AMENDMENTS 001-240
by the Committee on the Environment, Public Health and Food Safety

Report
Nathalie Colin-Oesterlé **A9-0250/2023**
Standards of quality and safety for substances of human origin intended for human application

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

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 ***quality and safety*** standards by ensuring, amongst others, the protection of SoHO donors, taking into consideration their fundamental role in the provision of SoHOs and for recipients, as well as measures to monitor and support the sufficiency of the supply of SoHOs that are critical for the health of patients. ***In accordance with Article 3 of the Charter of Fundamental Rights of the European Union, those safety standards should be based on the fundamental principle that the human body or its parts cannot be a source of financial gain.***

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 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.	(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 ***and the 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.
[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).	[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	[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).	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).

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

Amendment 4

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(9) All SoHOs that are intended to be applied to humans fall within the scope of this Regulation. SoHOs can be prepared and stored in a variety of ways**,** becoming SoHO preparations, which can be applied to recipients. In these circumstances, this	(9) All SoHOs that are intended to be applied to humans fall within the scope of this Regulation. ***Articles 53, 54, 55 and 56 of this Regulation should apply also to SoHO donations intended for research.*** SoHOs can be prepared and stored in a

Regulation should apply to all activities from donor recruitment to human application and outcome monitoring. SoHOs or SoHO preparations can also be used to manufacture products regulated by other Union legislation, or as the starting and raw material thereof, in particular on medical devices, regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council[19] , on medicinal products, regulated by Directive 2001/83/EC of the European Parliament and of the Council[20] and by Regulation (EC) No 726/2004 of the European Parliament and of the Council[21] , including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007 of the European Parliament and of the Council[22] , or on food, regulated by Regulation (EC) No 1925/2006 of the European Parliament and of the Council[23] . The criteria that define when SoHOs or SOHO preparations become products regulated under other Union legislation are not defined in this Regulation but are defined in those other acts. In addition, this Regulation should apply without prejudice to Union legislation on genetically modified organisms.

variety of ways becoming SoHO preparations, which can be applied to recipients. In these circumstances, this Regulation should apply to all activities from donor recruitment to human application and outcome monitoring. SoHOs or SoHO preparations can also be used to manufacture products regulated by other Union legislation, or as the starting and raw material thereof, in particular on medical devices, regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council[19], on medicinal products, regulated by Directive 2001/83/EC of the European Parliament and of the Council[20]and by Regulation (EC) No 726/2004 of the European Parliament and of the Council[21], including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007 of the European Parliament and of the Council[22], or on food, regulated by Regulation (EC) No 1925/2006 of the European Parliament and of the Council[23]. The criteria that define when SoHOs or SOHO preparations become products regulated under other Union legislation are not defined in this Regulation but are defined in those other acts. In addition, this Regulation should apply without prejudice to Union legislation on genetically modified organisms.

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

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

[21] Regulation (EC) No 726/2004 of the European Parliament and of the Council of

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

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

[21] Regulation (EC) No 726/2004 of the European Parliament and of the Council of

31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

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

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

31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

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

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

Amendment 5

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	(10) When SoHOs are used in the autologous setting without any manipulation, processing or storage, the application of this Regulation would not be proportionate to the limited quality and safety risks arising in such a setting. ***Furthermore, this Regulation should not apply where the handling of SoHOs occurs during a surgical intervention within a sterile field or within a closed-system medical device.*** 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

appear. Thus, the requirements for SoHO establishment authorisation should apply.	processed and also stored, risks of cross-contamination, ***contamination of medical personnel or environmental contamination,*** loss of traceability or damage to the biological properties inherent to the substance, and necessary for efficacy ***or functionality*** in the recipient, also appear. Thus, the requirements for SoHO establishment authorisation should apply.

Amendment 6

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 ***and Regulation (EU) No 536/2014 of the European Parliament and of the Council***[1a], 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.

[1a] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

Amendment 7

Proposal for a regulation
Recital 13

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

Amendment 8

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 donation***. Member States should notify the Commission ***as soon as possible after their introduction so that the other Member States can be informed accordingly, via the EU SoHO Platform,*** 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 ***based on scientific evidence and*** the means of achieving that aim are appropriate and necessary. ***In order to prevent any discrimination, it is appropriate to require that Member States report to the Commission any such measures that could constitute discrimination, in particular as several Member States have implemented restrictions against men who have sex with men in blood donation procedures. Member States should therefore replace donor eligibility criteria based on sexual orientation or gender identity with individual risk-based screening criteria for all donors, regardless of their gender or sexual orientation.***

Amendment 9

Proposal for a regulation
Recital 16

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

Amendment 10

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) This Regulation is not meant to cover research using SoHOs when that research	(17) This Regulation is not meant to cover research using SoHOs when that research

does not involve application to the human body, for example in vitro research or research in animals. However, human substances used in research involving studies where they are applied to the human body should comply with the rules laid down in this Regulation.

does not involve application to the human body, for example in vitro research or research in animals***, except provisions regarding donor protection***. However, human substances used in research involving studies where they are applied to the human body should comply with the rules laid down in this Regulation.

Amendment 11

Proposal for a regulation
Recital 18

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

	to their own health and to that of prospective recipients. ***Compensation and reimbursement should under no circumstances serve an incentive to recruit donors, should not expose vulnerable persons in society to exploitation and should not lead to competition among SoHO entities for the recruitment of donors.*** Such compensation should, therefore, be ***based on quantifiable criteria, for example. time given for the donation or proven expenses, and transparent criteria*** set by national authorities, at a level ***justified and*** appropriate in their Member State to ***respect the principle of financial neutrality***. ***Recruitment campaigns and advertisements should not refer to any compensation, in order to avoid risks to the health of donors or to that of prospective donors.***
[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.

Amendment 12

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) In order to maintain public trust in SoHO donation and use programmes, information that is given to prospective donors, recipients or physicians regarding the likely use and benefits of particular SoHOs or SoHO preparations when applied to recipients should accurately reflect reliable scientific evidence. This	(19) In order to maintain public trust in SoHO donation and use programmes, information that is given to prospective donors, recipients or physicians regarding the likely use and benefits of particular SoHOs or SoHO preparations when applied to recipients should accurately reflect reliable scientific evidence ***and***

should ensure that donors, or their families, are not coerced to donate by exaggerated descriptions of benefits and prospective ***patients*** are not given false hopes when making decisions on their options for treatment. The verification of compliance with this Regulation through supervisory activities is of fundamental importance to ensure that, across the Union, the objectives of the Regulation are effectively achieved. The responsibility to enforce this Regulation lies with the Member States, whose competent authorities should monitor and verify, through the organisation of supervisory activities, that relevant Union requirements are effectively complied with and enforced.	***under no circumstances attribute or imply levels of safety or efficacy that are not supported by scientific methods***. This should ensure that donors, or their families, are not coerced to donate by exaggerated descriptions of benefits and prospective ***recipients*** are not given false hopes when making decisions on their options for treatment. The verification of compliance with this Regulation through supervisory activities is of fundamental importance to ensure that, across the Union, the objectives of the Regulation are effectively achieved. The responsibility to enforce this Regulation lies with the Member States, whose competent authorities should monitor and verify, through the organisation of supervisory activities, that relevant Union requirements are effectively complied with and enforced.

