European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

2022/0216(COD)

18.01.2023

***I
DRAFT REPORT

on the proposal for a regulation of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC
(COM(2022)0338 – C9-0226/2022 – 2022/0216(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Nathalie Colin-Oesterlé

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (COM(2022)0338 – C9-0226/2022 – 2022/0216(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2022)0338),

– having regard to Article 294(2) and Article 168(4), point (a), of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0226/2022),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 27 October 2022[1],

– after consulting the Committee of the Regions,

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0000/2023),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

[1] Not yet published in the Official Journal.

Amendment 1

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. ***Under Article 3 of the Charter of Fundamental Rights of the European Union, these safety standards should be based on the fundamental principle of not allowing the human body to be a source of financial gain.***

Or. fr

Amendment 2

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	(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.

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 ***and cross-border sharing of these substances***. 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 3

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	(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.	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 of the substances, as recognised by the technical guidelines referred to in this Regulation***.
	Or. fr

Amendment 4

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 from medical personnel***, 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 5

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. fr

Justification

Issuing 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 6

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 ***and the EU 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 7

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	(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.

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.	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-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. fr

Amendment 8

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 induction training.

Amendment 9

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 with the relevant authorities responsible for other relevant regulatory frameworks, namely medicinal products, ***innovative therapies,*** 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 ***and submit a request to it for its opinion on the regulatory status of the substance***. 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. Member States ***should respect the Coordination Board's opinion*** on the regulatory status of ***substances***. 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.

Or. fr

Amendment 10

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, patient blood management, as recommended by the World Health Organization[1a]. Raising awareness among prescribers could avoid the application of SoHOs where therapeutic alternatives are available. This practice can also contribute to the sufficiency of supply by ensuring optimum use of SoHOs.
	[1a] 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 11

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	(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.

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***, on condition that they are aligned with the interests of the Member States. Preparation of these guidelines should include stakeholder consultations in order 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).

[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 12

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	(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, ***including those***

regarding the eligibility and testing of donors and the investigation of serious adverse occurrences involving suspected transmission of a communicable disease.	***exacerbated by climate change,*** 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. fr

Amendment 13

Proposal for a regulation
Recital 36 a (new)

Text proposed by the Commission	*Amendment*
	(36a) The Health Emergency Preparedness and Response Authority (HERA), established by Commission Decision 2021/C 393[1a], is a Commission service whose missions include strengthening health security coordination within the Union during preparedness and crisis response times, and ensuring the availability and equitable distribution of medical countermeasures during crises. This service should be given an observer role that allows it to access information that may fall within its remit in order to prepare, prevent and respond to the emergence of any diseases that might be transmitted by SoHOs. To this end, HERA will work with the competent national authorities, other Commission services and the ECDC.
	[1a] Commission Decision of 16 September 2021 establishing the Health Emergency

Preparedness and Response Authority (OJ C 393 I, 29.9.2021, p. 3).

Or. fr

Amendment 14

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 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. fr

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 15

Proposal for a regulation
Recital 37 a (new)

Text proposed by the Commission	*Amendment*
	(37a) 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 plasmapheresis programmes 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. fr

Amendment 16

Proposal for a regulation
Recital 37 b (new)

Text proposed by the Commission	*Amendment*
	(37b) 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 SoHO supply self-sufficiency, Member States should adopt national

priority action programmes for donor recruitment.

Or. fr

Amendment 17

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. ***Other Union institutions, services and bodies should be involved as observers, in particular the European Health Emergency Preparedness and Response Authority (HERA), the EMA and the European Parliament.***

Or. fr

Amendment 18

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. ***The competent national authorities should be encouraged to use the EU SoHO platform instead of maintaining national registers, in particular to limit the administrative burden.***

Or. fr

Amendment 19

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***	(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.

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. fr

Amendment 20

Proposal for a regulation
Recital 47 a (new)

Text proposed by the Commission	*Amendment*
	(47a) 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. fr

Justification

This provision should apply throughout the text and not only to SoHO exchanges. For the sake of clarity, it is therefore recommended that recital 47 be divided into two separate recitals.

Amendment 21

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. ***It ensures*** a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted reproduction***, and strengthens the continuity of supply of such substances***. 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. fr

Amendment 22

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

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

Or. fr

Amendment 23

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

Text proposed by the Commission	*Amendment*
	(ma) exchange of information on availability and stocks, and promotion of actions relating to the security of SoHO supply;

Or. fr

Amendment 24

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

Text proposed by the Commission	*Amendment*
	(mb) coordination of the competent authorities with the Commission and EU agencies in the event of the emergence of a disease transmissible via SoHOs.

Or. fr

Amendment 25

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,	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.	donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, collection of SoHOs from donors or patients ***and the continuity of supply of these substances*** 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. fr

Amendment 26

Proposal for a regulation
Article 3 – paragraph 1 – point 8

Text proposed by the Commission	*Amendment*
(8) ‘SoHO donor’ means any person ***who has presented themselves to a*** SoHO entity ***with a view to*** making a donation of SoHOs***, whether that donation is successful or*** not;	8) ‘SoHO donor’ means any person ***living or dead under the care of a*** SoHO entity ***for the purposes of*** making a donation of SoHOs***; the person providing sperm for use within the couple shall*** not ***deemed to be a donor of SoHOs, but rather a partner***;

Or. fr

Amendment 27

Proposal for a regulation
Article 3 – paragraph 1 – point 10

Text proposed by the Commission	*Amendment*
(10) ‘medically assisted reproduction’ means the facilitation of conception by intra-uterine insemination of sperm, in vitro fertilisation or any other laboratory or medical intervention that promotes conception;	(10) ‘medically assisted reproduction’ means the facilitation of conception by intra-uterine insemination of sperm, in vitro fertilisation or any other laboratory or medical intervention that promotes conception ***and involves the use of***

SoHOs;

Or. fr

Amendment 28

Proposal for a regulation
Article 3 – paragraph 1 – point 13

Text proposed by the Commission	*Amendment*
(13) 'donor recruitment' means any activity aimed at ***encouraging*** persons to ***become SoHO donors***;	(13) 'donor recruitment' means any activity aimed at ***informing*** persons ***about activities related*** to ***the donation of SoHOs or encouraging them to donate***;

Or. fr

Amendment 29

Proposal for a regulation
Article 3 – paragraph 1 – point 17

Text proposed by the Commission	*Amendment*
(17) 'storage' means the maintenance of SoHOs under appropriate controlled conditions until distribution;	(17) 'storage' means the maintenance of SoHOs under appropriate controlled conditions until distribution ***or issuing***;

