration of all such SoHO entities ***in special directories*** should ensure that competent authorities have a clear overview of the field and its scale and can take enforcement action when deemed necessary. A SoHO entity registration should refer to the legal entity, regardless of the number of physical sites associated with the entity.

Or. ro

Amendment 220
Tudor Ciuhodaru

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) Competent authorities should review the SoHO entities registered in their territory and ensure that those entities that carry out both processing and storage of SoHOs are inspected and authorised as SoHO establishments before starting those activities. A SoHO establishment authorisation should refer to the legal entity, even when one SoHO establishment has many physical sites. Competent authorities should consider the impact on safety, quality and efficacy of the SoHO activities carried out at SoHO entities that do not meet the definition of a SoHO establishment and decide whether particular entities should be subject to establishment authorisations due to the risk or scale associated with their activities. Similarly, SoHO entities that have a poor record in terms of compliance with reporting or other obligations might be suitable candidates for authorisation as SoHO establishments.	(32) Competent authorities should ***periodically*** review the SoHO entities registered in their territory and ensure that those entities that carry out both processing and storage of SoHOs are inspected and authorised as SoHO establishments before starting those activities. A SoHO establishment authorisation should refer to the legal entity, even when one SoHO establishment has many physical sites. Competent authorities should consider the impact on safety, quality and efficacy of the SoHO activities carried out at SoHO entities that do not meet the definition of a SoHO establishment and decide whether particular entities should be subject to establishment authorisations due to the risk or scale associated with their activities. Similarly, SoHO entities that have a poor record in terms of compliance with reporting or other obligations might be suitable candidates for authorisation as SoHO establishments.

Or. ro

Amendment 221
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) With regards to standards concerning donor, recipient and offspring protection, this Regulation should provide for a hierarchy of rules for their implementation. As risks and technologies change, this hierarchy of rules should facilitate an efficient and responsive uptake of the most up-to-date guidelines for implementing the standards set out in this Regulation. As part of that hierarchy, in the absence of Union legislation describing particular procedures to be applied and followed to meet the standards set out in this Regulation, following the guidelines of the European Centre for Disease Prevention and Control (ECDC) and the EDQM should be considered as a means to demonstrate compliance with the standards laid down in this Regulation to ensure high level of quality, safety and efficacy. SoHO entities should be permitted to follow other guidelines, provided that it has been demonstrated that those other guidelines achieve the same level of quality, safety and efficacy. In cases of detailed technical issues for which neither Union legislation nor the ECDC and the EDQM have defined a technical guideline or rule, operators should apply a locally defined rule that is in line with relevant internationally recognised guidelines and scientific evidence and is appropriate to mitigate any risk identified.	(33) With regards to standards concerning donor, recipient and offspring protection, this Regulation should provide for a hierarchy of rules for their implementation. As risks and technologies change, this hierarchy of rules should facilitate an efficient and responsive uptake of the most up-to-date guidelines for implementing the standards set out in this Regulation. As part of that hierarchy, in the absence of Union legislation describing particular procedures to be applied and followed to meet the standards set out in this Regulation, following the guidelines of the European Centre for Disease Prevention and Control (ECDC) and the EDQM should be considered as a means to demonstrate compliance with the standards laid down in this Regulation to ensure high level of quality, safety and efficacy. ***Member States should be involved in both the drafting and voting of these guidelines and should follow a transparent process of consultation with other relevant EU authorities and stakeholders.*** SoHO entities should be permitted to follow other guidelines, provided that it has been demonstrated that those other guidelines ***are based on the most up-to-date scientific evidence and*** achieve the same level of quality, safety and efficacy. In cases of detailed technical issues for which neither Union legislation nor the ECDC and the EDQM have defined a technical guideline or rule, operators should apply a locally defined rule that is in line with relevant internationally recognised guidelines and scientific evidence and is appropriate to mitigate any risk identified.

Amendment 222
Stelios Kympouropoulos, Tomislav Sokol, Peter Liese

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) With regards to standards concerning donor, recipient and offspring protection, this Regulation should provide for a hierarchy of rules for their implementation. As risks and technologies change, this hierarchy of rules should facilitate an efficient and responsive uptake of the most up-to-date guidelines for implementing the standards set out in this Regulation. As part of that hierarchy, in the absence of Union legislation describing particular procedures to be applied and followed to meet the standards set out in this Regulation, following the guidelines of the European Centre for Disease Prevention and Control (ECDC) and the EDQM should be considered as a means to demonstrate compliance with the standards laid down in this Regulation to ensure high level of quality, safety and efficacy. SoHO entities should be permitted to follow other guidelines, provided that it has been demonstrated that those other guidelines achieve the same level of quality, safety and efficacy. In cases of detailed technical issues for which neither Union legislation nor the ECDC and the EDQM have defined a technical guideline or rule, operators should apply a locally defined rule that is in line with relevant internationally recognised guidelines and scientific evidence and is appropriate to mitigate any risk identified.	(33) With regards to standards concerning donor, recipient and offspring protection, this Regulation should provide for a hierarchy of rules for their implementation. As risks and technologies change, this hierarchy of rules should facilitate an efficient and responsive uptake of the most up-to-date guidelines for implementing the standards set out in this Regulation. As part of that hierarchy, in the absence of Union legislation describing particular procedures to be applied and followed to meet the standards set out in this Regulation, following the guidelines of the European Centre for Disease Prevention and Control (ECDC) and the EDQM should be considered as a means to demonstrate compliance with the standards laid down in this Regulation to ensure high level of quality, safety and efficacy. SoHO entities should be permitted to follow other guidelines, provided that it has been demonstrated that those other guidelines achieve the same level of quality, safety and efficacy. In cases of detailed technical issues for which neither Union legislation nor the ECDC and the EDQM have defined a technical guideline or rule, operators should apply a locally defined rule that is in line with relevant internationally recognised guidelines and scientific evidence and is appropriate to mitigate any risk identified. ***When assesing scientific guidlines, it is important that the Commission, the ECDC, and the EDQM involve existing scientific, donor, and patient representative groups.***

Or. en

Amendment 223
Kateřina Konečná

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) With regards to standards concerning donor, recipient and offspring protection, this Regulation should provide for a hierarchy of rules for their implementation. As risks and technologies change, this hierarchy of rules should facilitate an efficient and responsive uptake of the most up-to-date guidelines for implementing the standards set out in this Regulation. As part of that hierarchy, in the absence of Union legislation describing particular procedures to be applied and followed to meet the standards set out in this Regulation, following the guidelines of the European Centre for Disease Prevention and Control (ECDC) and the EDQM should be considered as a means to demonstrate compliance with the standards laid down in this Regulation to ensure high level of quality, safety and efficacy. SoHO entities should be permitted to follow other guidelines, provided that it has been demonstrated that those other guidelines achieve the same level of quality, safety and efficacy. In cases of detailed technical issues for which neither Union legislation nor the ECDC and the EDQM have defined a technical guideline or rule, operators should apply a locally defined rule that is in line with relevant internationally recognised guidelines and scientific evidence and is appropriate to mitigate any risk identified.	(33) With regards to standards concerning donor, recipient and offspring protection, this Regulation should provide for a hierarchy of rules for their implementation. As risks and technologies change, this hierarchy of rules should facilitate an efficient and responsive uptake of the most up-to-date guidelines ***based on scientific evidence*** for implementing the standards set out in this Regulation. As part of that hierarchy, in the absence of Union legislation describing particular procedures to be applied and followed to meet the standards set out in this Regulation, following the guidelines of the European Centre for Disease Prevention and Control (ECDC) and the EDQM should be considered as a means to demonstrate compliance with the standards laid down in this Regulation to ensure high level of quality, safety and efficacy. SoHO entities should be permitted to follow other guidelines, provided that it has been demonstrated that those other guidelines achieve the same level of quality, safety and efficacy. In cases of detailed technical issues for which neither Union legislation nor the ECDC and the EDQM have defined a technical guideline or rule, operators should apply a locally defined rule that is in line with relevant internationally recognised guidelines and scientific evidence and is appropriate to mitigate any risk identified.

Or. en

Justification

This addition strengthens the spirit of the evaluation of the current legislation to ensure that scientific evidence based on facts and science drives EU policy in the field of SoHOs.

Amendment 224
Susana Solís Pérez

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) With regards to standards concerning donor, recipient and offspring protection, this Regulation should provide for a hierarchy of rules for their implementation. As risks and technologies change, this hierarchy of rules should facilitate an efficient and responsive uptake of the most up-to-date guidelines for implementing the standards set out in this Regulation. As part of that hierarchy, in the absence of Union legislation describing particular procedures to be applied and followed to meet the standards set out in this Regulation, following the guidelines of the European Centre for Disease Prevention and Control (ECDC) and the EDQM should be ***considered as a*** means to demonstrate compliance with the standards laid down in this Regulation to ensure high level of quality, safety and efficacy. SoHO entities should be permitted to follow other guidelines, provided that it has been demonstrated that those other guidelines achieve the same level of quality, safety and efficacy. In cases of detailed technical issues for which neither Union legislation nor the ECDC and the EDQM have defined a technical guideline or rule, operators should apply a locally defined rule that is in line with relevant internationally recognised guidelines and scientific evidence and is appropriate to mitigate any risk identified.	(33) With regards to standards concerning donor, recipient and offspring protection, this Regulation should provide for a hierarchy of rules for their implementation. As risks and technologies change, this hierarchy of rules should facilitate an efficient and responsive uptake of the most up-to-date guidelines ***based on scientific evidence*** for implementing the standards set out in this Regulation. As part of that hierarchy, in the absence of Union legislation describing particular procedures to be applied and followed to meet the standards set out in this Regulation, following the guidelines of the European Centre for Disease Prevention and Control (ECDC) and the EDQM should be ***one of the*** means to demonstrate compliance with the standards laid down in this Regulation to ensure high level of quality, safety and efficacy. SoHO entities should be permitted to follow other guidelines, provided that it has been demonstrated that those other guidelines achieve the same level of quality, safety and efficacy. In cases of detailed technical issues for which neither Union legislation nor the ECDC and the EDQM have defined a technical guideline or rule, operators should apply a locally defined rule that is in line with relevant internationally recognised guidelines and scientific evidence and is appropriate to mitigate any risk identified.

Or. en

Amendment 225
Andreas Glück, Ondřej Knotek, Peter Liese, Susana Solís Pérez, Jan Huitema

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) With regards to standards concerning donor, recipient and offspring protection, this Regulation should provide for a hierarchy of rules for their implementation. As risks and technologies change, this hierarchy of rules should facilitate an efficient and responsive uptake of the most up-to-date guidelines for implementing the standards set out in this Regulation. As part of that hierarchy, in the absence of Union legislation describing particular procedures to be applied and followed to meet the standards set out in this Regulation, following the guidelines of the European Centre for Disease Prevention and Control (ECDC) and the EDQM should be ***considered as a*** means to demonstrate compliance with the standards laid down in this Regulation to ensure high level of quality, safety and efficacy. SoHO entities should be permitted to follow other guidelines, provided that it has been demonstrated that those other guidelines achieve the same level of quality, safety and efficacy. In cases of detailed technical issues for which neither Union legislation nor the ECDC and the EDQM have defined a technical guideline or rule, operators should apply a locally defined rule that is in line with relevant internationally recognised guidelines and scientific evidence and is appropriate to mitigate any risk identified.	(33) With regards to standards concerning donor, recipient and offspring protection, this Regulation should provide for a hierarchy of rules for their implementation. As risks and technologies change, this hierarchy of rules should facilitate an efficient and responsive uptake of the most up-to-date guidelines for implementing the standards set out in this Regulation. As part of that hierarchy, in the absence of Union legislation describing particular procedures to be applied and followed to meet the standards set out in this Regulation, following the guidelines of the European Centre for Disease Prevention and Control (ECDC) and the EDQM should be ***one of the*** means to demonstrate compliance with the standards laid down in this Regulation to ensure high level of quality, safety and efficacy. SoHO entities should be permitted to follow other guidelines, provided that it has been demonstrated that those other guidelines achieve the same level of quality, safety and efficacy. In cases of detailed technical issues for which neither Union legislation nor the ECDC and the EDQM have defined a technical guideline or rule, operators should apply a locally defined rule that is in line with relevant internationally recognised guidelines and scientific evidence and is appropriate to mitigate any risk identified.

Or. en

Justification

Some Member States have developed well established guidelines. Members States with appropriate guidelines in place shall continue to apply national rules if they wish to do so.

Amendment 226
Alexandr Vondra, Joanna Kopcińska

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) With regards to standards concerning donor, recipient and offspring protection, this Regulation should provide for a hierarchy of rules for their implementation. As risks and technologies change, this hierarchy of rules should facilitate an efficient and responsive uptake of the most up-to-date guidelines for implementing the standards set out in this Regulation. As part of that hierarchy, in the absence of Union legislation describing particular procedures to be applied and followed to meet the standards set out in this Regulation, following the guidelines of the European Centre for Disease Prevention and Control (ECDC) and the EDQM should be considered as ***a*** means to ***demonstrate compliance*** with the standards laid down in this Regulation to ensure high level of quality, safety and efficacy. SoHO entities should be permitted to follow other ***guidelines, provided that it has been demonstrated that those other*** guidelines achieve ***the same*** level of quality, safety and efficacy. In cases of detailed technical issues for which neither Union legislation nor the ECDC and the EDQM have defined a technical guideline or rule, operators should apply a locally defined rule that is in line with relevant ***internationally*** recognised guidelines ***and scientific evidence*** and is appropriate to mitigate any risk identified.	(33) With regards to standards concerning donor, recipient and offspring protection, this Regulation should provide for a hierarchy of rules for their implementation. As risks and technologies change, this hierarchy of rules should facilitate an efficient and responsive uptake of the most up-to-date guidelines for implementing the standards set out in this Regulation. As part of that hierarchy, in the absence of Union legislation describing particular procedures to be applied and followed to meet the standards set out in this Regulation, following the guidelines of the European Centre for Disease Prevention and Control (ECDC) and the EDQM should be considered as ***one of the*** means to ***be compliant*** with the standards laid down in this Regulation to ensure high level of quality, safety and efficacy. ***Member States may decide that*** SoHO entities should be permitted to follow other ***recognised*** guidelines ***that are based on scientific evidence and*** achieve ***an appropriate*** level of quality, safety and efficacy. In cases of detailed technical issues for which neither Union legislation nor the ECDC and the EDQM have defined a technical guideline or rule, operators should apply a locally defined rule that is in line with relevant recognised guidelines and is appropriate to mitigate any risk identified.