Amendment 13

Proposal for a regulation
Recital 20

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

Amendment 14

Proposal for a regulation
Recital 21

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

Amendment 15

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	(24) When there is doubt about the regulatory status of a particular substance, product or activity under this Regulation, competent authorities should consult the relevant authorities responsible for other relevant regulatory frameworks, namely medicinal products, ***advanced therapies,*** medical devices, organs or food***, and the SoHO Coordination Board (SCB)***, with the aim of ensuring coherent procedures for the application of this Regulation ***and other relevant Union legislation***. Competent authorities should inform the ***SCB*** 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

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.

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 SCB's opinion*** on the regulatory status of ***substances***. 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 ***or the SCB***, decide on the regulatory status of a particular substance, product or activity under this Regulation.

Amendment 16

Proposal for a regulation
Recital 26

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

manner.	out their professional duties in an impartial manner.

Amendment 17

Proposal for a regulation
Recital 27

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

Amendment 18

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) With regard to SoHO preparations that pose a certain level of risk (low, moderate or high), the applicant should propose a plan for clinical outcome monitoring that should fulfil different requirements appropriate to the risk indicated. The most up-to-date guidance of the European Directorate for the Quality of Medicines & HealthCare (EDQM, a Directorate of the Council of Europe) should be considered relevant in the design of clinical follow-up studies proportionate in extent and complexity to the identified level of risk of the SoHO preparation. In the case of low risk, in addition to the mandatory continuous vigilance reporting, the applicant should organise proactive clinical follow-up for a defined number of patients. For moderate and high risk, in addition to the mandatory vigilance reporting and the clinical follow-up, the applicant should propose clinical investigation studies with monitoring of pre-defined clinical end-points. In case of high risk, these should include a comparison with standard treatments, ideally in a study with subjects allocated to test and control groups in a randomised manner. The competent authority should approve the plans before they are implemented and should assess the outcome data as part of a SoHO preparation authorisation.	(28) ***Applicants requesting authorisation for a SoHO preparation should use the Euro GTP II methodologies or equivalent tools to assess the risk level of their SoHO preparation. Applicants should share the results of the risk assessments with competent authorities when requesting authorisation.*** With regard to SoHO preparations that pose a certain level of risk (low, moderate or high), the applicant should propose a plan for clinical outcome monitoring that should fulfil different requirements appropriate to the risk indicated. The most up-to-date guidance of the European Directorate for the Quality of Medicines & HealthCare (EDQM, a Directorate of the Council of Europe) should be considered relevant in the design of clinical follow-up studies proportionate in extent and complexity to the identified level of risk of the SoHO preparation. In the case of low risk, in addition to the mandatory continuous vigilance reporting, the applicant should organise proactive clinical follow-up for a defined number of patients. For moderate and high risk, in addition to the mandatory vigilance reporting and the clinical follow-up, the applicant should propose clinical investigation studies with monitoring of pre-defined clinical end-points. In case of high risk, these should include a comparison with standard treatments, ideally in a study with subjects allocated to test and control groups in a randomised manner***, pursuant to Regulation (EU) No 536/2014. Where the standard treatment or control group is based on medicinal products, the studies should be considered to be clinical trials as defined in and regulated by Regulation (EU) No 536/2014***. The competent authority should approve the plans before they are implemented and should assess the outcome data as part of a SoHO

preparation authorisation.

Amendment 19

Proposal for a regulation
Recital 28 a (new)

Text proposed by the Commission	*Amendment*
	(28a) SoHO entities should request approval for SoHO clinical studies from the competent authorities, both in the context of the authorisation process of a new SoHO treatment or when comparing previously authorised treatments. In SoHO clinical studies, patients' rights, safety, dignity and well-being should always be the priority and the clinical study should be designed in a way that leads to reliable and robust data and conclusions.

Amendment 20

Proposal for a regulation
Recital 29

Text proposed by the Commission	*Amendment*
(29) In the interests of efficiency, it should be permitted to conduct clinical ***outcome*** studies using the established framework in the pharmaceutical sector for clinical trials, as set out in Regulation (EU) No 536/2014 of the European Parliament and of the Council[25] , when operators wish to do so. Whilst applicants can choose to record the clinical data generated during the clinical ***outcome monitoring*** themselves, they should also be permitted to use existing clinical data registries as a means of such recording when those registries have been verified by the competent authority, or are certified by an external institution, in terms of the	(29) In the interests of efficiency, it should be permitted to conduct clinical studies using the established framework in the pharmaceutical sector for clinical trials, as set out in Regulation (EU) No 536/2014 of the European Parliament and of the Council[25], when operators wish to do so***. The commitment to publish the clinical results obtained should be a requirement for SoHO clinical studies***. Whilst applicants can choose to record the clinical data generated during the clinical ***studies*** themselves, they should also be permitted to use existing clinical data registries as a means of such recording when those registries have been verified by the

reliability of their data management procedures.	competent authority, or are certified by an external institution, in terms of the reliability of their data management procedures. ***The existence of a registry of SoHO clinical studies at Union level is critical to facilitate patient participation in clinical studies, to boost multi-centre studies and to foster collaboration to generate more robust results and conclusions, and to make such generated knowledge available to other researchers, healthcare professionals, participants themselves and the general public.***
[25] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).	[25] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

Amendment 21

Proposal for a regulation
Recital 30

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

Amendment 22

Proposal for a regulation
Recital 32

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

Amendment 23

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) With regards to standards concerning donor, recipient and offspring protection, this Regulation should provide for a hierarchy of rules for their implementation. As risks and technologies change, this hierarchy of rules should facilitate an efficient and responsive uptake of the most	(33) With regards to standards concerning donor, recipient and offspring protection, this Regulation should provide for a hierarchy of rules for their implementation. As risks and technologies change, this hierarchy of rules should facilitate an efficient and responsive uptake of the most