Or. fr

Amendment 30

Proposal for a regulation
Article 3 – paragraph 1 – point 18

Text proposed by the Commission	*Amendment*
(18) 'release' means a process through which it is verified that a SoHO or a SoHO preparation meets defined safety and quality criteria and the conditions of any applicable authorisation before	(18) 'release' means a process through which it is verified that a SoHO or a SoHO preparation meets defined safety and quality criteria and the conditions of any applicable authorisation before distribution

distribution;	***or until issuing***;

Or. fr

Amendment 31

Proposal for a regulation
Article 3 – paragraph 1 – point 18 a (new)

Text proposed by the Commission	*Amendment*
	(18a) 'issuing' means the provision of SoHOs or preparations based on SoHOs, possibly following a medical prescription, for application to a specific recipient;

Or. fr

Amendment 32

Proposal for a regulation
Article 3 – paragraph 1 – point 31

Text proposed by the Commission	*Amendment*
(31) 'EU SoHO Platform' means the digital platform ***established*** by the Commission to exchange information concerning SoHO activities;	(31) 'EU SoHO platform' means the digital platform ***interoperable with other existing EU platforms set up*** by the Commission to exchange information concerning SoHO activities ***between the competent authorities, EU agencies and the Commission***;

Or. fr

Amendment 33

Proposal for a regulation
Article 3 – paragraph 1 – point 40

Text proposed by the Commission	*Amendment*
(40) 'SoHO establishment' means a	(40) 'SoHO establishment' means a

SoHO entity that carries out ***both*** processing and storage of SoHOs;	SoHO entity that carries out ***processing and storage or*** processing and ***release or*** storage ***and release*** of SoHOs;

Or. fr

Amendment 34

Proposal for a regulation
Article 3 – paragraph 1 – point 41

Text proposed by the Commission	*Amendment*
(41) ‘critical SoHO’ means a SoHO for which an insufficient supply will result in serious harm or risk of harm to ***patients***;	(41) ‘critical SoHO’ means a SoHO for which an insufficient supply will result in serious harm or risk of harm to ***recipients***;

Or. fr

Amendment 35

Proposal for a regulation
Article 3 – paragraph 1 – point 42

Text proposed by the Commission	*Amendment*
(42) ‘critical SoHO entity’ means a SoHO entity that carries out activities contributing to the supply of critical SoHOs and the scale of those activities is such that a failure to carry them out cannot be compensated by activities of other entities or alternative substances or products for ***patients***;	(42) ‘critical SoHO entity’ means a SoHO entity that carries out activities contributing to the supply of critical SoHOs and the scale of those activities is such that a failure to carry them out cannot be compensated by activities of other entities or alternative substances or products for ***recipients***;

Or. fr

Amendment 36

Proposal for a regulation
Article 3 – paragraph 1 – point 47 – introductory part

Text proposed by the Commission	*Amendment*
(47) 'traceability' means the ability to locate and identify SoHOs during any step from collection through processing and storage to ***distribution*** or disposal, including the ability to:	(47) 'traceability' means the ability to locate and identify SoHOs during any step from collection through processing and storage to ***human application*** or disposal, including the ability to:

Or. fr

Amendment 37

Proposal for a regulation
Article 3 – paragraph 1 – point 64

Text proposed by the Commission	*Amendment*
(64) 'compensation' means making good of any losses associated with donation;	(64) 'compensation' means making good of any ***quantifiable*** losses associated with donation; ***such compensation should never be intended or provided with a view to encouraging donations;***

Or. fr

Amendment 38

Proposal for a regulation
Article 3 – paragraph 1 – point 64 a (new)

Text proposed by the Commission	*Amendment*
	(64a) 'financial neutrality of donation' means that no financial gain or loss will be incurred by the donor as a result of the donation;

Or. fr

Justification

This definition is added for consistency with the EDQM's 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, which is cited numerous times in the Commission proposal and is

useful to clarify the principle of voluntary and unpaid donation.

Amendment 39

Proposal for a regulation
Article 3 – paragraph 1 – point 70 a (new)

Text proposed by the Commission	*Amendment*
	(70a) 'patient blood management' means an innovative organisational approach for the best possible management of patients undergoing surgery at risk of bleeding, based on the following three pillars:
	(a) optimising the patient's blood mass;
	(b) minimising blood loss;
	(c) improving the patient's tolerance to anaemia;

Or. fr

Justification

Definition based on the World Health Organisation resolution mentioned in recital 24(a),

Amendment 40

Proposal for a regulation
Article 3 – paragraph 1 – point 70 b (new)

Text proposed by the Commission	*Amendment*
	(70b) 'donor base resilience' means the capacity of the donation collection system to rely on a large number of donors to address the emergence of a health crisis;

Or. fr

Amendment 41

Proposal for a regulation
Article 3 – paragraph 1 – point 70 c (new)

Text proposed by the Commission	*Amendment*
	(70c) 'free and informed consent' means the donor's agreement has been obtained freely without coercion and after access to clear, comprehensive information in line with his or her capacity to understand;

Or. fr

Amendment 42

Proposal for a regulation
Article 3 – paragraph 1 – point 70 d (new)

Text proposed by the Commission	*Amendment*
	(70d) 'European self-sufficiency' means the Union's degree of independence on third countries for the collection of substances of human origin, the manufacture of preparations based on SoHOs and any other SoHO-related activities.

Or. fr

Amendment 43

Proposal for a regulation
Article 4 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1(a) Member States may introduce additional measures to help set up a European supply chain and to achieve the objective of European self-sufficiency. Such measures may also aim to reinforce the principle of voluntary and unpaid

donation.

Or. fr

Justification

It would be advisable to specify that Member States are free to take stricter measures with a view to restricting SoHO imports from third countries, whose collection systems are not necessarily based on the principle of voluntary and unpaid donation set out in this proposal for a regulation. This amendment is consistent with the desire to promote European self-sufficiency concerning SoHOs.

Amendment 44

Proposal for a regulation
Article 7 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Paragraph 2 shall also apply to the previous activities of staff members for a reasonable period, to be defined and made public by the competent authorities.

Or. fr

Amendment 45

Proposal for a regulation
Article 9 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) appropriate and properly maintained facilities and equipment to ensure that personnel can perform their SoHO supervisory activities efficiently and effectively;	(c) appropriate and properly maintained facilities and equipment to ensure that personnel can perform their SoHO supervisory activities ***safely,*** efficiently and effectively;

Or. fr

Amendment 46

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission	*Amendment*
1. In all cases where questions arise as to the regulatory status of a substance, product or activity, competent authorities shall consult with authorities established in other relevant Union legislation referred to in Article 2(3), as ***relevant***. In such cases, competent authorities shall also consult the compendium referred to Article 3 point (33).	1. In all cases where questions arise as to the regulatory status of a substance, product or activity, competent authorities shall consult with authorities established in other relevant Union legislation referred to in Article 2(3), ***such*** as ***the EMA and the Medical Device Coordination Group (MDCG)***. In such cases, competent authorities shall also consult the compendium referred to Article 3 point (33).