Or. en

Amendment 227

Kateřina Konečná

Proposal for a regulation
Recital 33 a (new)

Text proposed by the Commission	*Amendment*
	(33 a) It is important that the Commission, the ECDC, the EDQM, when assessing scientific guidelines to be implemented at the Union level, involve, when appropriate existing professional, scientific, donor and patient representative groups at Union level in the field of SoHOs.

Or. en

Justification

As a principle, stakeholders such as professional, scientific, industry, donor and patient representative groups should be included in the interest of transparency and expertise. With this addition, we would ensure that the transparency and consultation foreseen for the SoHO Coordination Board (SCB) as detailed in current Recital 38 is also foreseen for other institutions and bodies.

Amendment 228
Jessica Polfjärd

Proposal for a regulation
Recital 34

Text proposed by the Commission	*Amendment*
(34) Where evidence demonstrates that specific processing steps reduce or eliminate the risk of transmission of specific infectious or non-infectious disease agents, the quality and safety standards for the verification of donor eligibility by means of donor health evaluations, including testing, and the related guidelines for their implementation, should take this evidence into account. Thus, in the case of, for example, plasma for fractionation, that in a subsequent step in the manufacturing process of medicinal products undergoes sterilisation steps,	(34) Where evidence demonstrates that specific processing steps reduce or eliminate the risk of transmission of specific infectious or non-infectious disease agents, the quality and safety standards for the verification of donor eligibility by means of donor health evaluations, including testing, and the related guidelines for their implementation, should take this evidence into account. Thus, in the case of, for example, plasma for fractionation, that in a subsequent step in the manufacturing process of medicinal products undergoes sterilisation steps,

certain donor eligibility criteria used for donation of plasma for transfusion might not be necessary nor appropriate.

certain donor eligibility criteria used for donation of plasma for transfusion might not be necessary nor appropriate. ***Some Member States and SoHO entitites have introduced screening criteria that have been perceived to constiute discimination, notably against men who have sex with men. It is appropriate to lay down that such criteria to shall be science-based to avoid the perception that health systems engage in discrimination.***

Or. en

Amendment 229
Alexandr Vondra

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) The EDQM is a structural part of the Council of Europe working under the European Pharmacopoeia Partial Agreement. The text of the Convention on the elaboration of a European Pharmacopoeia (ETS No. 050), accepted by Council Decision 94/358/EC[26], is considered to be the text of the European Pharmacopoeia Partial Agreement. Member States of the Council of Europe that have signed and ratified the European Pharmacopoeia Convention are ***the***member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental bodies functioning within the framework of this partial agreement, including among others: the European Pharmacopoeia Commission, the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The European Pharmacopoeia Convention has been signed and ratified by the European Union and all its Member	(35) The EDQM is a structural part of the Council of Europe working under the European Pharmacopoeia Partial Agreement. The text of the Convention on the elaboration of a European Pharmacopoeia (ETS No. 050), accepted by Council Decision 94/358/EC[26], is considered to be the text of the European Pharmacopoeia Partial Agreement. Member States of the Council of Europe that have signed and ratified the European Pharmacopoeia Convention are ***also***member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental bodies functioning within the framework of this partial agreement, including among others: the European Pharmacopoeia Commission, the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The European Pharmacopoeia Convention has been signed and ratified by

States, all of whom are represented in their intergovernmental bodies. In this context, the work of the EDQM on developing and updating guidelines on safety and quality of blood, tissues and cells, should be considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance of safety and quality during collection, processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means to implement the technical standards provided for in this Regulation.

[26] Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).

the European Union and all its Member States, all of whom are represented in their intergovernmental bodies. In this context, the work of the EDQM on developing and updating guidelines on safety and quality of blood, tissues and cells, should be considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation***, without prejudice to the Union's legal autonomy***. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance of safety and quality during collection, processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means to implement the technical standards provided for in this Regulation. ***In order to comply with the Union requirements for review of Union legislation, a transparent and open stakeholder consultation process shall be put in place for the development of those provisions and guidelines from the expert bodies.The committees referred to and any working parties and scientific advisory groups established within those committees shall develop appropriate contacts with public and private key stakeholders, including patients, consumers, health professionals, and industry representatives.***

[26] Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).

Or. en

Amendment 230
Kateřina Konečná

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) The EDQM is a structural part of the Council of Europe working under the European Pharmacopoeia Partial Agreement. The text of the Convention on the elaboration of a European Pharmacopoeia (ETS No. 050), accepted by Council Decision 94/358/EC[26], is considered to be the text of the European Pharmacopoeia Partial Agreement. Member States of the Council of Europe that have signed and ratified the European Pharmacopoeia Convention are the member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental bodies functioning within the framework of this partial agreement, including among others: the European Pharmacopoeia Commission, the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The European Pharmacopoeia Convention has been signed and ratified by the European Union and all its Member States, all of whom are represented in their intergovernmental bodies. In this context, the work of the EDQM on developing and updating guidelines on safety and quality of blood, tissues and cells, should be considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance of safety and quality during collection, processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means to	(35) The EDQM is a structural part of the Council of Europe working under the European Pharmacopoeia Partial Agreement. The text of the Convention on the elaboration of a European Pharmacopoeia (ETS No. 050), accepted by Council Decision 94/358/EC[26], is considered to be the text of the European Pharmacopoeia Partial Agreement. Member States of the Council of Europe that have signed and ratified the European Pharmacopoeia Convention are the member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental bodies functioning within the framework of this partial agreement, including among others: the European Pharmacopoeia Commission, the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The European Pharmacopoeia Convention has been signed and ratified by the European Union and all its Member States, all of whom are represented in their intergovernmental bodies. In this context, the work of the EDQM on developing and updating guidelines on safety and quality of blood, tissues and cells, should be considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance of safety and quality during collection, processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means to

implement the technical standards provided for in this Regulation.	implement the technical standards provided for in this Regulation. ***In order to comply with the Union requirements for review of Union legislation, a transparent and inclusive stakeholder consultation process shall be put in place for the development of those provisions and guidelines from the expert bodies.The committees referred to and any working parties and scientific advisory groups established within those committees shall develop appropriate contacts with key stakeholders, including:patients, consumers, health professionals, and industry representatives.***
[26] Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).	[26] Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).

Or. en

Justification

In order to accomplish the objectives of the SoHO Regulation, it's critical that technical guidelines are based on the latest scientific evidence. Therefore, it's important that all relevant stakeholders are involved in the development of these guidelines.

Amendment 231
Margarita de la Pisa Carrión

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) The EDQM is a structural part of the Council of Europe working under the European Pharmacopoeia Partial Agreement. The text of the Convention on the elaboration of a European Pharmacopoeia (ETS No. 050), accepted by Council Decision 94/358/EC[26], is considered to be the text of the European	(Does not affect the English version.)

Pharmacopoeia Partial Agreement. Member States of the Council of Europe that have signed and ratified the European Pharmacopoeia Convention are the member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental bodies functioning within the framework of this partial agreement, including among others: the European Pharmacopoeia Commission, the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The European Pharmacopoeia Convention has been signed and ratified by the European Union and all its Member States, all of whom are represented in their intergovernmental bodies. In this context, the work of the EDQM on developing and updating guidelines on safety and quality of blood, tissues and cells, should be considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance of safety and quality during collection, processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means to implement the technical standards provided for in this Regulation.

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[26] Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).

Or. es

Amendment 232
Tilly Metz

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) The EDQM is a structural part of the Council of Europe working under the European Pharmacopoeia Partial Agreement. The text of the Convention on the elaboration of a European Pharmacopoeia (ETS No. 050), accepted by Council Decision 94/358/EC[26], is considered to be the text of the European Pharmacopoeia Partial Agreement. Member States of the Council of Europe that have signed and ratified the European Pharmacopoeia Convention are the member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental bodies functioning within the framework of this partial agreement, including among others: the European Pharmacopoeia Commission, the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The European Pharmacopoeia Convention has been signed and ratified by the European Union and all its Member States, all of whom are represented in their intergovernmental bodies. In this context, the work of the EDQM on developing and updating guidelines on safety and quality of blood, tissues and cells, should be considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance of safety and quality during collection,	(35) The EDQM is a structural part of the Council of Europe working under the European Pharmacopoeia Partial Agreement. The text of the Convention on the elaboration of a European Pharmacopoeia (ETS No. 050), accepted by Council Decision 94/358/EC[26], is considered to be the text of the European Pharmacopoeia Partial Agreement. Member States of the Council of Europe that have signed and ratified the European Pharmacopoeia Convention are the member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental bodies functioning within the framework of this partial agreement, including among others: the European Pharmacopoeia Commission, the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The European Pharmacopoeia Convention has been signed and ratified by the European Union and all its Member States, all of whom are represented in their intergovernmental bodies. In this context, the work of the EDQM on developing and updating guidelines on safety and quality of blood, tissues and cells, should be considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance of safety and quality during collection,

processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means to implement the technical standards provided for in this Regulation.

processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means to implement the technical standards provided for in this Regulation. ***In order to ensure impartiality and independence, and safeguard public interest, the Commission should establish a memorandum of understanding with the EDQM related to transparency of membership and outputs and conflict of interest rules for experts and stakeholders involved in drafting EDQM guidelines.***

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[26] Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).

[26] Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).

Or. en

Amendment 233
Radka Maxová

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) The EDQM is a structural part of the Council of Europe working under the European Pharmacopoeia Partial Agreement. The text of the Convention on the elaboration of a European Pharmacopoeia (ETS No. 050), accepted by Council Decision ***94/358/EC***[26], is considered to be the text of the European Pharmacopoeia Partial Agreement. Member States of the Council of Europe that have signed and ratified the European Pharmacopoeia Convention are the member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental bodies functioning within the framework of this partial	(35) The EDQM is a structural part of the Council of Europe working under the European Pharmacopoeia Partial Agreement. The text of the Convention on the elaboration of a European Pharmacopoeia (ETS No. 050), accepted by Council Decision ***94/358/EC13***, is considered to be the text of the European Pharmacopoeia Partial Agreement. Member States of the Council of Europe that have signed and ratified the European Pharmacopoeia Convention are the member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental bodies functioning within the framework of this partial

agreement, including among others: the European Pharmacopoeia Commission, the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The European Pharmacopoeia Convention has been signed and ratified by the European Union and all its Member States, all of whom are represented in their intergovernmental bodies. In this context, the work of the EDQM on developing and updating guidelines on safety and quality of blood, tissues and cells, should be considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other ***non-communicable***diseases and the assurance of safety and quality during collection, processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means to implement the technical standards provided for in this Regulation.

agreement, including among others: the European Pharmacopoeia Commission, the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The European Pharmacopoeia Convention has been signed and ratified by the European Union and all its Member States, all of whom are represented in their intergovernmental bodies. In this context, the work of the EDQM on developing and updating guidelines on safety and quality of blood, tissues and cells, should be considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other ***non-communicable*** diseases and the assurance of safety and quality during collection, processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means to implement the technical standards provided for in this Regulation. ***A transparent and inclusive stakeholder consultation process shall be put in place for the development of the provisions and guidelines from the expert bodies. The consultation should include all key stakeholders: patients, consumers, health professionals, and industry representatives - both public and private.***

[26] Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).

Or. en

Amendment 234
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) The EDQM is a structural part of the Council of Europe working under the European Pharmacopoeia Partial Agreement. The text of the Convention on the elaboration of a European Pharmacopoeia (ETS No. 050), accepted by Council Decision 94/358/EC[26], is considered to be the text of the European Pharmacopoeia Partial Agreement. Member States of the Council of Europe that have signed and ratified the European Pharmacopoeia Convention are the member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental bodies functioning within the framework of this partial agreement, including among others: the European Pharmacopoeia Commission, the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The European Pharmacopoeia Convention has been signed and ratified by the European Union and all its Member States, all of whom are represented in their intergovernmental bodies. In this context, the work of the EDQM on developing and updating guidelines on safety and quality of blood, tissues and cells, should be considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance	(35) The EDQM is a structural part of the Council of Europe working under the European Pharmacopoeia Partial Agreement. The text of the Convention on the elaboration of a European Pharmacopoeia (ETS No. 050), accepted by Council Decision 94/358/EC[26], is considered to be the text of the European Pharmacopoeia Partial Agreement. Member States of the Council of Europe that have signed and ratified the European Pharmacopoeia Convention are the member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental bodies functioning within the framework of this partial agreement, including among others: the European Pharmacopoeia Commission, the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The European Pharmacopoeia Convention has been signed and ratified by the European Union and all its Member States, all of whom are represented in their intergovernmental bodies. In this context, the work of the EDQM on developing and updating guidelines on safety and quality of blood, tissues and cells, should be considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance

of safety and quality during collection, processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means to implement the technical standards provided for in this Regulation.	of safety and quality during collection, processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means to implement the technical standards provided for in this Regulation. ***The development of the guidelines should include stakeholder consultations to ensure their suitability and transparency.Member States should have an active role in the development of the guidelines, in cooperation with the EDQM.***
[26] Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).	[26] Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).