up-to-date guidelines for implementing the standards set out in this Regulation. As part of that hierarchy, in the absence of Union legislation describing particular procedures to be applied and followed to meet the standards set out in this Regulation, following the guidelines of the European Centre for Disease Prevention and Control (ECDC) and the EDQM should be considered as a means to demonstrate compliance with the standards laid down in this Regulation ***to ensure high*** level of quality, safety and efficacy. SoHO entities should be permitted to follow other guidelines, provided that it has been demonstrated that those other guidelines achieve the same level of quality, safety and efficacy. In cases of detailed technical issues for which neither Union legislation nor the ECDC and the EDQM have defined a technical guideline or rule, operators should apply a locally defined rule that is in line with relevant internationally recognised guidelines and scientific evidence and is appropriate to mitigate any risk identified.	up-to-date guidelines ***based on scientific evidence*** for implementing the standards set out in this Regulation. As part of that hierarchy, in the absence of Union legislation describing particular procedures to be applied and followed to meet the standards set out in this Regulation, following the guidelines of the European Centre for Disease Prevention and Control (ECDC) and the EDQM should be considered as a means to demonstrate compliance with the standards laid down in this Regulation***. Member States should be able to decide that SoHO entities should be permitted to follow other recognised guidelines, provided that such guidelines are based on the most up-to-date scientific evidence and achieve the same*** level of quality, safety and efficacy***. Member States should be involved in both the drafting of and voting on those guidelines and should follow a transparent process of consultation with other relevant Union authorities and stakeholders***. SoHO entities should be permitted to follow other guidelines, provided that it has been demonstrated that those other guidelines ***are based on the most up-to-date scientific evidence and*** achieve the same level of quality, safety and efficacy. In cases of detailed technical issues for which neither Union legislation nor the ECDC and the EDQM have defined a technical guideline or rule, operators should apply a locally defined rule that is in line with relevant internationally recognised guidelines and scientific evidence and is appropriate to mitigate any risk identified. ***When assessing scientific guidelines, it is important that the Commission, the ECDC, and the EDQM involve existing scientific, donor and patient representative groups.***

Amendment 24

Proposal for a regulation

Recital 35

Text proposed by the Commission	*Amendment*
(35) The EDQM is a structural part of the Council of Europe working under the European Pharmacopoeia Partial Agreement. The text of the Convention on the elaboration of a European Pharmacopoeia (ETS No. 050), accepted by Council Decision 94/358/EC[26] , is considered to be the text of the European Pharmacopoeia Partial Agreement. Member States of the Council of Europe that have signed and ratified the European Pharmacopoeia Convention are ***the*** member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental bodies functioning within the framework of this partial agreement, including among others: the European Pharmacopoeia Commission, the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The European Pharmacopoeia Convention has been signed and ratified by the European Union and all its Member States, all of whom are represented in their intergovernmental bodies. In this context, the work of the EDQM on developing and updating guidelines on safety and quality of blood, tissues and cells, should be considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance of safety and quality during collection, processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means to implement the technical standards provided	(35) The EDQM is a structural part of the Council of Europe working under the European Pharmacopoeia Partial Agreement. The text of the Convention on the elaboration of a European Pharmacopoeia (ETS No. 050), accepted by Council Decision 94/358/EC[26], is considered to be the text of the European Pharmacopoeia Partial Agreement. Member States of the Council of Europe that have signed and ratified the European Pharmacopoeia Convention are ***also*** member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental bodies functioning within the framework of this partial agreement, including among others: the European Pharmacopoeia Commission, the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The European Pharmacopoeia Convention has been signed and ratified by the European Union and all its Member States, all of whom are represented in their intergovernmental bodies. In this context, the work of the EDQM on developing and updating guidelines on safety and quality of blood, tissues and cells, should be considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation***, without prejudice to the Union's legal autonomy***. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance of safety and quality during collection, processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means

for in this Regulation.

to implement the technical standards provided for in this Regulation. ***The Commission should also establish a memorandum of understanding with the EDQM related to transparency of membership and of outputs, and conflict of interest rules for experts and stakeholders involved in drafting EDQM guidelines. Such cooperation should be without prejudice to the autonomy of Union law and should take into account Union principles on transparency and stakeholder participation.***

[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).

Amendment 25

Proposal for a regulation
Recital 36

Text proposed by the Commission

(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)

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***,*** quality ***and sustainability*** 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

No 851/2004, regarding strategic and operational collaboration on technical and scientific issues, surveillance, responses to health threats, scientific opinions, scientific and technical assistance, collection of data, identification of emerging health threats, and public information campaigns related to the safety of SoHOs. This SoHO expert network should provide information or advice in relation to relevant outbreaks of communicable diseases, in particular regarding the eligibility and testing of donors and the investigation of serious adverse occurrences involving suspected transmission of a communicable disease.

Member States stated in Regulation (EC) No 851/2004, regarding ***transparent*** strategic and operational collaboration on technical and scientific issues, surveillance, responses to health threats, scientific opinions, scientific and 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 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).

Amendment 26

Proposal for a regulation
Recital 37

Text proposed by the Commission

(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

Amendment

(37) It is necessary ***and beneficial to all parties*** to promote information and awareness campaigns at national and Union level on the importance of SoHOs. The aim of these campaigns should be to ***ensure the broadest possible donor base, with a view to ensuring a more resilient supply system, and*** 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 ***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.	***equal access to*** SoHOs for medical treatments, Member States ***and the Union*** should ***support the establishment of public donation facilities and*** promote the ***voluntary and unpaid*** donation of SoHOs of high quality and safety ***with a view to*** increasing ***the collection capacity and autonomy*** in the Union. Member States are also urged to take steps to encourage a strong ***involvement of all relevant sectors, in particular the*** public and non-profit sector***,*** in the provision of SoHO services, in particular for critical SoHOs and the related research and development.

Amendment 27

Proposal for a regulation
Recital 37 a (new)

Text proposed by the Commission	*Amendment*
	(37a) The COVID-19 pandemic can be considered one of the biggest health crises to affect Europe. It 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. This crisis highlighted the vulnerabilities of the Union in very different aspects, ranging from the lack of coordination between Member States, which is essential to addressing such situations, to the Union's strong dependence on third countries for the production and supply of raw materials and active substances needed for the elaboration of medical treatments. In the case of SoHOs, the pandemic drastically reduced the number of donors and exports from third countries, putting the Union in a situation of shortages of some SoHOs and patients at serious risk due to a lack of adequate treatments. In this context, the initiatives for a strong European Health Union should work in favour of European autonomy, in

particular as regards the supply of SoHOs and the ability to minimise the risk of shortages, especially of SoHOs for therapeutic use. The lessons learned and the resulting measures taken at Union level should serve as a reference for the prevention, detection and resolution of future health crises. Regulation (EU) 2022/2371 of the European Parliament and of the Council[1a] lays down the guidelines to be followed for that purpose. To increase European autonomy in terms of SoHOs, Member States should be urged to increase their collection capacity and donor base for critical SoHOs, in particular plasma, by developing non-profit and public plasmapheresis programmes.

[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).