Or. fr

Amendment 47

Proposal for a regulation
Article 14 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
In the course of the consultation referred to in paragraph 1, the competent authorities ***may also submit*** a request to the SCB for its opinion on the regulatory status of the substance, product or activity under this Regulation ***and shall do so in all cases where the competent authorities, after the consultations referred to in paragraph 1, are not in a position to take a decision in that respect.***	In the course of the consultation referred to in paragraph 1, the competent authorities ***shall submit*** a request to the SCB for its opinion on the regulatory status of the substance, product or activity under this Regulation.

Or. fr

Amendment 48

Proposal for a regulation
Article 14 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
The competent authorities may also indicate that they consider there is a need that the SCB ***consults***, in accordance with Article 68(1), point (b), with the equivalent advisory bodies established in other relevant Union legislation referred to in Article 2(3).	The SCB shall ***consult***, in accordance with Article 68(1), point (b), with the equivalent advisory bodies established in other relevant Union legislation referred to in Article 2(3)***, such as the EMA and the Medical Device Coordination Group (MDCG)***.

Or. fr

Amendment 49

Proposal for a regulation
Article 14 – paragraph 3

Text proposed by the Commission	*Amendment*
3. ***The competent authorities shall inform the SCB of the subsequent decision taken in their Member State, f***ollowing the consultations referred to in paragraph 1 of this Article, regarding the regulatory status of the substance, product or activity concerned under this Regulation ***and*** on any consensus reached as a result of those consultations for publication in the compendium by the SCB.	3. ***F***ollowing the consultations referred to in paragraph 1 of this Article, regarding the regulatory status of the substance, product or activity concerned under this Regulation***, the competent authorities shall inform the SCB*** on any consensus reached as a result of those consultations for publication in the compendium by the SCB. ***To the extent possible, the competent authorities shall comply with the opinion of the SCB. In the event of non-compliance, they shall inform the SCB as soon as possible of the decision taken and justify their decision.***

Or. fr

Amendment 50

Proposal for a regulation
Article 18 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Instead of establishing a register of SoHO entities, as referred to in paragraph 1, a SoHO National Authority ***may*** use the EU SoHO Platform as referred to in Chapter XI. In this case, the SoHO National Authority shall instruct competent authorities, where necessary, and SoHO entities to register directly on the EU SoHO Platform.	2. Instead of establishing a register of SoHO entities, as referred to in paragraph 1, a SoHO National Authority ***shall be encouraged to*** use the EU SoHO Platform as referred to in Chapter XI. In this case, the SoHO National Authority shall instruct competent authorities, where necessary, and SoHO entities to register directly on the EU SoHO Platform.

Or. fr

Amendment 51

Proposal for a regulation
Article 20 – paragraph 3

Text proposed by the Commission	*Amendment*
3. SoHO preparation authorisations shall be valid throughout the Union for the period defined in the terms of the authorisation, when such a time period has been defined, or until a competent authority has suspended or withdrawn the authorisation. Where a Member State has adopted a more stringent measure, in accordance with Article 4, which relates to a specific SoHO preparation, that Member State may decline to recognise the validity of the SoHO preparation authorisation of another Member State ***pending verification that the*** more stringent measure has been met.	3. SoHO preparation authorisations shall be valid throughout the Union for the period defined in the terms of the authorisation, when such a time period has been defined, or until a competent authority has suspended or withdrawn the authorisation. Where a Member State has adopted a more stringent measure, in accordance with Article 4, which relates to a specific SoHO preparation, that Member State may decline to recognise the validity of the SoHO preparation authorisation of another Member State. ***That refusal shall end once the Member State which has adopted a*** more stringent measure ***has verified that the correct application of that measure by the Member State which granted the authorisation*** has been met. ***Where a Member State refuses to recognise the validity of the authorisation granted by another Member State, it shall***

without undue delay notify the SoHO Platform established by this Regulation.

Or. fr

Amendment 52

Proposal for a regulation
Article 21 a (new)

Text proposed by the Commission	*Amendment*
	Article 21a
	Exceptional derogation from the obligation to authorise SoHO preparations in situations where there is no therapeutic alternative
	1. By way of derogation from Article 21 of this Regulation, and after consulting the relevant best practices approved and documented by the SCB in accordance with Article 68(1)(c), the competent authorities may authorise, on an exceptional basis and at the request of a prescribing doctor within a SoHO entity, preparations of substances of human origin in situations where the procedures referred to in Article 21 have not been followed, provided that:
	(a) provision has been made for the use of such preparations for a given patient, in cases where that patient has no therapeutic alternative, when treatment cannot be postponed or when his or her condition is life threatening;
	(b) the preparation is deemed to be safe and effective on the basis of the available clinical data.
	2. The competent authorities shall inform the national SoHO authority of the authorised derogation. The national SoHO authority shall inform the Commission and the other Member States of any decision to authorise the distribution or preparation for immediate

application of substances of human origin in accordance with paragraph 1.

Or. fr

Justification

The only possibility for derogation in the Commission proposal concerns continuity of supply. An additional derogation seems necessary where therapeutic alternatives cannot be offered to a given patient. Such cases could be, for example, cell therapies for burn victims or for patients who have suffered accidental irradiation.

Amendment 53

Proposal for a regulation
Article 25 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Competent authorities shall authorise as SoHO establishments the SoHO entities that both process and store SoHOs in accordance with Article 27.	2. Competent authorities shall authorise as SoHO establishments the SoHO entities that both process and store ***or process and release or store and release*** SoHOs in accordance with Article 27.

Or. fr

Amendment 54

Proposal for a regulation
Article 25 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. Competent authorities may decide that certain SoHO entities that do not process and store SoHO also need to be authorised as SoHO establishments, in particular SoHO entities that:	3. Competent authorities may decide that certain SoHO entities that do not process and store ***or process and release or store and release*** SoHO also need to be authorised as SoHO establishments, in particular SoHO entities that:

Or. fr

Amendment 55

Proposal for a regulation
Article 25 – paragraph 5

Text proposed by the Commission	*Amendment*
5. SoHO establishment authorisations shall be valid throughout the Union for the period defined in the terms of the authorisation, when such a time period has been defined, or until a competent authority has suspended or withdrawn the authorisation or the establishment has ceased to conduct SoHO activities. Where a Member State has adopted a more stringent measure, in accordance with Article 4, which relates to a specific SoHO establishment authorisation, that Member State may decline to recognise the validity of the SoHO establishment authorisation of another Member State ***pending verification that the*** more stringent measure has been met.	5. SoHO establishment authorisations shall be valid throughout the Union for the period defined in the terms of the authorisation, when such a time period has been defined, or until a competent authority has suspended or withdrawn the authorisation or the establishment has ceased to conduct SoHO activities. Where a Member State has adopted a more stringent measure, in accordance with Article 4, which relates to a specific SoHO establishment authorisation, that Member State may decline to recognise the validity of the SoHO establishment authorisation of another Member State. ***That refusal shall end once the Member State which has adopted a*** more stringent measure ***has verified that the correct application of that measure by the Member State which granted the authorisation*** has been met.