Or. en

Amendment 235
Mathilde Androuët

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) The EDQM is a structural part of the Council of Europe working under the European Pharmacopoeia Partial Agreement. The text of the Convention on the elaboration of a European Pharmacopoeia (ETS No**.** 050), accepted by Council Decision 94/358/EC[26], is considered to be the text of the European Pharmacopoeia Partial Agreement. Member States of the Council of Europe that have signed and ratified the European Pharmacopoeia Convention are the member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental bodies functioning within the framework of this partial agreement, including among others: the	(35) The EDQM is a structural part of the Council of Europe working under the European Pharmacopoeia Partial Agreement. The text of the Convention on the elaboration of a European Pharmacopoeia (ETS No 050), accepted by Council Decision 94/358/EC[26], is considered to be the text of the European Pharmacopoeia Partial Agreement. Member States of the Council of Europe that have signed and ratified the European Pharmacopoeia Convention are the member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental bodies functioning within the framework of this partial agreement, including among others: the

European Pharmacopoeia Commission, the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The European Pharmacopoeia Convention has been signed and ratified by the European Union and all its Member States, all of whom are represented in their intergovernmental bodies. In this context, the work of the EDQM on developing and updating guidelines on safety and quality of blood, tissues and cells, should be considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance of safety and quality during collection, processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means to implement the technical standards provided for in this Regulation.

[26] Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).

European Pharmacopoeia Commission, the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The European Pharmacopoeia Convention has been signed and ratified by the European Union and all its Member States, all of whom are represented in their intergovernmental bodies. In this context, the work of the EDQM on developing and updating guidelines on safety and quality of blood, tissues and cells, should be considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance of safety and quality during collection, processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means to implement the technical standards provided for in this Regulation ***if, and only if, they respect the interests of the Member States and include consultation with specialised stakeholders to ensure the transparency of the process***.

[26] Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).

Or. fr

Amendment 236
Alexandr Vondra

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) The ECDC, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council[27], is a Union agency with the mission of strengthening Europe's defences against communicable diseases. The work of the ECDC on developing and updating guidelines on safety and quality of SoHOs from a communicable disease threat perspective, should be considered an important contribution in the field of SoHOs in the Union and should be reflected in this Regulation. In addition, the ECDC established an expert network for the Microbial Safety of SoHOs, which ensures the implementation of the requirements on the ECDC's relations with the Union Member States and EEA Member States stated in Regulation (EC) No 851/2004, regarding strategic and operational collaboration on technical and scientific issues, surveillance, responses to health threats, scientific opinions, scientific and technical assistance, collection of data, identification of emerging health threats, and public information campaigns related to the safety of SoHOs. This SoHO expert network should provide information or advice in relation to relevant outbreaks of communicable diseases, in particular regarding the eligibility and testing of donors and the investigation of serious adverse occurrences involving suspected transmission of a communicable disease.	(36) The ECDC, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council[27], is a Union agency with the mission of strengthening Europe's defences against communicable diseases. The work of the ECDC on developing and updating guidelines on safety and quality of SoHOs from a communicable disease threat perspective, should be considered an important contribution in the field of SoHOs in the Union and should be reflected in this Regulation. In addition, the ECDC established an expert network for the Microbial Safety of SoHOs, which ensures the implementation of the requirements on the ECDC's relations with the Union Member States and EEA Member States stated in Regulation (EC) No 851/2004, regarding strategic and operational collaboration on technical and scientific issues, surveillance, responses to health threats, scientific opinions, scientific and technical assistance, collection of data, identification of emerging health threats, and public information campaigns related to the safety of SoHOs. This SoHO expert network should provide information or advice in relation to relevant outbreaks of communicable diseases, in particular regarding the eligibility and testing of donors and the investigation of serious adverse occurrences involving suspected transmission of a communicable disease. ***In order to comply with the Union requirements for review of Union legislation, a transparent and participatory stakeholder consultation process shall be put in place for the development of those provisions and guidelines from the expert bodies.The committees referred to and any working parties and scientific advisory groups established within those committees shall develop appropriate contacts with public and private key stakeholders, including patients, consumers, health professionals,***

and industry representatives.

[27] Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004, establishing a European centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

[27] Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004, establishing a European centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

Or. en

Amendment 237
Susana Solís Pérez, Véronique Trillet-Lenoir

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) The ECDC, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council[27], is a Union agency with the mission of strengthening Europe's defences against communicable diseases. The work of the ECDC on developing and updating guidelines on safety ***and***quality of SoHOs from a communicable disease threat perspective, should be considered an important contribution in the field of SoHOs in the Union and should be reflected in this Regulation. In addition, the ECDC established an expert network for the Microbial Safety of SoHOs, which ensures the implementation of the requirements on the ECDC's relations with the Union Member States and EEA Member States stated in Regulation (EC) No 851/2004, regarding strategic and operational collaboration on technical and scientific issues, surveillance, responses to health threats, scientific opinions, scientific and technical assistance, collection of data, identification of emerging health threats, and public information campaigns related to the safety of SoHOs. This SoHO expert network should provide information or advice in relation to relevant outbreaks of	(36) The ECDC, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council[27], is a Union agency with the mission of strengthening Europe's defences against communicable diseases. The work of the ECDC on developing and updating guidelines on safety***,***quality ***and susainability***of SoHOs from a communicable disease threat perspective, should be considered an important contribution in the field of SoHOs in the Union and should be reflected in this Regulation. In addition, the ECDC established an expert network for the Microbial Safety of SoHOs, which ensures the implementation of the requirements on the ECDC's relations with the Union Member States and EEA Member States stated in Regulation (EC) No 851/2004, regarding strategic and operational collaboration on technical and scientific issues, surveillance, responses to health threats, scientific opinions, scientific and technical assistance, collection of data, identification of emerging health threats, and public information campaigns related to the safety of SoHOs. This SoHO expert network should provide information or

communicable diseases, in particular regarding the eligibility and testing of donors and the investigation of serious adverse occurrences involving suspected transmission of a communicable disease.

advice in relation to relevant outbreaks of communicable diseases, in particular regarding the eligibility and testing of donors and the investigation of serious adverse occurrences involving suspected transmission of a communicable disease.

[27] Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004, establishing a European centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

[27] Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004, establishing a European centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

Or. en

Amendment 238
Mathilde Androuët

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) The ECDC, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council[27]**,**is a Union agency with the mission of strengthening Europe's defences against communicable diseases. The work of the ECDC on developing and updating guidelines on safety and quality of SoHOs from a communicable disease threat perspective, should be considered an important contribution in the field of SoHOs in the Union and should be reflected in this Regulation. In addition, the ECDC established an expert network for the Microbial Safety of SoHOs, which ensures the implementation of the requirements on the ECDC's relations with the Union Member States and EEA Member States stated in Regulation (EC) No 851/2004, regarding strategic and operational collaboration on technical and scientific issues, surveillance, responses to health threats, scientific opinions, scientific and technical assistance, collection of data,	(36) The ECDC, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council [27] is a Union agency with the mission of strengthening Europe's defences against communicable diseases. The work of the ECDC on developing and updating guidelines on safety and quality of SoHOs from a communicable disease threat perspective, should be considered an important contribution in the field of SoHOs in the Union and should be reflected in this Regulation. In addition, the ECDC established an expert network for the Microbial Safety of SoHOs, which ensures the implementation of the requirements on the ECDC's relations with the Union Member States and EEA Member States stated in Regulation (EC) No 851/2004, regarding ***transparent,***strategic and operational collaboration on technical and scientific issues, surveillance, responses to health threats, scientific opinions, scientific and

identification of emerging health threats, and public information campaigns related to the safety of SoHOs. This SoHO expert network should provide information or advice in relation to relevant outbreaks of communicable diseases, in particular regarding the eligibility and testing of donors and the investigation of serious adverse occurrences involving suspected transmission of a communicable disease.

[27] Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004**,** establishing a European centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

technical assistance, collection of data, identification of emerging health threats, and public information campaigns related to the safety of SoHOs. This SoHO expert network should provide information or advice in relation to relevant outbreaks of communicable diseases, in particular regarding the eligibility and testing of donors and the investigation of serious adverse occurrences involving suspected transmission of a communicable disease.

[27] Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control (OJ L 142, 30.4.2004, p. 1).

Or. fr

Amendment 239
Nathalie Colin-Oesterlé

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, ***of high quality and safety, thereby also increasing self-sufficiency in the Union***. Member States ***are also urged to*** take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States ***and the Union*** should promote the ***voluntary, unpaid*** donation of SoHOs ***of high quality and safety***, including plasma, ***used as base material for manufacturing plasma-derived medicinal products. These measures support European self-sufficiency, based on the broadest possible donor base, with a view to ensuring a***

and the related research and development.	***more resilient supply system and safeguarding the health of donors and recipients***. Member States ***and the Union should also*** take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.
	Or. fr

Amendment 240
Tilly Metz

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. ***To ensure long-term sustainability, the campaigns should primarily focus on increasing the donor base for low-frequency donations.*** As there is a need to ensure the availability of SoHOs for medical treatments, Member States should ***support the establishment of public donation facilities and*** promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing ***the collection capacity and*** self-sufficiency in the Union. Member States are also urged to take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.
	Or. en

Amendment 241
Kateřina Konečná

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development. ***Where SoHO is the starting material, such as with plasma derived medicinal products, a more comprehensive reflection over the overall supply chain is needed to ensure equitable patient access to these products.***

Or. en

Justification

Some EU Member States are currently collecting more plasma than they require and yet they still lack access to sufficient plasma-derived medicinal products. The regulation should encourage a reflection at EU level so that this situation is these countries is addressed but also so that this is not happen to the EU, in a world that is increasingly using these products.

Amendment 242
Eric Andrieu

Proposal for a regulation

Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs***, including plasma,*** of high quality and safety, ***thereby also increasing*** self-sufficiency ***in the Union***. Member States ***are also urged to*** take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States ***and the Union*** should promote the donation of ***ethical*** SoHOs of high quality and safety, ***including plasma used as the starting material for manufacturing of plasma-derived medicinal products. These measures support European*** self-sufficiency***, based on the broadest possible donor base, with a view to ensuring a more resilient supply system***. Member States ***and the Union should also*** take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.

Or. en

Justification

Overly frequent plasma donations affect the protein content of the plasma collected and could thus affect the quality of the donation. The more a system relies on a large number of donors, the less likely it is to be affected by external factors (such as the emergence of a pandemic) as the proportion of donors unable to visit a donor centre is, by definition, lower.

Amendment 243
Kateřina Konečná

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*

(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development. ***Such services should prevent the fragmentation of SoHO supply among multiple suppliers without certainty that all products, including rare ones, remain accessible to all patients.***

Or. en

Justification

When commercial establishments in the field of blood supply reach a certain level of presence in the market, some rare blood products (e.g. special typing) stop being available or are only offered at exorbitant prices. These are products that do not offer profit margins due to the large investments in research required and the small number of patients needing them. The regulation should encourage Member States to avoid reaching a level of dependency on the commercial sector that risks patients' access to these products.

Amendment 244
Kateřina Konečná

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance

of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, ***thereby also increasing*** self-sufficiency in the Union. Member States are also urged to take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.	of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, ***aiming to increase*** self-sufficiency in the Union***, based on a large donor base with low frequency donations so as to ensure the resilience of the supply system***. Member States are also urged to take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.

Or. en

Justification

Relying on a narrow donor base and high frequency donations increases donor burden and is less protective of donor health, while fragilizing self-sufficiency in case of crisis.

The COVID-pandemic has also shown that donor collection systems that rely on a more varied group of donors (frequent and low frequent) had less drops of donations than those collection systems relying on frequent (often paid) donations. So diversity of donors is a major factor in increasing donor protection as well as quality and resilience of the donation system. The regulation should reflect this.

Amendment 245
Jessica Polfjärd

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be ***to ensuring the broadest possible doner base and*** to help European

their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.

citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability ***and equal access*** of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.

Or. en

Amendment 246
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing ***self-sufficiency in*** the Union. Member States are also urged to take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States ***and the Union*** should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing ***the autonomy of*** the Union***, based on a wider donor base***. Member States ***and the Union*** are also urged to take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs

and the related research and development.	and the related research and development.

Or. en

Justification

Some SoHOs, such as bone marrow stem cells, need a high level of compatibility so that they can be transplanted in the recipient, Therefore, these SoHOs should be managed at a global level. Taking this into account, we consider the term "autonomy" to be more suitable than "self-sufficiency"

Amendment 247
Tudor Ciuhodaru

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.	(37) It is necessary ***and beneficial to all parties*** to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.

Or. ro

Amendment 248
Cristian-Silviu Buşoi

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage ***a strong public and non-profit sector involvement in*** the provision of SoHO services, in particular for critical SoHOs and the related research and development.	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage the provision of SoHO services, in particular for critical SoHOs and the related research and development.

Or. en

Amendment 249
Alexandr Vondra, Joanna Kopcińska

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs,	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs,

including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage ***a strong public and non-profit sector involvement in*** the provision of SoHO services, in particular for critical SoHOs and the related research and development.	including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage the provision of SoHO services, in particular for critical SoHOs and the related research and development.

Or. en

Amendment 250
Sunčana Glavak

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage ***a strong public and non-profit sector involvement in*** the provision of SoHO services, in particular for critical SoHOs and the related research and development.	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage the provision of SoHO services, in particular for critical SoHOs and the related research and development.

Or. en

Amendment 251
Giuseppe Ferrandino

Proposal for a regulation

Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage ***a strong public and non-profit sector involvement in*** the provision of SoHO services, in particular for critical SoHOs and the related research and development.	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage the provision of SoHO services, in particular for critical SoHOs and the related research and development.

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. The private sector has also played a strong role for many years, working side by side with the public and non-profit sector, operating in well-regulated SoHO collection activities.