Amendment 28

Proposal for a regulation
Recital 37 b (new)

Text proposed by the Commission	*Amendment*
	(37b) In order to ensure autonomy and sustainability of supply of SoHOs, Member States should establish national SoHO emergency and continuity of supply plans setting out measures for cases where the supply situation for critical SoHOs presents or is likely to present a serious risk to human health. Such plans should include measures, including optimisation of use, that impact demand for critical SoHOs, targets to ensure autonomy of supply of critical SoHOs, donor recruitment and retainment

strategies and arrangements for cooperation between competent authorities, experts and relevant stakeholders. National SoHO emergency and continuity of supply plans should be further supplemented by the strategy for the promotion of European autonomy in terms of SoHO supply and the SoHO entity emergency and continuity of supply plans, primarily focusing on supply monitoring, reporting obligations and sharing of best practices within the Union. Moreover, Member States should be encouraged to establish certain areas, such as transfusion medicine, as an independent medical subject with structured training, including medical specialisation schools and programmes for continuous medical education for all medical staff. Providing training and better information for the prescribers would reduce the risk of unnecessary application of SoHOs. Furthermore, as recommended by the World Health Organization, Member States should additionally support optimal clinical use of SoHOs, in particular where there are alternatives which can reduce the demand for SoHOs. Member States would thus ensure efficient implementation of the Patient Blood Management (PBM) approach, which improves patients' safety by minimising the risks associated with transfusion, and improve patient outcomes, while at the same time ensuring sufficiency of blood supplies and reducing financial pressure on health systems.

Amendment 29

Proposal for a regulation
Recital 37 c (new)

Text proposed by the Commission	*Amendment*
	(37c) In cases where the availability of SoHO preparations or SoHO-derived

	products depends on potential commercial interests, such as some plasma-derived products, there is a risk of not having the interests of patients and research at the forefront. There could even be situations in which some products with low profitability are no longer produced, thereby hampering their accessibility for patients. Similarly, investment in research and innovation for this type of products could be very small or non-existent. Prices of SoHO-derived products, which are obtained from voluntary and unpaid donations, should be fair and transparent. For certain products with low profitability, Member States should encourage research and innovation and should ensure that such products continue to be manufactured.

Amendment 30

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	(38) In order to promote a coordinated ***and coherent*** 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

and the EDQM and existing professional, scientific and donor and patient representative groups at Union level in the field of SoHOs.	European expert ***agencies and*** bodies such as the ECDC and ***the European Medicines Agency (EMA). The European Parliament,*** the EDQM and existing professional, scientific ***experts*** and donor and ***recipient*** patient representative groups ***and stakeholders*** at Union level in the field of SoHOs ***could also be invited***. ***Other Union institutions, including the European Parliament, expert bodies, offices and agencies such as the EMA, ECDC and the EDQM, should have an observer role. All members of the SCB should provide declarations of interest, adhering to a high degree of transparency concerning its outputs. Members of the SCB, observers and experts should act independently, in the public interest and be free from any external influence that might affect the impartiality of their professional conduct.***

Amendment 31

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) Some substances, products or activities have been subject to different legal frameworks with different requirements in the Member States. This ***causes*** confusion among operators in the field, and the consequent legal uncertainty ***is*** a disincentive to professionals to develop new ways to prepare and use SoHOs. The SCB should receive relevant information on national decisions made on cases where questions were raised on the regulatory status of SoHOs. The SCB should keep a compendium of the opinions issued by the SCB or the competent authorities and of decisions made at Member State level, so that competent authorities considering the regulatory status under this Regulation of a particular substance, product or activity	(39) Some substances, products or activities have been subject to different legal frameworks with different requirements in the Member States. This ***can sometimes cause*** confusion among operators in the field, and the consequent legal uncertainty ***can be*** a disincentive to professionals to develop new ways to prepare and use SoHOs. The SCB should receive ***on an ongoing basis*** relevant information on national decisions made on cases where questions were raised on the regulatory status of SoHOs. The SCB should ***monitor those opinions in order to react quickly and in an informed manner to further requests for opinions from other Member States,*** keep a compendium of the opinions issued by the SCB or the

may inform their decision-making process by referring to that compendium. The SCB should also document agreed best practices to support a common Union approach. It should also cooperate with similar Union level bodies established in other Union legislation with a view to facilitating coordinated and coherent application of this Regulation between Member States and across bordering legislative frameworks. These measures should promote a coherent cross-sectoral approach and facilitate SoHO innovation.

competent authorities and of decisions made at Member State level, so that competent authorities considering the regulatory status under this Regulation of a particular substance, product or activity may inform their decision-making process by referring to that compendium. The SCB should also document agreed best practices to support a common Union approach. It should also cooperate with similar Union level bodies established in other Union legislation with a view to facilitating coordinated and coherent application of this Regulation between Member States and across bordering legislative frameworks. These measures should promote a coherent cross-sectoral approach***, ensure a high level of protection of public health,*** and facilitate SoHO innovation.

Amendment 32

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, to improve the*** transparency of national reporting and supervisory activities ***and ensure better communication, collaboration and coordination in relation to, and exchange of, SoHOs between Member States. The national competent authorities should be encouraged to use the EU SoHO Platform instead of maintaining national registers, in particular to limit the administrative burden. Member States should also be able to utilize the EU SoHO Platform as a***

	channel for national initiatives and campaigns to encourage the exchange of best practices. Such national initiatives and campaigns should be established in close cooperation with patient organisations, and aim to promote the need to maintain sustainable supplies of SoHO products. The EU SoHO Platform should also serve as a reliable source of information for the general public regarding the work of the SCB, national competent authorities and other expert bodies, including the EDQM, and SoHO entities and establishments. The online platform could be further used for the sharing of best practices between Member States with regard to initiatives, such as campaigns, to support the supply of SoHOs.

Amendment 33

Proposal for a regulation
Recital 43

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

Amendment 34

Proposal for a regulation
Recital 44

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

Amendment 35

Proposal for a regulation
Recital 44 a (new)

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

Amendment 36

Proposal for a regulation
Recital 45

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

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

Amendment 37

Proposal for a regulation
Recital 46

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

Amendment 38

Proposal for a regulation
Recital 47

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

Amendment 39

Proposal for a regulation
Recital 47 a (new)

Text proposed by the Commission	*Amendment*
	(47a) The objectives of this Regulation, namely to ensure that SoHOs are of high quality and safe and to provide a high level of protection for donors, need 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 those objectives. Member States in turn should enhance education and provide appropriate training for medical personnel regarding SoHO collection, processing, storage, application, transfusion and procurement.

Amendment 40

Proposal for a regulation
Recital 47 b (new)

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

Amendment 41

Proposal for a regulation
Article 1 – paragraph 1

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

reproduction. This Regulation is without prejudice to national legislation which establishes rules relating to aspects of SoHOs other than their quality and safety and the safety of SoHO donors.	reproduction ***and serves to strengthen the continuity of supply of SoHOs***. 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***, SoHO recipients and offspring from medically assisted reproduction***.