Or. fr

Amendment 56

Proposal for a regulation
Article 26 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Importing SoHO entity authorisations shall be valid throughout the Union for the period defined in the terms of the authorisation, when such a time period has been defined, or until a competent authority has suspended or withdrawn the authorisation or the entity has ceased to conduct SoHO activities. Where a Member State has adopted a more stringent measure, in accordance with	3. Importing SoHO entity authorisations shall be valid throughout the Union for the period defined in the terms of the authorisation, when such a time period has been defined, or until a competent authority has suspended or withdrawn the authorisation or the entity has ceased to conduct SoHO activities. Where a Member State has adopted a more stringent measure, in accordance with

Article 4, which relates to a specific importing SoHO entity authorisation, that Member State may decline to recognise the validity of the importing SoHO entity authorisation of another Member State ***pending verification that the*** more stringent measure ***has been*** met.	Article 4, which relates to a specific importing SoHO entity authorisation, that Member State may decline to recognise the validity of the importing SoHO entity authorisation of another Member State. ***That refusal shall end once the Member State which has adopted a*** more stringent measure ***has verified that the correct application of that measure by the Member State which granted the authorisation*** has been met. ***It may be based on the principle of voluntary and unpaid donation, in accordance with Article 4(1)(a) of this Regulation.***

Or. fr

Amendment 57

Proposal for a regulation
Article 32 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
In exceptional cases, competent authorities may consider that a person's considerable and relevant experience may exempt this person from the requirement set out in the first subparagraph.	In exceptional cases, competent authorities may consider that a person's considerable and relevant experience may exempt this person from the requirement set out in the first subparagraph. ***Their designation shall be the result of procedures which guarantee their independence and impartiality.***

Or. fr

Amendment 58

Proposal for a regulation
Article 32 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Competent authorities shall provide inspectors with a specific induction training before inspectors take up their	2. Competent authorities shall provide inspectors with a specific induction training before inspectors take up their

duties. For the specific induction training, competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).	duties. For the specific induction training, competent authorities ***shall ensure the independence and impartiality of inspectors and*** shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).

Or. fr

Amendment 59

Proposal for a regulation
Article 34 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Competent authorities shall establish procedures for the unique identification of SoHO establishments that are subject to the provisions on the Single European Code in Article 46. Competent authorities shall ensure that such identification complies with the technical standards defined for that coding system. For this purpose, competent authorities ***may*** use a SoHO establishment identification code generated by the EU SoHO Platform.	2. Competent authorities shall establish procedures for the unique identification of SoHO establishments that are subject to the provisions on the Single European Code in Article 46. Competent authorities shall ensure that such identification complies with the technical standards defined for that coding system. For this purpose, competent authorities ***shall*** use a SoHO establishment identification code generated by the EU SoHO Platform.

Or. fr

Amendment 60

Proposal for a regulation
Article 36 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. Where the IIG has consequences falling within the remit of HERA, the ECDC or the EMA, competent authorities shall provide them without undue delay with information that could reasonably be considered useful.

Or. fr

Amendment 61

Proposal for a regulation
Article 38 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The responsible person for release of SoHOs shall be in possession of a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned and shall have at least 2 years of experience in the relevant field.	2. The responsible person for release of SoHOs shall be in possession of a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned and shall have at least 2 years of experience in the relevant field ***and shall receive continuous training throughout his or her career in relation to innovative processing technologies and processes***.

Or. fr

Amendment 62

Proposal for a regulation
Article 38 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The responsible person for release of SoHOs may delegate the tasks specified in paragraph 1 to other persons who shall be qualified by training and experience to perform such tasks. In such cases, that person shall perform those tasks under the responsibility of the responsible person for release of SoHOs.	3. The responsible person for release of SoHOs may delegate the tasks specified in paragraph 1 to other persons who shall be qualified by training and experience to perform such tasks ***without necessarily having two years' experience***. In such cases, that person shall perform those tasks under the responsibility of the responsible person for release of SoHOs.

Or. fr

Amendment 63

Proposal for a regulation
Article 40 – paragraph 1

Text proposed by the Commission	*Amendment*
1. SoHO entities shall not release or, in an autologous context, prepare and apply immediately to a recipient, SoHO preparations without prior SoHO preparation authorisation. In cases where a SoHO entity modifies an activity carried out for an authorised SoHO preparation, it shall obtain an authorisation for that modified SoHO preparation.	1. SoHO entities shall not release or, in an autologous context, prepare and apply immediately to a recipient, SoHO preparations without prior SoHO preparation authorisation. In cases where a SoHO entity ***substantially*** modifies an activity carried out for an authorised SoHO preparation, it shall obtain an authorisation for that modified SoHO preparation.

Or. fr

Justification

Forcing SoHO entities to apply for a new authorisation for any changes may be too burdensome and difficult to implement. The introduction of a small degree of flexibility in this article would appear to be better adapted to the reality on the ground.

Amendment 64

Proposal for a regulation
Article 40 – paragraph 3

Text proposed by the Commission	*Amendment*
3. SoHO entities may request to their competent authorities a derogation from the requirement for a SoHO preparation authorisation in the exceptional circumstances referred to in ***Article*** 64.	3. SoHO entities may request to their competent authorities a derogation from the requirement for a SoHO preparation authorisation in the exceptional circumstances referred to in ***Articles 21a and*** 64.

Or. fr

Amendment 65

Proposal for a regulation
Article 41 – paragraph 5

Text proposed by the Commission	*Amendment*
5. SoHO entities shall not make any change to the chain of activities performed for an authorised SoHO preparation, without the prior written approval of their competent authorities. SoHO entities shall also inform their competent authorities of changes in the SoHO preparation authorisation holder's details.	5. SoHO entities shall not make any ***substantial*** change to the chain of activities performed for an authorised SoHO preparation, without the prior written approval of their competent authorities. SoHO entities shall also inform their competent authorities of changes in the SoHO preparation authorisation holder's details.

Or. fr

Justification

Same justification as proposed in the amendment to Article 40.