Amendment 252
Adam Jarubas, Ewa Kopacz, Bartosz Arłukowicz

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to

decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to ***take steps to*** encourage ***a*** strong public and non-profit sector involvement ***in the provision of SoHO services***, in particular for critical SoHOs and the related research and development.	decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to encourage ***effective, sufficient and safe provision of SoHO services, including*** strong public and non-profit sector involvement, in particular for critical SoHOs and the related research and development.

Or. en

Amendment 253
Stanislav Polčák

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage ***a strong public and non-profit sector involvement in*** the provision of SoHO services, in particular for critical SoHOs and the related research and development.	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage the provision of SoHO services, in particular for critical SoHOs and the related research and development.

Or. en

Amendment 254
Aldo Patriciello, Salvatore De Meo

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage a strong ***public and non-profit sector*** involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage a strong involvement ***of all stakeholders, including from public and private sector,*** in the provision of SoHO services, in particular for critical SoHOs and the related research and development.

Or. en

Amendment 255
Andreas Glück, Ondřej Knotek, Peter Liese, Susana Solís Pérez, Jan Huitema, Michal Wiezik

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance

of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage ***a strong public and non-profit sector*** involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.	of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to ***strongly*** encourage involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.

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 256
Pernille Weiss

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs,	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to help European citizens to decide whether to become donors during their lifetime and let their families or legal representatives know their wishes regarding donation after death. As there is a need to ensure the availability of SoHOs for medical treatments, Member States should promote the donation of SoHOs,

including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage ***a strong public and non-profit sector involvement in*** the provision of SoHO services, in particular for critical SoHOs and the related research and development.	including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage the provision of SoHO services ***according to their own model of supply of SoHOs***, in particular for critical SoHOs and the related research and development.

Or. en

Justification

Member States apply different models for collection of SoHOs. Members States' efforts to promote the donation of SoHOs should include all sectors relevant to that Member State, including where applicable the private sector.

Amendment 257
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 37 a (new)

Text proposed by the Commission	*Amendment*
	(37 a) The COVID-19 pandemic can be considered one of the biggest health crises that has recently affected Europe. This crisis highlighted the vulnerabilities of the Union in very different aspects, ranging from the lack of coordination between Member States, which is essential to address these situations, to the Union's strong dependence on third countries in the production and supply of raw materials and active substances needed for the elaboration of medical treatments. In the case of SoHO, the pandemic drastically reduced the number of donors and exports from third countries, putting the Union in a situation of shortages of some SoHOs and patients at serious risk due to lack of adequate treatments. The lessons learned and the resulting measures taken at Union's level should serve as a reference for the prevention, detection and resolution of future health

crises. Regulation (EU) 2022/2371 on serious cross-border threats to health defines the guidelines to be followed for that purpose.

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 258
Eric Andrieu

Proposal for a regulation
Recital 37 a (new)

Text proposed by the Commission	*Amendment*
	(37 a) The COVID-19 pandemic has had adverse effects on the resilience of the donor base in some countries, whose collection systems rely on a small number of donors donating more frequently than elsewhere. These adverse effects are particularly evident in plasma collections and imports. Member States are urged to develop non-profit and public plasmapheresis programs in order to increase their collection capacity. This will make the donor base more resilient by expanding it as far as possible and, as a result, it will ensure the continuity of supply, including in times of crisis.

Or. en

Amendment 259
Tilly Metz

Proposal for a regulation
Recital 37 a (new)

Text proposed by the Commission	*Amendment*
	(37 a) As recommended by the World Health Organisation (WHO), Member

States should additionally support optimal clinical use of SoHOs, particularly where there are alternatives which can reduce the demand for SoHOs. In such fashion, Member States should ensure efficient implementation of the Patient Blood Management (PBM), which improves patients' safety by minimising the risks associated with transfusion and improve patient outcomes, while at the same time ensuring sufficiency of blood supplies and reducing financial pressure on health system.

Or. en

Amendment 260
Mathilde Androuët

Proposal for a regulation
Recital 37 a (new)

Text proposed by the Commission	*Amendment*
	(37a) Given the negative effects of the COVID-19 pandemic on the frequency and quantity of plasma donation in some countries, Member States are invited to develop plasmapheresis programmes to increase their collection capacity and donor base.

Or. fr

Justification

EU countries do not recover enough plasma. The quality of plasma degrades in line with the frequency of donations, as the protein content decreases when donations are very regular. The donor base thus needs to be expanded with a view to improving the quality of plasma.

Amendment 261
Kateřina Konečná

Proposal for a regulation
Recital 37 a (new)

Text proposed by the Commission	*Amendment*
	(37 a) Member States are encouraged to develop or strengthen plasmapheresis programmes to ensure capacity to collect more plasma and the Commission shall assist them in this task by providing guidance and facilitating the exchange of best practices.

Or. en

Justification

By fostering more plasmapheresis, EU Member States will be in a position to increase their collection capacity. The Regulation should foresee the development of a European strategy with concrete time frames to address the patients' needs and the current European dependency on third countries for the plasma required for the PDMPs.

Amendment 262
Susana Solís Pérez, Ondřej Knotek, Véronique Trillet-Lenoir

Proposal for a regulation
Recital 37 a (new)

Text proposed by the Commission	*Amendment*
	(37 a) To ensure the capacity to better collect more plasma, Member States are encouraged to develop or strengthen their respective plasmapheresis programs. The Commission shall aid them through guidance and the exchange of best practices.

Or. en

Justification

Need to increase self-sufficiency in plasma collection for strategic autonomy issues in the domain of health.

Amendment 263
Tilly Metz

Proposal for a regulation
Recital 37 b (new)

Text proposed by the Commission	*Amendment*
	(37 b) In order to ensure self-sufficiency and sustainability of supply of SoHOs, Member States should establish national SoHO emergency plans setting out measures when the supply situation for critical SoHOs presents or is likely to present a serious risk to human health. Such plans shall include measures, including optimisation of use, that impact demand of critical SoHOs, targets to ensure self-sufficiency of supply of critical SoHOs, donor recruitment and retainment strategy and ways of cooperation between competent authorities, experts and relevant stakeholders. National emergency plans should be further supplemented by the EU Strategy for critical SoHO supply sufficiency, primarily focusing on supply monitoring, reporting obligations and sharing of best practices within the EU.

Or. en

Amendment 264
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 37 b (new)

Text proposed by the Commission	*Amendment*
	(37 b) On the other hand, it is essential to take steps to achieve, as soon as possible, an EU autonomy in the area of SoHO, especially in the case of plasma, which shows an increasing demand due to new therapeutic applications of plasma-derived medicines. Nowadays, the Union suffers from chronic shortages of plasma, resulting in its dependence on imports from third countries. It is necessary to specify the measures to be taken to increase the donor base, always in line

with the principles of voluntary and unpaid donation, as well as to improve the infrastructure to enable efficient collection of SoHO, in order to ensure the continued, adequate and safe supply, also in times of crisis.

Or. en

Amendment 265
Eric Andrieu

Proposal for a regulation
Recital 37 b (new)

Text proposed by the Commission	*Amendment*
	(37 b) The loss of European sovereignty in the area of public health was thrown into sharp relief during the COVID-19 crisis. In this context, the initiatives for a strong Europe of Health should work in favour of European self-sufficiency, in particular as regards the supply of SoHOs and the ability to minimise the risk of shortages, especially of SoHOs for therapeutic use. Following the publication of the strategy for the promotion of European ethical SoHO supply self-sufficiency, Member States should adopt national priority action programmes for donor recruitment via voluntary unpaid donation.

Or. en

Amendment 266
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 37 c (new)

Text proposed by the Commission	*Amendment*
	(37 c) In order to reach an appropriate

level of autonomy in the Union, it will be necessary to increase the collection of SoHO, but also to ensure its proper and efficient use. The factors and measures affecting SoHO's demand play a critical role in ensuring the quality, safety and sustainability of the SoHO system. Suboptimal clinical practices and unnecessary use of SoHO compromises patient safety and limits the availability of SoHO for other patients in need. Member States should take measures to promote the optimal use of SoHO, taking into account alternatives that may reduce the demand, always following the most up-to-date scientific guidelines. The competent authorities should train healthcare professionals to make optimal use of SoHO. Member States should draw up national plans to ensure the supply of SoHO, as well as national emergency plans.

Or. en

Amendment 267
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 37 d (new)

Text proposed by the Commission	*Amendment*
	(37 d) In cases where the availability of SoHO preparations or SoHO-derived products depend on profit-making entities, such as some plasma-derived products, there is a risk of altruistic donations turning into disproportionate profits and commercial interests taking precedence over the interests of patients and research. There could even be situations in which some low-profitable products are no longer produced, hampering their accessibility for patients. Similarly, investment in research and innovation for this type of products could be very small

or non-existent. Prices of SoHO-derived products, which are obtained from altruistic and unpaid donations, should be fair and transparent. For certain low-profitable products, Member States should encourage research and innovation and should ensure, through negotiations, incentives or public service obligations, that they continue to be manufactured.

Or. en

Amendment 268
Véronique Trillet-Lenoir, Max Orville, Susana Solís Pérez

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) In order to promote a coordinated application of this Regulation, a SoHO Coordination Board (SCB) should be set up. The Commission should participate in its activities and chair it. The SCB should contribute to a coordinating the application of this Regulation throughout the Union, including by helping Member States to conduct SoHO supervisory activities. The SCB should be composed of persons designated by the Member States based on their role and expertise in their competent authorities, and should also involve experts that are not working for competent authorities, for specific tasks where access to necessary in-depth technical expertise in the field of SoHOs is required. In the latter case, appropriate consideration should be given to the possibility of involving European expert bodies such as the ECDC and the EDQM and existing professional, scientific and donor and patient representative groups at Union level in the field of SoHOs.	(38) In order to promote a coordinated application of this Regulation, a SoHO Coordination Board (SCB) should be set up. The Commission should participate in its activities and chair it. The SCB should contribute to a coordinating the application of this Regulation throughout the Union, including by helping Member States to conduct SoHO supervisory activities. The SCB should be composed of persons designated by the Member States based on their role and expertise in their competent authorities, and should also involve experts that are not working for competent authorities, for specific tasks where access to necessary in-depth technical expertise in the field of SoHOs is required. In the latter case, appropriate consideration should be given to the possibility of involving European expert ***agencies and*** bodies such as the ECDC***, the EMA, the Health Emergency Preparedness and Response Authority (HERA) established as a Commission service by Commission Decision of 16 September 2021*** and the EDQM and existing professional, scientific and donor and patient representative groups at Union level in the field of

SoHOs. ***Other Union institutions, bodies, offices and agencies should have an observer role. A representative designated by the European Parliament should be able to participate in the SoHO Coordination Board (SCB) as an observer. All members of the SCB should provide declarations of interest.***

Or. en

Amendment 269
Tilly Metz

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) In order to promote a coordinated application of this Regulation, a SoHO Coordination Board (SCB) should be set up. The Commission should participate in its activities and chair it. The SCB should contribute to a coordinating the application of this Regulation throughout the Union, including by helping Member States to conduct SoHO supervisory activities. The SCB should be composed of persons designated by the Member States based on their role and expertise in their competent authorities, and should also involve experts that are not working for competent authorities, for specific tasks where access to necessary in-depth technical expertise in the field of SoHOs is required. In the latter case, appropriate consideration should be given to the possibility of involving European expert bodies such as the ECDC and the EDQM and existing professional, scientific and donor and patient representative groups at Union level in the field of SoHOs.	(38) In order to promote a coordinated application of this Regulation, a SoHO Coordination Board (SCB) should be set up. The Commission should participate in its activities and chair it. The SCB should contribute to a coordinating the application of this Regulation throughout the Union, including by helping Member States to conduct SoHO supervisory activities. The SCB should be composed of persons designated by the Member States based on their role and expertise in their competent authorities, and should also involve experts that are not working for competent authorities, for specific tasks where access to necessary in-depth technical expertise in the field of SoHOs is required. In the latter case, appropriate consideration should be given to the possibility of involving European expert bodies such as the ECDC and the EDQM and existing professional, scientific and donor and patient representative groups at Union level in the field of SoHOs. ***The SCB should adhere to high degree of transparency of its outputs and all it members, observers and experts should act independently, in the public interest and be free from any external influence that might affect the***

impartiality of their professional conduct.

Or. en

Amendment 270
Alexandr Vondra, Joanna Kopcińska

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) In order to promote a coordinated application of this Regulation, a SoHO Coordination Board (SCB) should be set up. The Commission should participate in its activities and chair it. The SCB should contribute to a coordinating the application of this Regulation throughout the Union, including by helping Member States to conduct SoHO supervisory activities. The SCB should be composed of persons designated by the Member States based on their role and expertise in their competent authorities, and should also involve experts that are not working for competent authorities, for specific tasks where access to necessary in-depth technical expertise in the field of SoHOs is required. In the latter case, appropriate consideration should be given to the possibility of involving European expert bodies such as the ECDC and the EDQM and existing professional, scientific and donor and patient representative groups at Union level in the field of SoHOs.	(38) In order to promote a coordinated application of this Regulation, a SoHO Coordination Board (SCB) should be set up. The Commission should participate in its activities and chair it. The SCB should contribute to a coordinating the application of this Regulation throughout the Union, including by helping Member States to conduct SoHO supervisory activities. The SCB should be composed of persons designated by the Member States based on their role and expertise in their competent authorities, and should also involve experts that are not working for competent authorities, for specific tasks where access to necessary in-depth technical expertise in the field of SoHOs is required. In the latter case, appropriate consideration should be given to the possibility of involving European expert bodies such as the ECDC and the EDQM and existing professional, scientific and donor and patient representative groups ***and industry experts*** at Union level in the field of SoHOs. ***When seeking the input of expert bodies such as the ECDC and the EDQM, the SCB shall have due regard to their respective areas of expertise and avoid duplication.***

Or. en

Amendment 271
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) In order to promote a coordinated application of this Regulation, a SoHO Coordination Board (SCB) should be set up. The Commission should participate in its activities and chair it. The SCB should contribute to a coordinating the application of this Regulation throughout the Union, including by helping Member States to conduct SoHO supervisory activities. The SCB should be composed of persons designated by the Member States based on their role and expertise in their competent authorities, and should also involve experts that are not working for competent authorities, for ***specific*** tasks where access to necessary ***in-depth*** technical expertise in the field of SoHOs is required. In the latter case, ***appropriate consideration should be given to the possibility of involving*** European expert bodies such as the ECDC and the EDQM and existing professional, scientific and donor and ***patient*** representative groups at Union level in the field of SoHOs.	(38) In order to promote a coordinated application of this Regulation, a SoHO Coordination Board (SCB) should be set up. The Commission should participate in its activities and chair it. The SCB should contribute to a coordinating the application of this Regulation throughout the Union, including by helping Member States to conduct SoHO supervisory activities. The SCB should be composed of persons designated by the Member States based on their role and expertise in their competent authorities, and should also involve experts that are not working for competent authorities, for tasks where access to necessary technical expertise in the field of SoHOs is required. In the latter case, European expert bodies such as the ECDC and the EDQM and existing professional, scientific***, experts*** and donor and ***recipient*** representative groups at Union level in the field of SoHOs ***may also be invited***.