Amendment 42

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

Text proposed by the Commission	*Amendment*
1. This Regulation shall apply to SoHOs intended for human application, to SoHO preparations, to products manufactured from SoHOs and intended for human application, to SoHO donors ***and*** recipients, and to the following SoHO activities:	1. This Regulation shall apply to SoHOs intended for human application, to SoHO preparations, to products manufactured from SoHOs and intended for human application, to SoHO donors***, SoHO*** recipients ***and offspring from medically assisted reproduction***, and to the following SoHO activities:

Amendment 43

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

Text proposed by the Commission	*Amendment*
(a) SoHO donor recruitment;	(a) SoHO donor recruitment***, except if that is the sole SoHO activity of the entity in which case only Article 54(3b) shall apply***;

Amendment 44

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

Text proposed by the Commission	*Amendment*

(ha) issuing of SoHOs;

Amendment 45

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

Text proposed by the Commission	*Amendment*
	(ma) SoHO clinical studies.

Amendment 46

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

Text proposed by the Commission	*Amendment*
	1a. Articles 53, 54, 55 and 56 shall apply also to SoHO donations intended for research.

Amendment 47

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

Text proposed by the Commission	*Amendment*
For SoHOs that are used to manufacture products in accordance with Union legislation on medical devices, regulated by Regulation (EU) 2017/745, on medicinal products, regulated by Regulation (EC) No 726/2004 and Directive 2001/83/EC, including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007, or on food, regulated by Regulation (EC) No 1925/2006, or as the starting and raw material thereof, the provisions of this Regulation applicable to the activities of SoHO donor recruitment, donor history review and eligibility	For SoHOs that are used to manufacture products in accordance with Union legislation on medical devices, regulated by Regulation (EU) 2017/745, on medicinal products, regulated by Regulation (EC) No 726/2004 and Directive 2001/83/EC, including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007, ***on investigational medicinal products regulated by Regulation (EU) No 536/2014,*** or on food, regulated by Regulation (EC) No 1925/2006, or as the starting and raw material thereof, the provisions of this Regulation applicable to

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.	the activities of SoHO donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, collection of SoHOs from donors or patients***, quality control testing of SoHOs, and the continuity of supply of SoHOs,*** 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.

Amendment 48

Proposal for a regulation
Article 2 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. This Regulation also establishes provisions on:
	(a) exchange of information on availability and stocks of SoHOs, and promotion of actions relating to the security of SoHO supply;
	(b) coordination between competent authorities and the Commission and Union agencies in the event of SoHO-related health emergencies.

Amendment 49

Proposal for a regulation
Article 2 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4b. This Regulation does not apply to breast milk that is expressed by a mother solely for the purpose of feeding her own child.

Amendment 50

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

Text proposed by the Commission	*Amendment*
(1) 'blood' means the liquid that circulates in arteries and veins carrying oxygen to and carbon dioxide from the tissues of the body;	(1) 'blood' means the liquid that circulates in arteries and veins carrying oxygen to and carbon dioxide from the tissues of the body ***and its constituent parts***;

Amendment 51

Proposal for a regulation
Article 3 – paragraph 1 – point 5

Text proposed by the Commission	*Amendment*
(5) 'substance of human origin' (SoHO) means any substance collected from the human body in whatever manner, whether it contains cells or not and whether those cells are living or not. For the purposes of this Regulation, SoHO does not include organs in the sense of Article 3, point (h), of Directive 2010/53/EU;	(5) 'substance of human origin' (SoHO) means any substance collected from the human body in whatever manner, whether it contains cells or not and whether those cells are living or not. For the purposes of this Regulation, SoHO does not include organs in the sense of Article 3, point (h), of Directive 2010/53/EU***, but includes substances which can be extracted from them***;

Amendment 52

Proposal for a regulation
Article 3 – paragraph 1 – point 7

Text proposed by the Commission	*Amendment*
(7) 'SoHO activity' means an action, or series of actions, that has a direct impact on the safety, quality ***or*** efficacy of SoHOs, as listed in Article 2(1);	(7) 'SoHO activity' means an action, or series of actions, that has a direct impact on the safety, quality***,*** efficacy ***or functionality*** of SoHOs, as listed in Article 2(1);

Amendment 53

Proposal for a regulation
Article 3 – paragraph 1 – point 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) 'SoHO donation' means a process by which a person voluntarily and altruistically gives SoHOs from their own body to people in need, or authorises their use after their death; it includes the necessary medical formalities, examination and treatments and monitoring of the SoHO donor, irrespective of whether that donation is successful or not; it also includes when consent is given by an authorised person in accordance with national legislation;

Amendment 54

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 ***a living or deceased SoHO donor***;

Amendment 55

Proposal for a regulation
Article 3 – paragraph 1 – point 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) 'living SoHO donor' means a living person who has presented themselves to a SoHO entity, or has been presented by a person granting consent on their behalf, in accordance with national legislation,

	with a view to making a SoHO donation, except donors of SoHOs for reproduction within relationship use;

Amendment 56

Proposal for a regulation
Article 3 – paragraph 1 – point 8 b (new)

Text proposed by the Commission	*Amendment*
	(8b) 'deceased SoHO donor' means a deceased person who has been referred to a SoHO entity and for whom consent or authorisation, or an absence of express refusal, to donation is in place, in accordance with national legislation;

Amendment 57

Proposal for a regulation
Article 3 – paragraph 1 – point 9

Text proposed by the Commission	*Amendment*
(9) 'SoHO recipient' means the person to whom SoHOs are applied;	(9) 'SoHO recipient' means the person to whom SoHOs are applied ***or for whom such an application is envisaged***;

Amendment 58

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***;

Amendment 59

Proposal for a regulation
Article 3 – paragraph 1 – point 11

Text proposed by the Commission	*Amendment*
(11) 'offspring from medically assisted reproduction' means ***fetuses and*** children that are born following medically assisted reproduction;	(11) 'offspring from medically assisted reproduction' means children that are born following medically assisted reproduction;

Amendment 60

Proposal for a regulation
Article 3 – paragraph 1 – point 11 a (new)

Text proposed by the Commission	*Amendment*
	(11a) 'unborn offspring from medically assisted reproduction' means embryos and foetuses conceived by medically assisted reproduction;

Amendment 61

Proposal for a regulation
Article 3 – paragraph 1 – point 12 – point a

Text proposed by the Commission	*Amendment*
(a) has been subjected to one or more SoHO activities***, including processing,*** in accordance with defined quality and safety parameters;	(a) has been subjected to ***processing and, where relevant,*** one or more ***other*** SoHO activities in accordance with defined quality and safety parameters;