Amendment 66

Proposal for a regulation
Article 48 – paragraph 1

Text proposed by the Commission	*Amendment*
1. SoHO establishments shall not carry out any activities without prior SoHO establishment authorisation. This shall apply whether all activities are carried out by the establishment itself or one or more are contracted to another SoHO entity.	1. SoHO establishments shall not carry out any ***SoHO*** activities without prior SoHO establishment authorisation. This shall apply whether all activities are carried out by the establishment itself or one or more are contracted to another SoHO entity.

Or. fr

Amendment 67

Proposal for a regulation
Article 52 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. SoHO entities shall ensure that the state of health of donors does not pose a

detectable risk to donations.

Or. fr

Amendment 68

Proposal for a regulation
Article 53 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) provide donors or their relatives or any persons granting authorisation on their behalf, in accordance with national legislation, with the information referred to in Article 55 and in a way that ***is adequate in view of their capacity to understand it***;	(b) provide donors or their relatives or any persons granting authorisation on their behalf, in accordance with national legislation, with the information referred to in Article 55 and in a way that ***enables them to give free and informed consent***;

Or. fr

Amendment 69

Proposal for a regulation
Article 53 – paragraph 3

Text proposed by the Commission	*Amendment*
3. SoHO entities that collect SoHOs from donors that are subjected to a surgical procedure in order to donate, that are treated with hormones to facilitate donation, or that donate on a frequent and repeated basis, shall register such donors and the results of their donor health evaluations in a cross-entity registry that allows interconnection with other such registries, as referred to in paragraph 1, point (j). SoHO entities that manage such registries shall ensure interconnectivity between them.	3. SoHO entities that collect SoHOs from donors that are subjected to a surgical procedure in order to donate, that are treated with hormones to facilitate donation, or that donate on a frequent and repeated basis, shall register such donors and the results of their donor health evaluations in a cross-entity registry that allows interconnection with other such registries***, including cross-border ones***, as referred to in paragraph 1, point (j). SoHO entities that manage such registries shall ensure interconnectivity between them. ***The concept of frequent and repeated donations shall be defined in accordance with the EDQM guidelines for each type of donation.***

Or. fr

Amendment 70

Proposal for a regulation
Article 53 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this Regulation in cases where additional standards are needed in order to ensure the protection of donors.	6. The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this Regulation in cases where additional standards are needed in order to ensure the protection of donors***, in particular as regards the permitted frequency of donations in the event of non-application of the guidelines referred to in Article 56***.

Or. fr

Amendment 71

Proposal for a regulation
Article 54 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States may allow for the compensation ***or reimbursement*** from the SoHO entities to donors for losses related to their participation in donations ***through fixed rate allowances***. In such case, Member States shall establish the conditions for such ***allowances*** in national legislation, including the setting of an upper limit that ensures that ***allowances*** are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such ***allowances*** to independent bodies that are established in accordance with national legislation.	2. Member States may allow for the compensation from the SoHO entities to donors for losses related to their participation in donations***, the compensation payments being strictly proportional to any losses incurred.*** In such case, Member States shall establish the conditions for such ***compensation payments*** in national legislation, including the setting of an upper limit that ensures that ***they*** are ***always*** financially neutral and consistent with the standards laid down in this Article. They may ***make compensation payments subject to the filing of applications by donors and*** delegate the setting of conditions for such ***payments*** to

independent bodies that are established in accordance with national legislation. ***The donor may also choose not to be compensated for losses associated with his donation.***

Or. fr

Amendment 72

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

Text proposed by the Commission	*Amendment*
	3a. Compensation payments must not serve as an incentive for donations or engender financial competition, including cross-border competition, between institutions and entities that are seeking donors.

Or. fr

Amendment 73

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

Text proposed by the Commission	*Amendment*
	3b Member States shall report to the Commission on the conditions for granting such compensation and setting the limits thereof two years after the entry into force of this Regulation and every three years thereafter. On the basis of those reports, the Commission shall inform the European Parliament and the Council of the necessary additional measures it intends to take at Union level to ensure compliance with the principle of voluntary and unpaid donation in accordance with Article 3 of the Charter of Fundamental Rights of the European

Union.

Or. fr

Amendment 74

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

Text proposed by the Commission	*Amendment*
	3c. On the basis of those reports, and in order to ensure the implementation of the principle of voluntary and unpaid donation, the Commission shall be empowered to adopt delegated acts in accordance with Article 77 in order to establish a single register of European donors.

Or. fr

Justification

If deemed necessary and on the basis of the reports provided for in paragraph 3b, the Commission must be able to propose a delegated act establishing a single register of donors. This will ensure, for example, that it is not possible to donate more than is reasonable simply by crossing an EU internal border.

Amendment 75

Proposal for a regulation
Article 55 – paragraph 2

Text proposed by the Commission	*Amendment*
2. SoHO entities shall provide the information referred to in paragraph 1 before the consent is given or authorisation is granted for the donation. SoHO entities shall provide the information in an accurate and clear manner, using terms that are easily understood by the prospective donors or the persons to consent or authorise the donation. It shall not mislead	2. SoHO entities shall provide the information referred to in paragraph 1 before the consent is given or authorisation is granted for the donation. SoHO entities shall provide the information in an accurate and clear manner, using terms that are easily understood by the prospective donors or the persons to consent or authorise the donation***, ensuring that this***

the prospective donors or persons granting authorisation on their behalf, in particular, as to the benefits of the donation to future recipients of the SoHO concerned.	***is a free and informed decision***. It shall not mislead the prospective donors or persons granting authorisation on their behalf, in particular, as to the benefits of the donation to future recipients of the SoHO concerned.

Or. fr

Amendment 76

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

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

Or. fr

Amendment 77

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

Text proposed by the Commission	*Amendment*
(e) the analytical tests that will be performed in course of the donor health evaluation;	(e) the analytical tests that will be performed in course of the donor health evaluation ***and the purpose thereof***;

Or. fr

Amendment 78

Proposal for a regulation
Article 57 – paragraph 1

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

Or. fr

Amendment 79

Proposal for a regulation
Article 57 – paragraph 1 – point a (new)

Text proposed by the Commission	*Amendment*
	(a) identifying, minimising or eliminating those risks;

Or. fr

Amendment 80

Proposal for a regulation
Article 57 – paragraph 1 – point b (new)

Text proposed by the Commission	*Amendment*
	(b) ensuring compliance with the voluntary and unpaid nature of donations of substances of human origin in accordance with Article 54.