Or. en

Amendment 272
Tudor Ciuhodaru

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) In order to promote a coordinated application of this Regulation, a SoHO Coordination Board (SCB) should be set up. The Commission should participate in its activities and chair it. The SCB should contribute to a coordinating the application of this Regulation throughout the Union,	(38) In order to promote a ***coherent and*** coordinated application of this Regulation, a SoHO Coordination Board (SCB) should be set up. The Commission should participate in its activities and chair it. The SCB should contribute to a coordinating the application of this Regulation

including by helping Member States to conduct SoHO supervisory activities. The SCB should be composed of persons designated by the Member States based on their role and expertise in their competent authorities, and should also involve experts that are not working for competent authorities, for specific tasks where access to necessary in-depth technical expertise in the field of SoHOs is required. In the latter case, appropriate consideration should be given to the possibility of involving European expert bodies such as the ECDC and the EDQM and existing professional, scientific and donor and patient representative groups at Union level in the field of SoHOs.	throughout the Union, including by helping Member States to conduct SoHO supervisory activities. The SCB should be composed of persons designated by the Member States based on their role and expertise in their competent authorities, and should also involve experts that are not working for competent authorities, for specific tasks where access to necessary in-depth technical expertise in the field of SoHOs is required. In the latter case, appropriate consideration should be given to the possibility of involving European expert bodies such as the ECDC and the EDQM and existing professional, scientific and donor and patient representative groups at Union level in the field of SoHOs.
	Or. ro

Amendment 273
Alexandr Vondra, Joanna Kopcińska

Proposal for a regulation
Recital 38 a (new)

Text proposed by the Commission	*Amendment*
	(38 a) The Commission shall cooperate with the EDQM in relation to the guidelines issued by that body. 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 274
Margarita de la Pisa Carrión

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) Some substances, products or activities have been subject to different legal frameworks with different requirements in the Member States. This ***causes*** confusion among operators in the field, and the consequent legal uncertainty ***is*** a disincentive to professionals to develop new ways to prepare and use SoHOs. The SCB should receive relevant information on national decisions made on cases where questions were raised on the regulatory status of SoHOs. The SCB should keep a compendium of the opinions issued by the SCB or the competent authorities and of decisions made at Member State level, so that competent authorities considering the regulatory status under this Regulation of a particular substance, product or activity may inform their decision-making process by referring to that compendium. The SCB should also document agreed best practices to support a common Union approach. It should also cooperate with similar Union level bodies established in other Union legislation with a view to facilitating coordinated and coherent application of this Regulation between Member States and across bordering legislative frameworks. These measures should promote a coherent cross-sectoral approach and facilitate SoHO innovation.	(39) Some substances, products or activities have been subject to different legal frameworks with different requirements in the Member States. This ***may sometimes cause*** confusion among operators in the field, and the consequent legal uncertainty ***may be*** a disincentive to professionals to develop new ways to prepare and use SoHOs***. However, in the area of assisted reproduction, a number of technical and ethical circumstances justify differentiated treatment and the observance of the provisions in force at national level***. The SCB should receive relevant information on national decisions made on cases where questions were raised on the regulatory status of SoHOs. The SCB should keep a compendium of the opinions issued by the SCB or the competent authorities and of decisions made at Member State level, so that competent authorities considering the regulatory status under this Regulation of a particular substance, product or activity may inform their decision-making process by referring to that compendium. The SCB should also document agreed best practices to support a common Union approach. It should also cooperate with similar Union level bodies established in other Union legislation with a view to facilitating coordinated and coherent application of this Regulation between Member States and across bordering legislative frameworks. These measures should promote a coherent cross-sectoral approach and facilitate SoHO innovation.

Or. es

Amendment 275
Ondřej Knotek, Susana Solís Pérez

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) Some substances, products or activities have been subject to different legal frameworks with different requirements in the Member States. This causes confusion among operators in the field, and the consequent legal uncertainty is a disincentive to professionals to develop new ways to prepare and use SoHOs. ***The*** SCB should receive relevant information on national decisions made on cases where questions were raised on the regulatory status of SoHOs. The SCB should keep a compendium of the opinions issued by the SCB or the competent authorities and of decisions made at Member State level, so that competent authorities considering the regulatory status under this Regulation of a particular substance, product or activity may inform their decision-making process by referring to that compendium. The SCB should also document agreed best practices to support a common Union approach. It should also cooperate with similar Union level bodies established in other Union legislation with a view to facilitating coordinated and coherent application of this Regulation between Member States and across bordering legislative frameworks. These measures should promote a coherent cross-sectoral approach and facilitate ***SoHO*** innovation.	(39) Some substances, products or activities have been subject to different legal frameworks with different requirements in the Member States. This causes confusion among operators in the field, and the consequent legal uncertainty is a disincentive to professionals to develop new ways to prepare and use SoHOs. ***In case a product could be classified both as SoHO or SoHO preparation and medicinal product, the classification as medicinal product should prevail.The*** SCB should receive relevant information on national decisions made on cases where questions were raised on the regulatory status of SoHOs. The SCB should keep a compendium of the opinions issued by the SCB or the competent authorities and of decisions made at Member State level, so that competent authorities considering the regulatory status under this Regulation of a particular substance, product or activity may inform their decision-making process by referring to that compendium. The SCB should also document agreed best practices to support a common Union approach. It should also cooperate with similar Union level bodies established in other Union legislation with a view to facilitating coordinated and coherent application of this Regulation between Member States and across bordering legislative frameworks. These measures should promote a coherent cross-sectoral approach***, ensure high protection of public health,*** and facilitate innovation.

Or. en

Amendment 276
Tudor Ciuhodaru

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) Some substances, products or activities have been subject to different legal frameworks with different requirements in the Member States. This causes confusion among operators in the field, and the consequent legal uncertainty is a disincentive to professionals to develop new ways to prepare and use SoHOs. The SCB should receive relevant information on national decisions made on cases where questions were raised on the regulatory status of SoHOs. The SCB should keep a compendium of the opinions issued by the SCB or the competent authorities and of decisions made at Member State level, so that competent authorities considering the regulatory status under this Regulation of a particular substance, product or activity may inform their decision-making process by referring to that compendium. The SCB should also document agreed best practices to support a common Union approach. It should also cooperate with similar Union level bodies established in other Union legislation with a view to facilitating coordinated and coherent application of this Regulation between Member States and across bordering legislative frameworks. These measures should promote a coherent cross-sectoral approach and facilitate SoHO innovation.	(39) Some substances, products or activities have been subject to different legal frameworks with different requirements in the Member States. This causes confusion among operators in the field, and the consequent legal uncertainty is a disincentive to professionals to develop new ways to prepare and use SoHOs. The SCB should receive ***ongoing and constant*** relevant information on national decisions made on cases where questions were raised on the regulatory status of SoHOs. The SCB should ***monitor these opinions in order to react quickly and in an informed manner to further requests for opinions from other Member States,*** keep a compendium of the opinions issued by the SCB or the competent authorities and of decisions made at Member State level, so that competent authorities considering the regulatory status under this Regulation of a particular substance, product or activity may inform their decision-making process by referring to that compendium. The SCB should also document agreed best practices to support a common Union approach. It should also cooperate with similar Union level bodies established in other Union legislation with a view to facilitating coordinated and coherent application of this Regulation between Member States and across bordering legislative frameworks. These measures should promote a coherent cross-sectoral approach and facilitate SoHO innovation.

Or. ro

Amendment 277
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, João Albuquerque, Romana Jerković, Biljana Borzan, César Luena

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) Some substances, products or activities have been subject to different legal frameworks with different requirements in the Member States. This causes confusion among operators in the field, and the consequent legal uncertainty is a disincentive to professionals to develop new ways to prepare and use SoHOs. The SCB should receive relevant information on national decisions made on cases where questions were raised on the regulatory status of SoHOs. The SCB should keep a compendium of the opinions issued by the SCB or the competent authorities and of decisions made at Member State level, so that competent authorities considering the regulatory status under this Regulation of a particular substance, product or activity may inform their decision-making process by referring to that compendium. The SCB should also document agreed best practices to support a common Union approach. It should also cooperate with similar Union level bodies established in other Union legislation with a view to facilitating coordinated and coherent application of this Regulation between Member States and across bordering legislative frameworks. These measures should promote a coherent cross-sectoral approach and facilitate SoHO innovation.	(39) Some substances, products or activities have been subject to different legal frameworks with different requirements in the Member States. This causes confusion among operators in the field, and the consequent legal uncertainty is a disincentive to professionals to develop new ways to prepare and use SoHOs. The SCB should receive relevant information on national decisions made on cases where questions were raised on the regulatory status of SoHOs. The SCB should keep a compendium of the opinions issued by the SCB***, the Classification Advisory Council*** or the competent authorities and of decisions made at Member State level, so that competent authorities considering the regulatory status under this Regulation of a particular substance, product or activity may inform their decision-making process by referring to that compendium. The SCB should also document agreed best practices to support a common Union approach. It should also cooperate with similar Union level bodies established in other Union legislation with a view to facilitating coordinated and coherent application of this Regulation between Member States and across bordering legislative frameworks. These measures should promote a coherent cross-sectoral approach and facilitate SoHO innovation.

Or. en

Amendment 278
Alexandr Vondra

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(40) The concept of a plasma master file (PMF) was established in Commission Directive 2003/63/EC[28]. Since that	(40) The concept of a plasma master file (PMF) was established in Commission Directive 2003/63/EC[28]. Since that

Directive provided for a specific regulatory role for the European Medicines Agency (EMA) in relation to authorisation of plasma for fractionation, the SCB should also collaborate with the relevant EMA expert working groups to exchange experience and good practices so that criteria for the eligibility of donors of plasma for fractionation ***and of donors of blood for transfusion***are implemented by Member States in a consistent and coherent way.	Directive provided for a specific regulatory role for the European Medicines Agency (EMA) in relation to authorisation of plasma for fractionation, the SCB should also collaborate with the relevant EMA expert working groups to exchange experience and good practices so that criteria for the eligibility of donors of plasma for fractionation are implemented by Member States in a consistent and coherent way.
[28] Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 159, 27.6.2003, p. 46).	[28] Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 159, 27.6.2003, p. 46).

Or. en

Amendment 279
Susana Solís Pérez, Véronique Trillet-Lenoir

Proposal for a regulation
Recital 41

Text proposed by the Commission	*Amendment*
(41) In order to limit administrative burden on competent authorities and the Commission, the latter should establish an online platform (the 'EU SoHO Platform') to facilitate timely submission of data and reports as well as improved transparency of national reporting and supervisory activities.	(41) In order to limit administrative burden on competent authorities and the Commission, the latter should establish an online platform (the 'EU SoHO Platform') to facilitate timely submission of data and reports as well as improved transparency of national reporting and supervisory activities. ***The EU SoHO Platform might also be utilized by Member States as a channel for national initiatives and campaigns to encourage the exchange of best practices. Said national campaigns and campaigns shall, in close cooperation with patient organizations, aim to promote donation and sustainable supplies of SoHO products.***

Or. en

Amendment 280
Tilly Metz

Proposal for a regulation
Recital 41

Text proposed by the Commission	*Amendment*
(41) In order to limit administrative burden on competent authorities and the Commission, the latter should establish an online platform (the 'EU SoHO Platform') to facilitate timely submission of data and reports as well as improved transparency of national reporting and supervisory activities.	(41) In order to limit administrative burden on competent authorities and the Commission, the latter should establish an online platform (the 'EU SoHO Platform') to facilitate timely submission of data and reports as well as improved transparency of national reporting and supervisory activities. ***The EU SoHO Platform should also serve as a reliable source of information for the general public regarding the work of the SoHO Coordination Board, national competent authorities and other expert bodies, including the EDQM, and SoHO entities and establishments.***

Or. en

Amendment 281
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Radka Maxová, Robert Hajšel

Proposal for a regulation
Recital 41

Text proposed by the Commission	*Amendment*
(41) In order to limit administrative burden on competent authorities and the Commission, the latter should establish an online platform (the 'EU SoHO Platform') to facilitate timely submission of data and reports as well as improved transparency of national reporting and supervisory activities.	(41) In order to limit administrative burden on competent authorities and the Commission, the latter should establish an online platform (the 'EU SoHO Platform') to facilitate timely submission of data and reports as well as improved transparency of national reporting and supervisory activities ***and better communication, collaboration, coordination and exchange***

of SoHO between Member States**. **Member States should preferably use this new platform in their exchanges to limit the administrative burden.