Amendment 62

Proposal for a regulation
Article 3 – paragraph 1 – point 12 – point b

Text proposed by the Commission	*Amendment*
(b) meets a pre-defined specification; ***and***	(b) meets a pre-defined specification;

Amendment 63

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 SoHO donation or at*** encouraging ***them to donate SoHOs***;

Amendment 64

Proposal for a regulation
Article 3 – paragraph 1 – point 15

Text proposed by the Commission	*Amendment*
(15) 'processing' means any operation involved in the handling of SoHOs, including washing, shaping, separation, fertilisation, decontamination, sterilisation, preservation and packaging;	(15) 'processing' means any operation involved in the handling of SoHOs, including washing, shaping, separation, fertilisation, decontamination, sterilisation, preservation and packaging; ***it does not include the handling of SoHOs within the same sterile field during a surgical intervention or within a closed-system medical device, where those SoHOs are either released or for autologous application;***

Amendment 65

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***, issuing, export or human application***;

Amendment 66

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

Amendment 67

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 SoHO preparations, where relevant following a medical prescription, for application to a specific recipient;

Amendment 68

Proposal for a regulation
Article 3 – paragraph 1 – point 23

Text proposed by the Commission	*Amendment*
(23) 'autologous use' means collection of SoHO from one individual for ***subequent*** application to the same individual***, with or without further SoHO activities between***	(23) 'autologous use' means collection of SoHO from one individual for ***subsequent*** application to the same individual;

collection and application;

Amendment 69

Proposal for a regulation
Article 3 – paragraph 1 – point 27

Text proposed by the Commission	*Amendment*
(27) 'adverse occurrence' means any incident ***that*** caused harm to a living SoHO donor, harm to a SoHO recipient or to offspring from medically assisted reproduction or that implied a risk of such harm;	(27) 'adverse occurrence' means any incident ***associated with the donation or human application of SoHOs, which*** caused harm to a living SoHO donor, harm to a SoHO recipient***, to offspring from medically assisted reproduction*** or to ***unborn*** offspring from medically assisted reproduction or that implied a risk of such harm;

Amendment 70

Proposal for a regulation
Article 3 – paragraph 1 – point 28 – point h a (new)

Text proposed by the Commission	*Amendment*
	(ha) the transfer of embryos to a person other than the person intended;

Amendment 71

Proposal for a regulation
Article 3 – paragraph 1 – point 29

Text proposed by the Commission	*Amendment*
(29) 'SoHO rapid alert' means a communication regarding ***a SAO***, a communicable disease outbreak or other information that might be of relevance to the safety and quality of SoHOs in more than one Member State and is to be transmitted rapidly between competent authorities and the Commission to facilitate	(29) 'SoHO rapid alert' means a communication regarding ***an adverse occurrence***, a communicable disease outbreak or other information that might be of relevance to the safety and quality of SoHOs in more than one Member State and is to be transmitted rapidly between competent authorities and the Commission

the implementation of mitigating measures;	to facilitate the implementation of ***preventing or*** mitigating measures;

Amendment 72

Proposal for a regulation
Article 3 – paragraph 1 – point 33

Text proposed by the Commission	*Amendment*
(33) 'the compendium' means a list kept up-to-date by the SoHO Coordination Board of decisions, taken at Member State level, and opinions, issued by competent authorities and by the SCB, on the regulatory status of specific substances, products or activities and published on the EU SoHO platform;	(33) 'the compendium ***of SoHOs***' means a list kept up-to-date by the SoHO Coordination Board of decisions, taken at Member State level, and opinions, issued by competent authorities and by the SCB, on the regulatory status of specific substances, products or activities and published on the EU SoHO platform;

Amendment 73

Proposal for a regulation
Article 3 – paragraph 1 – point 38

Text proposed by the Commission	*Amendment*
(38) 'Union training' means activities for the personnel of competent authorities and, where appropriate, for personnel of delegated bodies performing SoHO supervisory activities;	(38) 'Union training' means ***training*** activities for the personnel of competent authorities and, where appropriate, for personnel of delegated bodies performing SoHO supervisory activities;

Amendment 74

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

Text proposed by the Commission	*Amendment*
(40) 'SoHO establishment' means a SoHO entity that carries out ***both*** processing and storage of SoHOs;	(40) 'SoHO establishment' means a SoHO entity that carries out processing and storage ***or processing and release or storage and release*** of SoHOs;

Amendment 75

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 ***SoHO recipients***;

Amendment 76

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 ***SoHO recipients***;

Amendment 77

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:

Amendment 78

Proposal for a regulation
Article 3 – paragraph 1 – point 51

Text proposed by the Commission	*Amendment*
(51) 'imputability' means the likelihood that ***a serious*** adverse occurrence, in a SoHO donor, is related to the ***donation*** process or, in a recipient, to the application of the SoHOs;	(51) 'imputability' means the likelihood that ***an*** adverse occurrence, in a SoHO donor, is related to the ***collection*** process or, in a ***SoHO*** recipient ***or offspring from medically assisted reproduction***, to the application of the SoHOs;

Amendment 79

Proposal for a regulation
Article 3 – paragraph 1 – point 60

Text proposed by the Commission	*Amendment*
(60) 'Annual SoHO Activity Report' means the annual report published by the Commission aggregating the data reports from SoHO entities carrying out the following activities: donor recruitment, collection, distribution, import, export and human application of SoHOs;	(60) 'Annual SoHO Activity Report' means the annual report published by the Commission aggregating the data reports from SoHO entities carrying out the following activities: donor recruitment, collection, ***storage,*** distribution, import, export and human application of SoHOs;

Amendment 80

Proposal for a regulation
Article 3 – paragraph 1 – point 61

Text proposed by the Commission	*Amendment*
(61) '***reproductive cells***' means all cells intended to be used for the purpose of medically assisted reproduction;	(61) '***SoHO for reproduction***' means all cells intended to be used for the purpose of medically assisted reproduction***, and embryos resulting from fertilisation***;

Amendment 81

Proposal for a regulation
Article 3 – paragraph 1 – point 62

Text proposed by the Commission	*Amendment*
(62) 'third party donation' means a donation of ***reproductive cells*** by a person to a ***person*** or a couple with whom the donor does not have an intimate physical relationship;	(62) 'third party donation' means a donation of ***a SoHO for reproduction*** by a person to a ***recipient*** or a couple with whom the donor does not have an intimate physical relationship;

Amendment 82

Proposal for a regulation
Article 3 – paragraph 1 – point 62 a (new)

Text proposed by the Commission	*Amendment*
	(62a) 'ID release' means the disclosure of information that permits the identification of donors of a SoHO for reproduction to donor-conceived offspring or their legal parents, as provided for in national legislation;