Or. fr

Amendment 81

Proposal for a regulation
Article 58 – paragraph 1

Text proposed by the Commission	*Amendment*
1. SoHO entities shall establish procedures with measures, and, where necessary, combinations of measures, that ensure high levels of safety and quality and demonstrate benefits for SoHO recipients and offspring from medically assisted reproduction that outweigh any risks. They shall, in particular, achieve a high level of assurance that pathogens, toxins or genetic conditions are not transmitted to recipients or offspring from medically assisted reproduction.	1. SoHO entities shall establish procedures with measures, and, where necessary, combinations of measures, that ensure high levels of safety and quality and demonstrate benefits for SoHO recipients and offspring from medically assisted reproduction that outweigh any risks. They shall, in particular, achieve a high level of assurance that pathogens, toxins or genetic conditions are not transmitted to recipients or offspring from medically assisted reproduction. ***Where possible, they shall use technologies designed to reduce the risk of human error and improve the quality of substances of human origin.***

Or. fr

Amendment 82

Proposal for a regulation
Article 58 – paragraph 5 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) where appropriate, specifying and using technologies for detecting and deactivating pathogens affecting SoHOs.

Or. fr

Amendment 83

Proposal for a regulation
Article 58 – paragraph 7 – point a

Text proposed by the Commission	*Amendment*
(a) conducting comprehensive process validation and equipment qualification as referred to in Article 41(2), point (a)(vii);	(a) conducting comprehensive process validation and equipment qualification as referred to in Article 41(2), point (a)(vii)***, unless the equipment has already been***

assessed and carries EC certification as provided for in Regulations (EU) 2017/746[1a] and (EU) 2017/745;

_____

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

Or. fr

Amendment 84

Proposal for a regulation
Article 58 – paragraph 8 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) when feasible, using processing technologies that reduce or eliminate any possible immune or infection risk to the recipient.

Or. fr

Amendment 85

Proposal for a regulation
Article 58 – paragraph 10 – point b

Text proposed by the Commission	*Amendment*
(b) apply SoHO preparations to recipients unnecessarily;	(b) apply SoHO preparations to recipients unnecessarily ***based on widespread patient blood management practices***;

Or. fr

Amendment 86

Proposal for a regulation
Article 58 – paragraph 11 – subparagraph 2

Text proposed by the Commission	*Amendment*
For donors that donate repeatedly, the interviews referred to in the first subparagraph may be limited to aspects that might have changed and may be replaced with questionnaires.	For donors that donate repeatedly, the interviews referred to in the first subparagraph may be limited to aspects that might have changed and may be replaced with questionnaires***, without prejudice to Article 53(1)(e) and (f) and 53(2).***

Or. fr

Amendment 87

Proposal for a regulation
Article 61 – paragraph 1

Text proposed by the Commission	*Amendment*
The physician referred to in Article 51 may authorise the responsible person for release of SoHOs pursuant to Article 38***, to*** release a certain SoHO preparation for application to a certain recipient in cases where that SoHO preparation does not meet all of the relevant standards and guidelines referred to in Article 59, when the significant potential benefit for the recipient outweighs the risks and no alternative is available. ***The physician*** shall authorise such an exceptional release only when the physician treating the intended recipient is in agreement. ***The physician referred to in Article 51*** shall document the decision process in a risk-benefit assessment. In such circumstances, the intended recipient shall be informed of the exceptional release and shall give consent in accordance with national legislation prior to the SoHO application.	The responsible person for release of SoHOs pursuant to Article 38 ***may*** release a certain SoHO preparation for application to a certain recipient in cases where that SoHO preparation does not meet all of the relevant standards and guidelines referred to in Article 59, when the significant potential benefit for the recipient outweighs the risks and no alternative is available. ***The responsible person*** shall authorise such an exceptional release only when the physician treating the intended recipient is in agreement. ***The responsible person*** shall document the decision process in a risk-benefit assessment. In such circumstances, the intended recipient shall be informed of the exceptional release and shall give consent in accordance with national legislation prior to the SoHO application.

Or. fr

Justification

Under this article, the physician treating the recipient bears the responsibility for exceptional release. It appears disproportionate to involve two physicians and a responsible person, especially as the responsible person and the physician referred to in Article 51 could be the same person.

Amendment 88

Proposal for a regulation
Article 62 – paragraph 1

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

Or. fr

Justification

Although it is necessary for the safety of recipients that this regulation apply to all uses of SoHOs (therapeutic, aesthetic, nutritional...), it may be necessary to establish priorities in case of supply problems.

Amendment 89

Proposal for a regulation
Article 62 – paragraph 2

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

doing***, they shall encourage the collection of SoHO with a strong public and non-profit sector involvement.***	doing***:***

Or. fr

Amendment 90

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

Text proposed by the Commission	*Amendment*
	(a) they shall encourage the collection of SoHO with a strong public and non-profit sector involvement;

Or. fr

Amendment 91

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

Text proposed by the Commission	*Amendment*
	(b) they shall endeavour to implement the measures recommended in the European strategy for promoting the donation of substances of human origin in accordance with Article 62a.

Or. fr

Amendment 92

Proposal for a regulation
Article 62 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) potential risks to the supply of critical SoHOs;	(a) potential risks to the supply of critical SoHOs, ***in particular as regards***

	the resilience of the donor base in a crisis situation;

Or. fr

Amendment 93

Proposal for a regulation
Article 62 – paragraph 3 – point e

Text proposed by the Commission	*Amendment*
(e) a procedure for the development of preparedness plans for specific identified risks, in particular those concerning communicable disease outbreaks;	(e) a procedure for the development of preparedness plans for specific identified risks, in particular those concerning communicable disease outbreaks***, in order in particular to ensure pandemic prevention and preparedness***;

Or. fr

Amendment 94

Proposal for a regulation
Article 62 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Member States shall take into account the guidance of the ECDC, for emergencies related to epidemiological outbreaks, and of the guidelines published by the EDQM, for emergency planning in general.	5. Member States shall take into account the guidance of the ECDC, for emergencies related to epidemiological outbreaks, ***in order in particular to ensure pandemic prevention and preparedness,*** and of the guidelines published by the EDQM, for emergency planning in general.