Or. en

Amendment 282
Pernille Weiss

Proposal for a regulation
Recital 41

Text proposed by the Commission	*Amendment*
(41) In order to limit administrative burden on competent authorities and the Commission, the latter should establish an online platform (the 'EU SoHO Platform') to facilitate timely submission of data and reports as well as improved transparency of national reporting and supervisory activities.	(41) In order to limit administrative burden on competent authorities and the Commission, the latter should establish an online platform (the 'EU SoHO Platform') to facilitate timely submission of data and reports as well as improved transparency of national reporting and supervisory activities. ***The online platform could be further used for the sharing of best practice between Member States with regard to initatives, such as campaigns, to support the supply of SoHOs.***

Or. en

Amendment 283
Mathilde Androuët

Proposal for a regulation
Recital 41

Text proposed by the Commission	*Amendment*
(41) In order to limit administrative burden on competent authorities and the Commission, the latter should establish an online platform (the 'EU SoHO Platform') to facilitate timely submission of data and reports ***as well as improved*** transparency of national reporting and supervisory activities.	(41) In order to limit administrative burden on competent authorities and the Commission, the latter should establish an online platform (the 'EU SoHO Platform') to facilitate timely submission of data and reports***, to make it possible to share the elements used to determine the regulatory status of a substance and to improve the***

transparency of national reporting and supervisory activities.

Or. fr

Amendment 284
Tudor Ciuhodaru

Proposal for a regulation
Recital 41

Text proposed by the Commission	*Amendment*
(41) In order to limit administrative burden on competent authorities and the Commission, the latter should establish an online platform (the 'EU SoHO Platform') to facilitate timely submission of data and reports as well as improved transparency of national reporting and supervisory activities.	(41) In order to limit administrative burden on competent authorities and the Commission, the latter should establish an online platform (the 'EU SoHO Platform') to facilitate timely submission of data and reports ***and the centralisation of this data in order to apply the most viable solutions,*** as well as improved transparency of national reporting and supervisory activities.

Or. ro

Amendment 285
Andreas Glück, Ondřej Knotek, Véronique Trillet-Lenoir, Peter Liese, Susana Solís Pérez, Jan Huitema

Proposal for a regulation
Recital 42

Text proposed by the Commission	*Amendment*
(42) The processing of personal data under this Regulation should be subject to strict guarantees of confidentiality and should comply with the rules on the protection of personal data laid down in Regulation (EU) 2016/679 of the European Parliament and of the Council and in Regulation (EU) 2018/1725 of the European Parliament and of the Council .	(42) The processing of personal data under this Regulation should be subject to strict guarantees of confidentiality and should comply with the rules on the protection of personal data laid down in Regulation (EU) 2016/679 of the European Parliament and of the Council and in Regulation (EU) 2018/1725 of the European Parliament and of the Council. ***The Commission may also decide that information on SoHO donations are***

added to donors Electronic Health Records (EHRs).

Or. en

Justification

With more progress happening in the digitalisation of the European health sector, data on donations should also be stored on donors/patients electronic health records. This is important information to any physician, thus increasing donor safety, but will also facilitate the maintenance of registries and data-exchange.

Amendment 286
Stelios Kympouropoulos, Tomislav Sokol, Peter Liese

Proposal for a regulation
Recital 43

Text proposed by the Commission	*Amendment*
(43) As the EU SoHO Platform requires the processing of personal data, it will be designed respecting the principles of data protection. Any processing of personal data should be limited to achieving the objectives and obligations of this Regulation. Access to the EU SoHO Platform should be limited to the extent necessary to carry out supervisory activities provided for in this Regulation.	(43) As the EU SoHO Platform requires the processing of personal data, it will be designed respecting the principles of data protection. Any processing of personal data should be limited to achieving the objectives and obligations of this Regulation. Access to the EU SoHO Platform***, once established, should be granted within the framework of the European Health Data Space (EHDS) and otherwise*** should be limited to the extent necessary to carry out supervisory activities provided for in this Regulation.

Or. en

Amendment 287
Tudor Ciuhodaru

Proposal for a regulation
Recital 43

Text proposed by the Commission	*Amendment*
(43) As the EU SoHO Platform requires the processing of personal data, it will be	(43) As the EU SoHO Platform requires the processing of personal data, it will be

designed respecting the principles of data protection. Any processing of personal data should be limited to achieving the objectives and obligations of this Regulation. Access to the EU SoHO Platform should be limited to the extent necessary to carry out supervisory activities provided for in this Regulation.	designed respecting the principles of data protection. Any processing of personal data should be limited to achieving the objectives and obligations of this Regulation. Access to the EU SoHO platform should be limited ***in time and with regard to the number of persons authorised to access these data and*** to the extent necessary to carry out supervisory activities provided for in this Regulation.

Or. ro

Amendment 288
Joanna Kopcińska

Proposal for a regulation
Recital 43

Text proposed by the Commission	*Amendment*
(43) As the EU SoHO Platform requires the processing of personal data, it will be designed respecting the principles of data protection. Any processing of personal data should be limited to achieving the objectives and obligations of this Regulation. Access to the EU SoHO Platform should be limited to the extent necessary to carry out supervisory activities provided for in this Regulation.	(43) As the EU SoHO Platform requires the processing of personal data, it will be designed respecting the principles of data protection. Any processing of personal data should be limited to achieving the objectives and obligations of this Regulation. Access to the EU SoHO Platform should be limited to the extent necessary to carry out supervisory activities provided for in this Regulation. ***In addition, the personal data and curriculum vitae of the persons responsible for the release of SoHOs should not be made public.***

Or. pl

Amendment 289
Andreas Glück, Ondřej Knotek, Véronique Trillet-Lenoir, Peter Liese, Susana Solís Pérez

Proposal for a regulation
Recital 43

Text proposed by the Commission	*Amendment*
(43) As the EU SoHO Platform requires the processing of personal data, it will be designed respecting the principles of data protection. Any processing of personal data should be limited to achieving the objectives and obligations of this Regulation. Access to the EU SoHO Platform should be limited to the extent necessary to carry out supervisory activities provided for in this Regulation.	(43) As the EU SoHO Platform requires the processing of personal data, it will be designed respecting the principles of data protection. Any processing of personal data should be limited to achieving the objectives and obligations of this Regulation. Access to the EU SoHO Platform should***, once it is established, be granted within the framework of the European Health Data Space and otherwise*** be limited to the extent necessary to carry out supervisory activities provided for in this Regulation.

Or. en

Justification

Access to health data will be governed by the Regulation on the European Health Data Space, once it is established.

Amendment 290
Tilly Metz

Proposal for a regulation
Recital 43

Text proposed by the Commission	*Amendment*
(43) As the EU SoHO Platform requires the processing of personal data, it will be designed respecting the principles of data protection. Any processing of personal data should be limited to achieving the objectives and obligations of this Regulation. Access to the EU SoHO Platform should be limited to the extent necessary to carry out supervisory activities provided for in this Regulation.	(43) As the EU SoHO Platform requires the processing of personal data, it will be designed respecting the principles of data protection ***laid down in Article 5 of Regulation (EU) 2016/679***. Any processing of personal data should be limited to achieving the objectives and obligations of this Regulation. Access to the EU SoHO Platform should be limited to the extent necessary to carry out supervisory activities provided for in this Regulation.

Or. en

Amendment 291
Tilly Metz

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and in particular human dignity, the integrity of the person**,** the protection of personal data, the freedom of art and science and to conduct business, non-discrimination, the right to health protection and access to health care, and the rights of the child. To achieve these aims, all supervisory and SoHO activities should always be carried out in a manner that fully respects those rights and principles. The right for dignity and integrity of donors, recipients and of offspring born from medically assisted reproduction should always be taken into account, amongst others, by ensuring that consent for donation is freely given and donors or their representatives are informed with regards to the intended use of the donated material, that donor eligibility criteria are based on scientific evidence, that the use of SoHOs in humans is not promoted for commercial purposes or with false or misleading information regarding efficacy so that the donors and recipients can make well-informed and deliberate choices, that activities are conducted in a transparent manner that prioritises the safety of donors and recipients, and that allocation and equitable access to SoHOs are defined in a transparent manner, on the basis of an objective evaluation of medical needs. This Regulation should therefore be applied accordingly.	(44) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and in particular human dignity, the integrity of the person ***and the prohibition of making the human body and its parts as such a source of financial gain*** the protection of ***natural persons with regard to the processing of their*** personal data, the freedom of art and science and to conduct business, non-discrimination, the right to health protection and access to health care, and the rights of the child. To achieve these aims, all supervisory and SoHO activities should always be carried out in a manner that fully respects those rights and principles. The right for dignity and integrity of donors, recipients and of offspring born from medically assisted reproduction should always be taken into account, amongst others, by ensuring that consent for donation is freely given and donors or their representatives are informed with regards to the intended use of the donated material, that donor eligibility criteria are based on scientific evidence, that the use of SoHOs in humans is not promoted for commercial purposes or with false or misleading information regarding efficacy so that the donors and recipients can make well-informed and deliberate choices, that activities are conducted in a transparent manner that prioritises the safety of donors and recipients, and that allocation and equitable access to SoHOs are defined in a transparent manner, on the basis of an objective evaluation of medical needs. This Regulation should therefore be applied accordingly.

Amendment 292
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Cyrus Engerer, Robert Hajšel

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and in particular human dignity, the integrity of the person, the protection of personal data, the freedom of art and science and to conduct business, non-discrimination, the right to health protection and access to health care, and the rights of the child. To achieve these aims, all supervisory and SoHO activities should always be carried out in a manner that fully respects those rights and principles. The right for dignity and integrity of donors, recipients and of offspring born from medically assisted reproduction should always be taken into account, amongst others, by ensuring that consent for donation is freely given and donors or their representatives are informed with regards to the intended use of the donated material, that donor eligibility criteria are based on scientific evidence, that the use of SoHOs in humans is not promoted for commercial purposes or with false or misleading information regarding efficacy so that the donors and recipients can make well-informed and deliberate choices, that activities are conducted in a transparent manner that prioritises the safety of donors and recipients, and that allocation and equitable access to SoHOs are defined in a transparent manner, on the basis of an objective evaluation of medical needs. This Regulation should therefore be applied	(44) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and in particular human dignity***, the prohibition of making the human body and its parts a source of economic gain***, the integrity of the person, the protection of personal data, the freedom of art and science and to conduct business, non-discrimination, the right to health protection and access to health care, and the rights of the child. To achieve these aims, all supervisory and SoHO activities should always be carried out in a manner that fully respects those rights and principles. The right for dignity and integrity of donors, recipients and of offspring born from medically assisted reproduction should always be taken into account, amongst others, by ensuring that consent for donation is freely given and donors or their representatives are informed with regards to the intended use of the donated material, that donor eligibility criteria are based on scientific evidence, that the use of SoHOs in humans is not promoted for commercial purposes or with false or misleading information regarding efficacy so that the donors and recipients can make well-informed and deliberate choices, that activities are conducted in a transparent manner that prioritises the safety of donors and recipients, and that allocation and equitable ***and non-discriminatory*** access to SoHOs are defined in a transparent manner, on the

accordingly.

basis of an objective evaluation of medical needs. This Regulation should therefore be applied accordingly.

Or. en

Amendment 293
Tudor Ciuhodaru

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and in particular human dignity, the integrity of the person, the protection of personal data, the freedom of art and science and to conduct business, non-discrimination, the right to health protection and access to health care, and the rights of the child. To achieve these aims, all supervisory and SoHO activities should always be carried out in a manner that fully respects those rights and principles. The right for dignity and integrity of donors, recipients and of offspring born from medically assisted reproduction should always be taken into account, amongst others, by ensuring that consent for donation is freely given and donors or their representatives are informed with regards to the intended use of the donated material, that donor eligibility criteria are based on scientific evidence, that the use of SoHOs in humans is not promoted for commercial purposes or with false or misleading information regarding efficacy so that the donors and recipients can make well-informed and deliberate choices, that activities are conducted in a transparent manner that prioritises the safety of donors and recipients, and that allocation and equitable access to SoHOs are defined in a	(44) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and in particular human dignity, the integrity of the person, the protection of personal data, the freedom of art and science and to conduct business, non-discrimination, the right to health protection and access to health care, and the rights of the child. To achieve these aims, all supervisory and SoHO activities should always be carried out in a manner that fully respects those rights and principles. The right for dignity and integrity of donors, recipients and of offspring born from medically assisted reproduction should always be taken into account, amongst others, by ensuring that consent for donation is freely given and donors or their representatives are informed with regards to the intended use of the donated material, that donor eligibility criteria are based on scientific evidence ***and criteria of compatibility between donors and recipients***, that the use of SoHOs in humans is not promoted for commercial purposes or with false or misleading information regarding efficacy so that the donors and recipients can make well-informed and deliberate choices, that activities are conducted in a transparent manner that prioritises the safety of donors and recipients, and that allocation and

transparent manner, on the basis of an objective evaluation of medical needs. This Regulation should therefore be applied accordingly.

equitable access to SoHOs are defined in a transparent manner, on the basis of an objective evaluation of medical needs. This Regulation should therefore be applied accordingly.

Or. ro

Amendment 294
Mathilde Androuët

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and in particular human dignity, the integrity of the person, the protection of personal data, the freedom of art and science and to conduct business, non-discrimination, the right to health protection and access to health care, and the rights of the child. To achieve these aims, all supervisory and SoHO activities should always be carried out in a manner that fully respects those rights and principles. The right for dignity and integrity of donors, recipients and of ***offspring*** born from medically assisted reproduction should always be taken into account, amongst others, by ensuring that consent for donation is freely given and donors or their representatives are informed with regards to the intended use of the donated material, that donor eligibility criteria are based on scientific evidence, that the use of SoHOs in humans is not promoted for commercial purposes or with false or misleading information regarding efficacy so that the donors and recipients can make well-informed and deliberate choices, that activities are conducted in a transparent manner that prioritises the safety of donors and	(44) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and in particular human dignity, the integrity of the person, the protection of personal data, the freedom of art and science and to conduct business, non-discrimination, the right to health protection and access to health care, and the rights of the child. To achieve these aims, all supervisory and SoHO activities should always be carried out in a manner that fully respects those rights and principles. The right for dignity and integrity of donors, recipients and of ***persons*** born from medically assisted reproduction should always be taken into account, amongst others, by ensuring that consent for donation is freely given and donors or their representatives are informed with regards to the intended use of the donated material, that donor eligibility criteria are based on scientific evidence, that the use of SoHOs in humans is not promoted for commercial purposes or with false or misleading information regarding efficacy so that the donors and recipients can make well-informed and deliberate choices, that activities are conducted in a transparent manner that prioritises the safety of donors and

recipients, and that allocation and equitable access to SoHOs are defined in a transparent manner, on the basis of an objective evaluation of medical needs. This Regulation should therefore be applied accordingly.	recipients, and that allocation and equitable access to SoHOs are defined in a transparent manner, on the basis of an objective evaluation of medical needs. This Regulation should therefore be applied accordingly.