Amendment 83

Proposal for a regulation
Article 3 – paragraph 1 – point 63

Text proposed by the Commission	*Amendment*
(63) 'within ***couple*** use' means use of reproductive cells for medically assisted reproduction ***from two*** persons with an intimate physical relationship, where ***one*** person ***supplies*** their own oocytes and ***the other*** person supplies their own sperm;	(63) 'within ***relationship*** use' means use of reproductive cells for medically assisted reproduction ***between*** persons with an intimate physical relationship, where ***a*** person ***provides*** their own oocytes and ***another*** person supplies their own sperm ***for the human application to a person within the relationship;***

Amendment 84

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 ***and reimbursement of expenses*** associated with donation;

Amendment 85

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;

Amendment 86

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

Text proposed by the Commission	*Amendment*
	(70a) ‘donor base resilience’ means the capacity of the donation collection system to rely on a large number of donors for a given SoHO category;

Amendment 87

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

Text proposed by the Commission	*Amendment*
	(70b) ‘informed consent’ means that the donor’s agreement has been obtained freely without coercion and after the donor has been provided with access to clear, comprehensive information in line with the donor’s capacity to understand,

for SoHO donation or use;

Amendment 88

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

Text proposed by the Commission	*Amendment*
	(70c) 'SoHO clinical study' means an experimental evaluation of a SoHO or a SoHO preparation in humans, with the objective of drawing conclusions regarding its efficacy and safety;

Amendment 89

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

Text proposed by the Commission	*Amendment*
	(70d) 'European autonomy' means the Union's degree of independence from third countries in relation to the collection of SoHOs, the manufacture of SoHO preparations and any other SoHO activities.

Amendment 90

Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States may maintain or introduce within their territories measures that are more stringent than the ones provided for in this Regulation on condition that those national measures are compatible with Union law, and are proportionate to the risk to human health.	1. Member States may maintain or introduce within their territories measures that are more stringent than the ones provided for in this Regulation on condition that those national measures are ***based on scientific evidence, are*** compatible with Union law, and are

proportionate to the risk to human health.

Such measures:

(a) shall not directly or indirectly constitute discrimination between SoHO donors based on any of the grounds recognised by Article 21 of the Charter of Fundamental Rights of the European Union, in particular discrimination based on sexual orientation. Member States shall report to the Commission any restrictions that they or SoHO entities in their territory impose that can reasonably be considered to constitute such discrimination and provide a summary of the scientific evidence used to justify these measures to protect SoHO donors, SoHO recipients or offspring from medically assisted reproduction;

(b) may contribute to setting up a European supply chain and to achieving the objective of European autonomy and coordination between Member States; they may also be aimed at reinforcing the principle of voluntary and unpaid donation.

Amendment 91

Proposal for a regulation
Article 5 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) have the autonomy to act and make decisions independently and impartially while respecting the internal administrative organisational requirements determined ***by the Constitutions of the Member States***;	(a) have the autonomy to act and make decisions independently and impartially while respecting the internal administrative organisational requirements determined ***in national legislation***;

Amendment 92

Proposal for a regulation
Article 5 – paragraph 3 – point b – point ii

Text proposed by the Commission	*Amendment*
(ii) to order the immediate suspension or cessation of a SoHO activity that poses immediate risk to SoHO donors, SoHO recipients or the general public;	(ii) to order the immediate suspension or cessation of a SoHO activity that poses immediate risk to SoHO donors, SoHO recipients or the general public ***or that does not comply with the conditions of its authorisation or with this Regulation***;

Amendment 93

Proposal for a regulation
Article 5 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) have sufficient resources, operational capacity, and expertise to achieve the aims of, and fulfil their obligations under, this Regulation;	(c) have sufficient ***human and financial*** resources, operational capacity, and expertise***, including technical expertise,*** to achieve the aims of, and fulfil their obligations under, this Regulation;

Amendment 94

Proposal for a regulation
Article 5 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Each Member State shall designate a single SoHO National Authority, in conformity with Member States' constitutional requirements, responsible for coordinating exchanges with the Commission and with other Member States' SoHO National Authorities.	4. Each Member State shall designate a single SoHO National Authority, in conformity with Member States' constitutional requirements, responsible for coordinating exchanges with the Commission and with other Member States' SoHO National Authorities. ***The Commission shall make publicly available the list of SoHO National Authorities on the EU SoHO Platform.***

Amendment 95

Proposal for a regulation

Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Competent authorities shall act independently, in the public interest and free from any external influence.	1. Competent authorities ***and members of the SCB*** shall act independently, in the public interest and free from any external influence.

Amendment 96

Proposal for a regulation
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Competent authorities shall ensure that their personnel have no direct or indirect economic, financial or personal interest that might be considered prejudicial to their independence and, in particular, that they are not in a situation that may, directly or indirectly, affect the impartiality of their professional conduct.	2. Competent authorities shall ensure that their personnel have no direct or indirect economic, financial or personal interest that might be considered prejudicial to their independence and, in particular, that they are not in a situation that may, directly or indirectly, affect the impartiality of their professional conduct. ***All relevant personnel shall make an annual declaration of their interests, which shall be published on the competent authorities' website.***

Amendment 97

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 prior to them being recruited by the competent authorities, to be determined and made public by the competent authorities.

Amendment 98

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Without prejudice to Article 75, competent authorities shall carry out their supervisory activities in a transparent manner and they shall make accessible and clear to the public decisions taken in cases where a SoHO entity has failed to comply with an obligation under this Regulation and where such failure causes or may cause a serious risk to human health.	1. Without prejudice to Article 75, competent authorities ***and members of the SCB*** shall carry out their supervisory activities in a transparent manner and they shall make accessible and clear to the public decisions taken in cases where a SoHO entity has failed to comply with an obligation under this Regulation and where such failure causes or may cause a serious risk to human health***, including decisions to revoke, suspend or reinstate an authorisation for SoHO activities***. ***Competent authorities shall also be transparent about the criteria used for the assessment and authorisation of SoHO preparations and SoHO entities.***

Amendment 99

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Competent authorities shall be responsible for the SoHO supervisory activities referred to in Chapter III in order to verify the effective compliance of SoHO entities in their territory with the requirements set out in this Regulation.	1. Competent authorities shall be responsible for the SoHO supervisory activities referred to in Chapter III in order to verify the effective compliance of SoHO entities ***and SoHO preparations authorised*** in their territory with the requirements set out in this Regulation.