Or. fr

Amendment 95

Proposal for a regulation
Article 62 – paragraph 6

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

Or. fr

Amendment 96

Proposal for a regulation
Article 62 a (new)

Text proposed by the Commission	*Amendment*
	Article 62a
	Development of a strategy for the promotion of European SoHO supply self-sufficiency
	1. Within two years after adoption of this Regulation, the Commission shall publish a strategy for the promotion of European SoHO supply self-sufficiency. That strategy shall set ambitious targets for each SoHO, laid down by the Commission in coordination with national competent authorities, the European Parliament, scientists from professional associations and patient associations, as well as all other relevant stakeholders. Without prejudice to Articles 53 and 54, and in particular the principle of voluntary and unpaid donation, it shall promote action to:
	(a) publicise at European level the various types of SoHO donations that are achievable;
	(b) introduce a European day given over to the donation of essential SoHOs;
	(c) encourage extending opening days and hours of SoHO collection entities and

establishments outside traditional working hours;

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

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

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

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

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

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

Or. fr

Justification

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

Amendment 97

Proposal for a regulation
Article 63 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Critical SoHO entities shall without undue delay launch a SoHO supply alert to their competent authorities in case of a significant interruption, indicating the underlying reason, the expected impact on patients and any mitigating actions taken including possible alternative supply channels if appropriate. Interruptions shall be considered significant when the application of critical SoHO is cancelled or postponed due to unavailability and this poses a serious risk to health.	1. Critical SoHO entities shall without undue delay launch a SoHO supply alert to their competent authorities in case of a significant interruption, indicating the underlying reason, the expected impact on patients and any mitigating actions taken including possible alternative supply channels if appropriate. Interruptions shall be considered significant when the application of critical SoHO is cancelled or postponed due to unavailability and this poses a serious risk to ***human*** health.

Or. fr

Amendment 98

Proposal for a regulation
Article 63 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) implement measures to mitigate the risks***, if and*** to the extent possible; and	(b) implement measures to mitigate the risks to the extent possible; and

Or. fr

Amendment 99

Proposal for a regulation
Article 63 – paragraph 3

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

Or. fr

Amendment 100

Proposal for a regulation
Article 64 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Competent authorities shall inform the SoHO National Authority of the emergency authorisation. The SoHO National Authority shall inform the Commission and the other Member States of any decision to permit the distribution or preparation for immediate application of SoHO preparations in accordance with paragraph 1***, in cases where such SoHO preparations might be distributed to other Member States***.	2. Competent authorities shall inform the SoHO National Authority of the emergency authorisation. The SoHO National Authority shall inform the Commission and the other Member States of any decision to permit the distribution or preparation for immediate application of SoHO preparations in accordance with paragraph 1.

Or. fr

Amendment 101

Proposal for a regulation
Article 65 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	In accordance with the Treaties, application of this Article shall be based on public-health protection grounds determined in proportion to risks in such a way as to minimise the effect on the free movement of goods and persons within the Union.

Or. fr

Amendment 102

Proposal for a regulation
Article 67 – paragraph 2

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

Or. fr

Amendment 103

Proposal for a regulation
Article 67 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Commission shall ensure the independence and impartiality of experts and observers invited to attend SoHO Coordination Board meetings.

Or. fr

Amendment 104

Proposal for a regulation
Article 67 – paragraph 6 – point i

Text proposed by the Commission	*Amendment*
(i) invitation of individuals, organisations, or public entities in the capacity of observers;	(i) invitation of individuals, ***private*** organisations ***or associations***, or public entities in the capacity of observers;

Or. fr

Amendment 105

Proposal for a regulation
Article 67 – paragraph 6 – point j a (new)

Text proposed by the Commission	*Amendment*
	(ja) publicity and transparency, as well as access to minutes of meetings;

Or. fr

Amendment 106

Proposal for a regulation
Article 68 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) preparing opinions at the request of competent authorities in accordance with Article 14(2) first sub-paragraph, on the regulatory status under this Regulation of a substance, product or activity and transmitting its opinions to the compendium;	(a) preparing opinions at the request of competent authorities in accordance with Article 14(2) first sub-paragraph, on the regulatory status under this Regulation of a substance, product or activity and transmitting its opinions to the compendium ***and to the authorities established in other relevant Union legislation referred to in Article 2(3), such as the EMA and the Medical Device Coordination Group (MDCG)***;

Or. fr

Amendment 107

Proposal for a regulation
Article 68 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) liaising for the exchange of experience and good practices, as relevant, with the EDQM and the ECDC regarding technical standards, ***and*** with the EMA on authorisations and supervisory activities concerning the implementation of the PMF certification pursuant to Directive 2003/63/EC, to support the harmonised implementation of standards and technical guidelines;	(e) liaising for the exchange of experience and good practices, as relevant, with the EDQM and the ECDC regarding technical standards, with the EMA on authorisations and supervisory activities concerning the implementation of the PMF certification pursuant to Directive 2003/63/EC***, and with the ECDC and HERA regarding prevention, preparedness and response in connection with serious cross-border threats to health pursuant to Regulation (EU) 2022/2371***[1a], to support the harmonised implementation of standards and technical guidelines;

[1a] 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 (OJ L 314, 6.12.2022, p. 26).

Or. fr

Amendment 108

Proposal for a regulation
Article 68 – paragraph 1 – point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) drawing up recommendations on modifications to preparations requiring fresh applications for authorisation in accordance with Articles 40 and 41.

Or. fr

Amendment 109

Proposal for a regulation
Article 71 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The Commission shall ensure that those guidelines reflect the interests of Member States and, where appropriate, may adopt implementing acts laying down standards in line with those interests.

Or. fr

Amendment 110

Proposal for a regulation
Article 73 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission shall make a summary of data of public interest and make it accessible to the public on the EU SoHO Platform in aggregated and anonymised formats. The EU SoHO Platform shall provide a channel for restricted exchange of information and data between competent authorities, ***and*** between SoHO entities and their respective competent authorities.	2. The Commission shall make a summary of data of public interest and make it accessible to the public on the EU SoHO Platform in aggregated and anonymised formats. The EU SoHO Platform shall provide a channel for restricted exchange of information and data between competent authorities, between SoHO entities and their respective competent authorities***, and between the various Union institutions, bodies, offices and agencies that are active on the coordination board established by this Regulation***.

Or. fr

Amendment 111

Proposal for a regulation
Article 73 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. In order in particular to prevent supply tensions and to ensure donor and recipient security, the Commission shall ensure that the EU SoHO Platform is interoperable with the other existing Union platforms, in particular the EMA's European Shortages Monitoring Platform established by Regulation (EU) 2022/123[1a].
	[1a] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).

Or. fr

Amendment 112

Proposal for a regulation
Article 73 – paragraph 5 b (new)

Text proposed by the Commission	*Amendment*
	5b. The Commission shall ensure that the EMA, ECDC and HERA have access to the SoHO Platform information falling within their respective remits, as laid down in Regulation (EU) 2022/123, Regulation (EU) 2022/2370[1a] and Commission Decision 2021/C 393.
	[1a] Regulation (EU) 2022/123 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (OJ L 314, 6.12.2022, p. 1).