Or. fr

Amendment 295
Pernille Weiss

Proposal for a regulation
Recital 44 a (new)

Text proposed by the Commission	*Amendment*
	(44 a) Highlights that anonymous donations of eggs, sperm or embryos for the purpose of medically assisted reproduction carries risks to the children born from this. Risks entail insufficient access to information about medical history, as available medical data of the donor may evolve after the time of donation, as well as a breach of the right of the children to information fundamental for their identity. Encourages Member States and the Commission to conduct further studies on this issue, as well as to consider possible measures to ban the practice of anonymous donations of eggs, sperm or embryos for the purpose of medically assisted reproduction. Recalls in this regard that several Member States have already banned the practice of anonymous donation.

Or. en

Amendment 296
Tilly Metz

Proposal for a regulation
Recital 44 a (new)

Text proposed by the Commission	*Amendment*
	(44 a) Due to the high sensitivity of donor anonymity and taking into account the rights of offspring born from medically assisted reproduction with third party donation, SoHO entities should ensure donors of reproductive cells are duly informed about the possibility of ID release and the implication hereof, pursuant to provisions laid down in national legislation;

Or. en

Amendment 297
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 45

Text proposed by the Commission	*Amendment*
(45) SoHOs, by definition, relate to persons, and there are circumstances where the processing of personal data relating to donors and recipients may be necessary to achieve the objectives and requirements of this Regulation, especially provisions relating to vigilance and communication between competent authorities. This Regulation should provide a legal basis under Article 6 and, where relevant, fulfil the conditions under Article 9(2), point (i), of Regulation (EU) 2016/679 for processing of such personal data. With respect to personal data processed by the Commission, this Regulation should provide a legal basis under Article 5 and, where relevant, fulfil the conditions under Article 10(2), point (i), of Regulation (EU) 2018/1725. Data on safety and efficacy of new SoHO preparations in recipients should also be shared, with appropriate protective measures, to allow aggregation at Union level for more robust evidence	(45) SoHOs, by definition, relate to persons, and there are circumstances where the processing of personal data relating to donors and recipients may be necessary to achieve the objectives and requirements of this Regulation, especially provisions relating to vigilance and communication between competent authorities. This Regulation should provide a legal basis under Article 6 and, where relevant, fulfil the conditions under Article 9(2), point (i), of Regulation (EU) 2016/679 for processing of such personal data. With respect to personal data processed by the Commission, this Regulation should provide a legal basis under Article 5 and, where relevant, fulfil the conditions under Article 10(2), point (i), of Regulation (EU) 2018/1725. Data on safety and efficacy of new SoHO preparations in recipients should also be shared, with appropriate protective measures ***and, where possible, anonymised***, to allow aggregation at Union

gathering on the clinical efficacy of SoHO preparations. For all data processing, such processing should be necessary and appropriate with a view to ensuring compliance with this Regulation in order to protect human health. Data on donors, recipients and offspring should hence be limited to the minimum necessary and pseudonymised. donors, recipients and offspring should be informed of the processing of their personal data in line with the requirements of Regulations (EU) 2016/679 and (EU) 2018/1725, and in particular as provided for under this Regulation, including the possibility of exceptional cases where circumstances require such processing.

level for more robust evidence gathering on the clinical efficacy of SoHO preparations. For all data processing, such processing should be necessary and appropriate with a view to ensuring compliance with this Regulation in order to protect human health. Data on donors, recipients and offspring should hence be limited to the minimum necessary and pseudonymised***, or anonymised, as appropiate in each case***. Donors, recipients and offspring should be informed of the processing of their personal data in line with the requirements of Regulations (EU) 2016/679 and (EU) 2018/1725, and in particular as provided for under this Regulation, including the possibility of exceptional cases where circumstances require such processing.

Or. en

Amendment 298
Joanna Kopcińska

Proposal for a regulation
Recital 45

Text proposed by the Commission	*Amendment*
(45) SoHOs, by definition, relate to persons, and there are circumstances where the processing of personal data relating to donors and recipients may be necessary to achieve the objectives and requirements of this Regulation, especially provisions relating to vigilance and communication between competent authorities. This Regulation should provide a legal basis under Article 6 and, where relevant, fulfil the conditions under Article 9(2), point (i), of Regulation (EU) 2016/679 for processing of such personal data. With respect to personal data processed by the Commission, this Regulation should provide a legal basis under Article 5 and, where relevant, fulfil the conditions under Article 10(2), point (i), of Regulation (EU)	(45) SoHOs, by definition, relate to persons, and there are circumstances where the processing of personal data relating to donors and recipients may be necessary to achieve the objectives and requirements of this Regulation, especially provisions relating to vigilance and communication between competent authorities. This Regulation should provide a legal basis under Article 6 and, where relevant, fulfil the conditions under Article 9(2), point (i), of Regulation (EU) 2016/679 for processing of such personal data. With respect to personal data processed by the Commission, this Regulation should provide a legal basis under Article 5 and, where relevant, fulfil the conditions under Article 10(2), point (i), of Regulation (EU)

2018/1725. Data on safety and efficacy of new SoHO preparations in recipients should also be shared, with appropriate protective measures, to allow aggregation at Union level for more robust evidence gathering on the clinical efficacy of SoHO preparations. For all data processing, such processing should be necessary and appropriate with a view to ensuring compliance with this Regulation in order to protect human health. Data on donors, recipients and offspring should hence be limited to the minimum necessary and ***pseudonymised***. donors, recipients and offspring should be informed of the processing of their personal data in line with the requirements of Regulations (EU) 2016/679 and (EU) 2018/1725, and in particular as provided for under this Regulation, including the possibility of exceptional cases where circumstances require such processing.

2018/1725. Data on safety and efficacy of new SoHO preparations in recipients should also be shared, with appropriate protective measures, to allow aggregation at Union level for more robust evidence gathering on the clinical efficacy of SoHO preparations. For all data processing, such processing should be necessary and appropriate with a view to ensuring compliance with this Regulation in order to protect human health. Data on donors, recipients and offspring should hence be limited to the minimum necessary and ***processed in fully anonymised form, using a donor or donation number***. Donors, recipients and offspring should be informed of the processing of their personal data in line with the requirements of Regulations (EU) 2016/679 and (EU) 2018/1725, and in particular as provided for under this Regulation, including the possibility of exceptional cases where circumstances require such processing.

Or. pl

Amendment 299
Tilly Metz

Proposal for a regulation
Recital 45

Text proposed by the Commission	*Amendment*
(45) SoHOs, by definition, relate to persons, and there are circumstances where the processing of personal data relating to donors and recipients may be necessary to achieve the objectives and requirements of this Regulation, especially provisions relating to vigilance and communication between competent authorities. This Regulation should provide a legal basis under Article 6 and, where relevant, fulfil the conditions under Article 9(2), point (i), of Regulation (EU) 2016/679 for processing of such personal data. With respect to personal data processed by the	(45) SoHOs, by definition, relate to ***natural*** persons, and there are circumstances where the processing of personal data relating to donors and recipients may be necessary to achieve the objectives and requirements of this Regulation, especially provisions relating to vigilance and communication between competent authorities. This Regulation should provide a legal basis under Article 6 and, where relevant, fulfil the conditions under Article 9(2), point (i), of Regulation (EU) 2016/679 for processing of such personal data. With respect to personal data

Commission, this Regulation should provide a legal basis under Article 5 and, where relevant, fulfil the conditions under Article 10(2), point (i), of Regulation (EU) 2018/1725. Data on safety and efficacy of new SoHO preparations in recipients should also be shared, with appropriate protective measures, to allow aggregation at Union level for more robust evidence gathering on the clinical efficacy of SoHO preparations. For all data processing, such processing should be necessary and appropriate with a view to ensuring compliance with this Regulation in order to protect human health. Data on donors, recipients and offspring should hence be limited to the minimum necessary and pseudonymised. donors, recipients and offspring should be informed of the processing of their personal data in line with the requirements of Regulations (EU) 2016/679 and (EU) 2018/1725, and in particular as provided for under this Regulation, including the possibility of exceptional cases where circumstances require such processing.

processed by the Commission, this Regulation should provide a legal basis under Article 5 and, where relevant, fulfil the conditions under Article 10(2), point (i), of Regulation (EU) 2018/1725. Data on safety and efficacy of new SoHO preparations in recipients should also be shared, with appropriate protective measures, to allow aggregation at Union level for more robust evidence gathering on the clinical efficacy of SoHO preparations. For all data processing, such processing should be necessary and appropriate with a view to ensuring compliance with this Regulation in order to protect human health. Data on donors, recipients and offspring should hence be limited to the minimum necessary and pseudonymised. Donors, recipients and offspring should be informed of the processing of their personal data in line with the requirements of Regulations (EU) 2016/679 and (EU) 2018/1725, and in particular as provided for under this Regulation, including the possibility of exceptional cases where circumstances require such processing.

Or. en

Amendment 300
Tudor Ciuhodaru

Proposal for a regulation
Recital 46

Text proposed by the Commission	*Amendment*
(46) In order to enable better access to health data in the interests of public health, Member States should entrust competent authorities as data controllers within the meaning of Regulation (EU) 2016/679 with powers to take decisions on the access to and re-use of such data.	(46) In order to enable better access to health data in the interests of public health, Member States should entrust competent authorities as data controllers within the meaning of Regulation (EU) 2016/679 with powers to take decisions on the access to and re-use of such data***, specifying the period for which they are to be retained and how they are to be accessed or the number of persons having access and for***

how long.

Or. ro

Amendment 301
Andreas Glück, Ondřej Knotek, Véronique Trillet-Lenoir, Peter Liese, Susana Solís Pérez

Proposal for a regulation
Recital 46

Text proposed by the Commission	*Amendment*
(46) In order to enable better access to health data in the interests of public health, Member States should entrust competent authorities as data controllers within the meaning of Regulation (EU) 2016/679 with powers to take decisions on the access to and re-use of such data.	(46) In order to enable better access to health data in the interests of public health, Member States should entrust competent authorities as data controllers within the meaning of Regulation (EU) 2016/679 with powers to take decisions on the access to and re-use of such data. ***Furthermore, access to secondary data for reseach purposes should be made available via the European Health Data Space, once it is established.***

Or. en

Justification

Access to health data will be governed by the Regulation on the European Health Data Space, once it is established.

Amendment 302
Mathilde Androuët

Proposal for a regulation
Recital 47

Text proposed by the Commission	*Amendment*
(47) The exchange of SoHOs between Member States is necessary for ensuring optimal patient access and sufficiency of supply, particularly in the case of local crises or shortages. For certain SoHOs that need to be matched between the donor and	(47) The exchange of SoHOs between Member States is necessary for ensuring optimal patient access and sufficiency of supply, particularly in the case of local crises or shortages. For certain SoHOs that need to be matched between the donor and

the recipient, such exchanges are essential to allow patients to receive the treatment they need. ***In this context, the objective of this Regulation, namely to ensure quality and safety of SoHOs and a high level of protection of donors, needs to be achieved at Union level, by establishing high standards of quality and safety for SoHOs, based on a common set of requirements that are implemented in a consistent manner across the Union. Thus, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.***	the recipient, such exchanges are essential to allow patients to receive the treatment they need.

Or. fr

Amendment 303
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Radka Maxová, Robert Hajšel

Proposal for a regulation
Recital 47

Text proposed by the Commission	*Amendment*
(47) The exchange of SoHOs between Member States is necessary for ensuring optimal patient access and sufficiency of supply, particularly in the case of local crises or shortages. For certain SoHOs that need to be matched between the donor and the recipient, such exchanges are essential to allow patients to receive the treatment they need. ***In this context, the objective of this Regulation, namely to ensure quality and safety of SoHOs and a high level of protection of donors, needs to be achieved at Union level, by establishing high standards of quality and safety for SoHOs, based on a common set of requirements that are implemented in a***	(47) The exchange of SoHOs between Member States is necessary for ensuring optimal patient access and sufficiency of supply, particularly in the case of local crises or shortages. For certain SoHOs that need to be matched between the donor and the recipient, such exchanges are essential to allow patients to receive the treatment they need. This Regulation ***will increase coordination between Member States and facilitate the cross-border exchange of SoHO***.

consistent manner across the Union. Thus, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation ***does not go beyond what is necessary in order to achieve that objective***.

Or. en

Amendment 304
Tudor Ciuhodaru

Proposal for a regulation
Recital 47

Text proposed by the Commission	*Amendment*
(47) The exchange of SoHOs between Member States is necessary for ensuring optimal patient access and sufficiency of supply, particularly in the case of local crises or shortages. For certain SoHOs that need to be matched between the donor and the recipient, such exchanges are essential to allow patients to receive the treatment they need. In this context, the objective of this Regulation, namely to ensure quality and safety of SoHOs and a high level of protection of donors, needs to be achieved at Union level, by establishing high standards of quality and safety for SoHOs, based on a common set of requirements that are implemented in a consistent manner across the Union. Thus, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.	(47) The exchange of SoHOs between Member States is necessary for ensuring optimal patient access and sufficiency of supply, particularly in the case of local crises or shortages***, using a database to trace the availability thereof in various Member States***. For certain SoHOs that need to be matched between the donor and the recipient, such exchanges are essential to allow patients to receive the treatment they need ***in the optimal timeframe to achieve the desired results***. In this context, the objective of this Regulation, namely to ensure quality and safety of SoHOs and a high level of protection of donors, needs to be achieved at Union level, by establishing high standards of quality and safety for SoHOs, based on a common set of requirements that are implemented in a consistent manner across the Union. Thus, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to

achieve that objective.

Or. ro

Amendment 305
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Radka Maxová, Robert Hajšel

Proposal for a regulation
Recital 47 a (new)

Text proposed by the Commission	*Amendment*
	(47 a) The objective of this Regulation, namely to ensure quality and safety of SoHOs and a high level of protection of donors, needs to be achieved at Union level, by establishing high standards of quality and safety for SoHOs, based on a common set of requirements that are implemented in a consistent manner across the Union. Thus, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

Or. en

Amendment 306
Tilly Metz

Proposal for a regulation
Recital 47 a (new)

Text proposed by the Commission	*Amendment*
	(47 a) In order to successfully implement this Regulation and ensure high quality and safety standards of SoHOs in the long-term, Member States should enhance education and provide appropriate

training for medical personnel regarding SoHO collection, processing, storage, application, transfusion and procurement.

Or. en

Amendment 307
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Recital 47 b (new)

Text proposed by the Commission	*Amendment*
	(47 b) In some cases such as bone marrow or haematopoietic stem cell transplants, the level of donor/recipient compatibility has to be extremely high. Therefore, excellent coordination is needed at a global level, beyond the Union level, so that each patient has more options of finding a compatible donor.

Or. en

Amendment 308
Margarita de la Pisa Carrión

Proposal for a regulation
Recital 48

Text proposed by the Commission	*Amendment*
(48) In order to be able to supplement this Regulation where necessary with additional standards concerning the protection of donors, recipients and offspring ***from medically assisted reproduction*** to take into account technical and scientific developments in the field of SoHOs, and with additional rules on the authorisation of importing SoHO entities, on obligations and procedures for importing SoHO entities, on the organisation of Union training and	(48) In order to be able to supplement this Regulation where necessary with additional standards concerning the protection of donors, recipients and offspring ***conceived by means of fertility treatment*** to take into account technical and scientific developments in the field of SoHOs, and with additional rules on the authorisation of importing SoHO entities, on obligations and procedures for importing SoHO entities, on the organisation of Union training and

exchange programmes, on technical specifications concerning the EU SoHO Platform, and on data protection, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[29]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

[29] OJ L 123, 12.5.2016**,** p. 1.

exchange programmes, on technical specifications concerning the EU SoHO Platform, and on data protection, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[29]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

[29] OJ L 123, 12.5.2016 p. 1.

Or. es

Amendment 309
Joanna Kopcińska

Proposal for a regulation
Recital 51 a (new)

Text proposed by the Commission	*Amendment*
	(51a) In view of the significant systemic changes that will result from the entry into force of this draft Regulation, it is essential to give Member States sufficient time to redesign existing national solutions so that they can comprehensively, coherently and reliably amend national legislation in all areas covered by the Regulation;

Or. pl

Amendment 310
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Radka Maxová, Robert Hajšel

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
This Regulation establishes measures setting high standards of quality and safety for all substances of human origin ('SoHOs') intended for human application and for activities related to those substances in order to ensure a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted reproduction. This Regulation is without prejudice to national legislation which establishes rules relating to aspects of SoHOs other than their quality and safety and the safety of SoHO donors.	This Regulation establishes measures setting high standards of quality and safety for all substances of human origin ('SoHOs') intended for human application and for activities related to those substances in order to ensure a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted reproduction***, and for enhanced coordination between Member States to improve the availability and accessibility of SoHO across the Union***. This Regulation is without prejudice to national legislation which establishes rules relating to aspects of SoHOs other than their quality and safety and the safety of SoHO donors***, recipients and offspring of medically assisted reproduction***.

Or. en

Amendment 311
Véronique Trillet-Lenoir, Max Orville, Susana Solís Pérez

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
This Regulation establishes measures setting high standards of quality and safety for all substances of human origin ('SoHOs') intended for human application and for activities related to those substances in order to ensure a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted	This Regulation establishes measures setting high standards of quality and safety for all substances of human origin ('SoHOs') intended for human application and for activities related to those substances in order to ensure a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted

reproduction. This Regulation is without prejudice to national legislation which establishes rules relating to aspects of SoHOs other than their quality and safety and the safety of SoHO donors.	reproduction. This Regulation is without prejudice to national legislation which establishes rules relating to aspects of SoHOs other than their ***efficacy,*** quality and safety and the safety of SoHO donors.

Or. en

Amendment 312
Margarita de la Pisa Carrión

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
This Regulation establishes measures setting high standards of quality and safety for all substances of human origin ('SoHOs') intended for human application and for activities related to those substances in order to ensure a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring ***from medically assisted reproduction***. This Regulation is without prejudice to national legislation which establishes rules relating to aspects of SoHOs other than their quality and safety and the safety of SoHO donors.	This Regulation establishes measures setting high standards of quality and safety for all substances of human origin ('SoHOs') intended for human application and for activities related to those substances in order to ensure a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring ***conceived by means of fertility treatment***. This Regulation is without prejudice to national legislation which establishes rules relating to aspects of SoHOs other than their quality and safety and the safety of SoHO donors.

Or. es

Amendment 313
Véronique Trillet-Lenoir, Max Orville, Susana Solís Pérez

Proposal for a regulation
Article 2 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. This Regulation shall apply to SoHOs intended for human application, to SoHO preparations, to products manufactured from SoHOs and intended for human application, to SoHO donors	1. This Regulation shall apply to SoHOs intended for human application, to SoHO preparations, to products manufactured from SoHOs and intended for human application, to SoHO donors

and recipients, and to the following SoHO activities:	and recipients, and to the following SoHO activities ***that have a direct impact on the safety, quality or efficacy of SoHOs*** :

Or. en

Amendment 314
Mathilde Androuët

Proposal for a regulation
Article 2 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. This Regulation shall apply to SoHOs intended for human application, to SoHO preparations, to products manufactured from SoHOs and intended for human application, to SoHO donors and recipients, and to the following SoHO activities:	1. This Regulation shall apply ***exclusively*** to SoHOs intended for human application, to SoHO preparations, to products manufactured from SoHOs and intended for human application, to SoHO donors and recipients ***who have not been duly declared dead***, and to the following SoHO activities:

Or. fr

Justification

This Regulation excludes the use of substances of animal origin in conjunction with that of SoHOs.

Amendment 315
Andreas Glück, Ondřej Knotek, Véronique Trillet-Lenoir, Susana Solís Pérez, Jan Huitema

Proposal for a regulation
Article 2 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) SoHO donor recruitment;	(a) SoHO donor recruitment; ***except if the entity is not subject to further SoHO activites as listed in this paragraph.***

Or. en

Justification

The Regulation should be in force as soon as the donor is undergoing SoHO donor history review and eligibility assessment as mentioned in point b. Solely recruiting people who might be interested in donation should not fall under the regulation and would put an inadequate burden on the collecting organization.

Amendment 316
Kateřina Konečná

Proposal for a regulation
Article 2 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) SoHO donor recruitment;	(a) SoHO donor recruitment***, except if that is the full extent of an entity's SoHO activity***;

Or. en

Justification

A strict, literal interpretation of the text proposed by the European Commission, could mean that organisations that only call for SoHO donations, such as donor and patient organisations, might find themselves under the scope of the regulation, which does not seem to be the goal of the legislator or a desired outcome.

Amendment 317
Mathilde Androuët

Proposal for a regulation
Article 2 – paragraph 1 – point h a (new)

Text proposed by the Commission	*Amendment*
	(ha) SoHO dispensing;

Or. fr

Amendment 318
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 2 – paragraph 1 – point h a (new)

Text proposed by the Commission	*Amendment*
	(h a) issuing of SoHOs;

Or. en

Amendment 319
Margarita de la Pisa Carrión

Proposal for a regulation
Article 2 – paragraph 1 – point m – point i (new)

Text proposed by the Commission	*Amendment*
	(i) promotion and coordination actions to ensure SoHO supplies and foster donation culture.

Or. es

Amendment 320
Mathilde Androuët

Proposal for a regulation
Article 2 – paragraph 1 – point m a (new)

Text proposed by the Commission	*Amendment*
	(ma) The exchange and sharing of data or information on quantities or stocks of SoHOs, and the promotion of activities related to security of supply;

Or. fr

Amendment 321
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 2 – paragraph 1 – point m a (new)

Text proposed by the Commission	*Amendment*
	(m a) clinical studies with SoHO.

Or. en

Amendment 322
Ondřej Knotek, Susana Solís Pérez

Proposal for a regulation
Article 2 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. In cases of autologous use of SoHOs where:	2. In cases of autologous use of SoHOs***, with the exception of processes involving a substantial manipulation or application intended for a non-homologous use,*** where:

Or. en

Amendment 323
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 2 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. In cases of autologous use of SoHOs where:	2. In cases of autologous use of SoHOs***, excluding cases where the processing involves a substantial modification or where its application is non-homologous,*** where:

Or. en

Amendment 324
Andreas Glück

Proposal for a regulation
Article 2 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) SoHOs are not processed and not stored before application, this Regulation shall not apply**.**	(c) SoHOs are not ***or minimally*** processed ***to maintain or establish their applicability during medical treatment and surgeries*** and not stored before application, this Regulation shall not apply

Or. en

Justification

The exemptions are formulated too narrow. For example, during surgeries blood needs to be reprocessed (filtered, washed, etc.) or the edges of skin and cornea need to be cut in order to establish applicability. Moreover, the term minimally processed should include all manipulations which are conducted within a closed system using a medical device.

Amendment 325
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 2 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
For SoHOs that are used to manufacture products in accordance with Union legislation on medical devices, regulated by Regulation (EU) 2017/745, on medicinal products, regulated by Regulation (EC) No 726/2004 and Directive 2001/83/EC, including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007, or on food, regulated by Regulation (EC) No 1925/2006, or as the starting and raw material thereof, the provisions of this Regulation applicable to the activities of SoHO donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, ***and*** collection of SoHOs from donors or patients shall apply. Insofar as the activities of SoHO release, distribution, import and export relate to SoHOs prior to their distribution to an operator regulated by the other Union	For SoHOs that are used to manufacture products in accordance with Union legislation on medical devices, regulated by Regulation (EU) 2017/745, on medicinal products, regulated by Regulation (EC) No 726/2004 and Directive 2001/83/EC, including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007, or on food, regulated by Regulation (EC) No 1925/2006, or as the starting and raw material thereof, the provisions of this Regulation applicable to the activities of SoHO donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, collection of SoHOs from donors or patients***, quality control testing of SoHOs, and the continuity of supply of these substances,*** shall apply. Insofar as the activities of SoHO release, distribution, import and export relate to

legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.	SoHOs prior to their distribution to an operator regulated by the other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.

Or. fr

Amendment 326
Stelios Kympouropoulos, Tomislav Sokol

Proposal for a regulation
Article 2 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
For SoHOs that are used to manufacture products in accordance with Union legislation on medical devices, regulated by Regulation (EU) 2017/745, on medicinal products, regulated by Regulation (EC) No 726/2004 and Directive 2001/83/EC, including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007, or on food, regulated by Regulation (EC) No 1925/2006, or as the starting and raw material thereof, the provisions of this Regulation applicable to the activities of SoHO donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, and collection of SoHOs from donors or patients shall apply. Insofar as the activities of SoHO release, distribution, import and export relate to SoHOs prior to their distribution to an operator regulated by the other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.	For SoHOs that are used to manufacture products in accordance with Union legislation on medical devices, regulated by Regulation (EU) 2017/745, on medicinal products, regulated by Regulation (EC) No 726/2004 and Directive 2001/83/EC, including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007***, on investigational medicinal products regulated by Regulation 536/2014***, or on food, regulated by Regulation (EC) No 1925/2006, or as the starting and raw material thereof, the provisions of this Regulation applicable to the activities of SoHO donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, and collection of SoHOs from donors or patients shall apply. Insofar as the activities of SoHO release, distribution, import and export relate to SoHOs prior to their distribution to an operator regulated by the other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.

Or. en

Amendment 327
Susana Solís Pérez, Ondřej Knotek, Véronique Trillet-Lenoir

Proposal for a regulation
Article 2 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
For SoHOs that are used to manufacture products in accordance with Union legislation on medical devices, regulated by Regulation (EU) 2017/745, on medicinal products, regulated by Regulation (EC) No 726/2004 and Directive 2001/83/EC, including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007, or on food, regulated by Regulation (EC) No 1925/2006, or as the starting and raw material thereof, the provisions of this Regulation applicable to the activities of SoHO donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, and collection of SoHOs from donors or patients shall apply. Insofar as the activities of SoHO release, distribution, import and export relate to SoHOs prior to their distribution to an operator regulated by the other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.	For SoHOs that are used to manufacture products in accordance with Union legislation on medical devices, regulated by Regulation (EU) 2017/745, on medicinal products, regulated by Regulation (EC) No 726/2004 and Directive 2001/83/EC, including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007***, on investigational medicinal products regulated by Regulation 536/2014***, or on food, regulated by Regulation (EC) No 1925/2006, or as the starting and raw material thereof, the provisions of this Regulation applicable to the activities of SoHO donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, and collection of SoHOs from donors or patients shall apply. Insofar as the activities of SoHO release, distribution, import and export relate to SoHOs prior to their distribution to an operator regulated by the other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.

Or. en

Justification

Complementing the listing of existing relevant Union legislation with the addition of the Clinical Trials Regulation.