Or. fr

Amendment 113

Proposal for a regulation
Article 74 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The EU SoHO platform shall also provide a secure environment for the exchange of information between competent authorities and the Commission, in particular in relation to SAO and ***rapid*** alerts. It shall also provide public access to information regarding the registration and authorisation status of SoHO entities and shall indicate the applicable guidelines to be followed to meet the technical standards laid down in Articles 56 and 59.	2. The EU SoHO platform shall also provide a secure environment for the exchange of information between competent authorities and the ***competent departments of the*** Commission, in particular in relation to SAO***, rapid alerts*** and ***SoHO supply*** alerts***, and between competent authorities and HERA, the EMA and the ECDC***. It shall also provide public access to information regarding the registration and authorisation status of SoHO entities and shall indicate the applicable guidelines to be followed to meet the technical standards laid down in Articles 56 and 59.

Or. fr

Amendment 114

Proposal for a regulation
Article 77 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The power to adopt delegated acts referred to in Articles 28(10), 42(3), 53(6), 58(15), 69(6), 73(4)***,*** and 76(8) shall be conferred on the Commission for an indeterminate period of time from … [OP please insert the date = date of entry into force of this Regulation].	2. The power to adopt delegated acts referred to in Articles 28(10), 42(3), 53(6), ***54(3)(c),*** 58(15), 69(6), 73(4) and 76(8) shall be conferred on the Commission for an indeterminate period of time from … [OP please insert the date = date of entry into force of this Regulation].

Or. fr

Amendment 115

Proposal for a regulation
Article 77 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The delegation of power referred to in Articles 28(10), 42(3), 53(6), 58(15), 69(6), 73(4), and 76(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in Articles 28(10), 42(3), 53(6), ***54(3)(c),*** 58(15), 69(6), 73(4), and 76(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Or. fr

Amendment 116

Proposal for a regulation
Article 87 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
Unless otherwise provided for in ***paragraph*** 2, it shall apply from … [OP please insert the date = two years after the date of entry into force of this Regulation].	Unless otherwise provided for in ***paragraphs 2 and*** 2***a***, it shall apply from … [OP please insert the date = two years after the date of entry into force of this Regulation].

Or. fr

Amendment 117

Proposal for a regulation
Article 87 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Article 62 shall apply from … [OP please insert the date = twelve months after the date of entry into force of this Regulation].

Or. fr

EXPLANATORY STATEMENT

Donations of substances of human origin (SoHOs) are used in a range of medical procedures that are essential to helping patients recover and people have children throughout the EU. As many as 25 million blood transfusions, 35 000 stem cell transplants and 1 million medically assisted reproduction cycles are carried out each year on our continent.

The European Commission's proposal is good and comes at just the right time. It will contribute to the overall target of building a strong Europe of Health that is able to offer EU citizens the best health security in the world and is prepared to tackle any future pandemics. More specifically, this proposal, repealing the Blood Directive (2002/98/EC) and Tissues and Cells Directive (2004/23/EC) and their implementing legislation, aims to:

- Ensure safety and quality for patients treated with SoHO therapies and fully protect them from avoidable risks linked to SoHOs;
- Ensure safety and quality for SoHO donors and for children born from donated eggs, sperm or embryos;
- Strengthen and allow for the harmonisation of oversight practices among Member States;
- Facilitate the development of innovative, safe and effective SoHO therapies;
- Improve the sector's resilience by reducing the risk of shortages.

SoHO therapies require special attention as there are ethical factors to consider and they rely on the charity of voluntary citizens. The main challenge is ensuring the availability of SoHOs for recipients while reducing to the maximum extent possible the risks for donors.
This is especially important for plasma, which is essential for the production of medicines to treat immune deficiencies, cancers and more. One third of EU plasma needs are currently imported from third countries where people are paid for donations, potentially inciting them to give more than a reasonable amount and damage their health.
The EU needs to put an end to this situation and build up its self-sufficiency while respecting the fundamental principle of voluntary and unpaid donation in line with Article 3 of the EU Charter of Fundamental Rights and the clause on the prohibition on making the human body a source of financial gain.

The current EU legislative framework, adopted 20 years ago, needs to be adapted to harmonise collection and distribution systems, which remain too nationally oriented.
By the Commission's own admission, there are shortcomings in the current legislation:

- Patients are not fully protected from avoidable risks because of outdated technical rules;
- Blood, tissues and cells donors and children born from donated eggs, sperm or embryos (offspring) are exposed to avoidable risks;
- Member States have different approaches to oversight, hampering cross-border exchanges of blood, tissues and cells.

There is a need for greater coordination on many levels. Among other things, it would allow for SoHOs to be transported to patients living in countries without or with low quantities of the required donations, alerts to be sounded about outbreaks of communicable diseases, and the Member States' regulatory frameworks for a given SoHO to be aligned.

This last point is crucial: if we want to be able to develop SoHO-based therapies in Europe, the same SoHO cannot be considered a medicinal product in one Member State, an advanced therapy in another and a medical device in another still.

With this in mind, the following measures are recommended to complement the Commission's proposal:

Harmonisation of national systems to facilitate cross-border exchanges:

- Make more systematic use of the SoHO Coordination Board and EU SoHO platform established in this regulation to optimise the exchange of information between national and EU authorities;
- Limit the risk of a given SoHO being subject to different legislative frameworks in the Member States by providing more incentive for Member States to comply with the opinions of the Coordination Board and by strengthening cooperation with equivalent advisory bodies established in other relevant EU legislation, such as the European Medicines Agency (EMA) and Medical Device Coordination Group (MDCG);
- Ensure that any Member State that decides to apply stricter measures regularly reassesses its stance and does not use these measures to restrict intra-EU exchanges of SoHOs.

Protection of donors and recipients through the highest quality and safety standards:

- Harmonise the implementation of the principle of voluntary and unpaid donation, with a view in particular to stopping differences in national rules from encouraging citizens to donate in other countries than their own for financial reasons;
- Make greater efforts to harmonise donation frequency rules between the Member States by giving the European Commission the power to adopt delegated acts on this specific matter;
- Promote the use of the most innovative technologies to mitigate the risk of human error and improve the quality of SoHOs;
- Strengthen respect for the principles of impartiality, independence and transparency in oversight activities to protect the competent authorities from undue interference and influence;
- Create a legislative framework that fosters coordination among Commission services, EU agencies and competent authorities on serious adverse events to prepare, prevent and respond to outbreaks of communicable diseases via SoHOs.

Building-up of EU SoHO supply self-sufficiency:

- Adopt a proper strategy for promoting EU self-sufficiency that sets ambitious collection targets and assesses how this can be achieved (communication, establishment of a European day dedicated to essential SoHO donations, better management of available SoHO stocks, etc.);
- Develop the practice of patient blood management to optimise the use of SoHOs while promoting less invasive treatment alternatives for patients;
- Prioritise therapeutic uses of SoHOs in the event of EU supply shortages in the national SoHO emergency plans.