Amendment 100

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

Text proposed by the Commission	*Amendment*
(a) ***a sufficient number of suitably***	(a) ***human and financial resources,***

qualified personnel to carry out the supervisory functions provided for in this Regulation;	***operational capacity, and expertise, including technical expertise,*** to carry out the supervisory functions provided for in this Regulation;

Amendment 101

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

Text proposed by the Commission	*Amendment*
(b) procedures to ensure the independence, impartiality, effectiveness, quality, suitability for purpose and consistency of their SoHO supervisory activities;	(b) procedures to ensure the independence, impartiality***, transparency***, effectiveness, quality, suitability for purpose and consistency of their SoHO supervisory activities;

Amendment 102

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 efficiently***, safely*** and effectively;

Amendment 103

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,	1. In all cases where questions arise as to the regulatory status of a substance, product or activity, competent authorities shall consult with ***the national*** authorities established in other relevant Union legislation referred to in Article 2(3), as

competent authorities shall also consult the compendium referred to Article 3 point (33).	relevant In such cases, competent authorities shall also consult the compendium referred to Article 3**,** point (33).

Amendment 104

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).	***If*** the SCB ***deems it necessary, it 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).

Amendment 105

Proposal for a regulation
Article 14 – paragraph 3 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	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.

Amendment 106

Proposal for a regulation
Article 16 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) make the declarations of interest referred to in Article 7(2) publicly

available on their website;

Amendment 107

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 pending verification that the more stringent measure has been met. ***This information shall be notified, without undue delay, on the EU SoHO Platform.***

Amendment 108

Proposal for a regulation
Article 21 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Where the conditional authorisation referred to in point (c) has been granted, appropriate information for practitioners and patients on the conditional nature of the authorisation shall be provided by the SoHO entity.

Amendment 109

Proposal for a regulation

Article 21 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Competent authorities shall conclude the SoHO preparation authorisation steps, referred to in paragraph 2 of this Article, within 3 months from receipt of the application, excluding the time needed for clinical outcome monitoring or studies. They may suspend this time limit for the duration of the consultation processes referred to in Article 14(1) and (2).	4. Competent authorities shall conclude the SoHO preparation authorisation steps, referred to in paragraph 2 of this Article, within 3 months from receipt of the application, excluding the time needed for clinical outcome monitoring or studies. They may suspend this time limit for the duration of the consultation processes referred to in Article 14(1) and (2) ***or if further information is required from the SoHO entity that made the request***.

Amendment 110

Proposal for a regulation
Article 21 – paragraph 6 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) such preparation, or any of the activities performed for that preparation, do not comply with the conditions of its authorisation or the requirements of this Regulation; ***and***	(a) such preparation, or any of the activities performed for that preparation, do not comply with the conditions of its authorisation or the requirements of this Regulation; ***or***

Amendment 111

Proposal for a regulation
Article 21 – paragraph 8

Text proposed by the Commission	*Amendment*
8. Competent authorities may, in accordance with national legislation, withdraw the authorisation of a SoHO preparation if the competent authorities have confirmed that the SoHO preparation in question does not comply with subsequently updated criteria for authorisation or the SoHO entity has ***repeatedly*** failed to comply with the	8. Competent authorities may, in accordance with national legislation, withdraw the authorisation of a SoHO preparation if the competent authorities have confirmed that the SoHO preparation in question does not comply with subsequently updated criteria for authorisation or the SoHO entity has failed to comply with the conditions of its

conditions of its authorisation.	authorisation.

Amendment 112

Proposal for a regulation
Article 27 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Competent authorities shall provide guidelines and templates to allow that applications from SoHO entities for their authorisation as SoHO establishments are submitted in accordance with Article 49. When developing ***these*** guidelines and templates, competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).	1. Competent authorities shall provide guidelines and templates to allow that applications from SoHO entities for their authorisation as SoHO establishments are submitted in accordance with Article 49. When developing ***those*** guidelines and templates, competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).

Amendment 113

Proposal for a regulation
Article 27 – paragraph 3 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) does not comply with the conditions of its authorisation or the provisions of this Regulation; ***and***	(a) does not comply with the conditions of its authorisation or the provisions of this Regulation; ***or***

Amendment 114

Proposal for a regulation
Article 27 – paragraph 3 – subparagraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) does not take corrective or preventive action following an inspection by national authorities pursuant to Article 29(14); and

Amendment 115

Proposal for a regulation
Article 27 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Competent authorities may, in accordance with national legislation, withdraw the authorisation of a SoHO establishment if the competent authorities have confirmed that the SoHO establishment no longer complies with updated criteria for authorisation or the SoHO establishment has ***repeatedly*** failed to comply with the conditions of its authorisation.	5. Competent authorities may, in accordance with national legislation, withdraw the authorisation of a SoHO establishment if the competent authorities have confirmed that the SoHO establishment no longer complies with updated criteria for authorisation or the SoHO establishment has failed to comply with the conditions of its authorisation.

Amendment 116

Proposal for a regulation
Article 28 – paragraph 5 – point a

Text proposed by the Commission	*Amendment*
(a) that the SoHO entity in question does not comply with the conditions of the authorisation or the provisions of this Regulation; ***and***	(a) that the SoHO entity in question does not comply with the conditions of the authorisation or the provisions of this Regulation; ***or***

Amendment 117

Proposal for a regulation
Article 28 – paragraph 5 – point b

Text proposed by the Commission	*Amendment*
(b) that this non-compliance, or suspected non-compliance, implies a risk to the safety of recipients or offspring from medically assisted reproduction.	(b) that this non-compliance, or suspected non-compliance, implies a risk to the safety of ***SoHO*** recipients or offspring from medically assisted reproduction.

Amendment 118

Proposal for a regulation
Article 28 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Competent authorities may, in accordance with national legislation, withdraw the authorisation of an importing SoHO entity if the competent authorities have confirmed that the importing SoHO entity no longer complies with updated criteria for authorisation or the importing SoHO entity has ***repeatedly*** failed to comply with the conditions of its authorisation.	7. Competent authorities may, in accordance with national legislation, withdraw the authorisation of an importing SoHO entity if the competent authorities have confirmed that the importing SoHO entity no longer complies with updated criteria for authorisation or the importing SoHO entity has failed to comply with the conditions of its authorisation.

Amendment 119

Proposal for a regulation
Article 28 – paragraph 9

Text proposed by the Commission	*Amendment*
9. By derogation from paragraph 1, in case of emergency competent authorities may authorise imports of SoHOs for immediate application to a specific recipient when justified by the clinical circumstances on a case-by-case basis.	9. By ***way of*** derogation from paragraph 1, in ***the exceptional situations referred to in Article 61a or in*** case of emergency***,*** competent authorities may authorise imports of SoHOs for immediate application to a specific recipient when ***duly*** justified by the clinical circumstances on a case-by-case basis.

Amendment 120

Proposal for a regulation
Article 29 – paragraph 11

Text proposed by the Commission	*Amendment*
11. The interval between ***two on-site*** inspections shall not exceed 4 years.	11. The interval between inspections ***shall be decided on based on the frequency necessary to mitigate any identified risks and*** shall not exceed 4 years.

Amendment 121

Proposal for a regulation
Article 32 – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	Inspectors shall be designated in accordance with procedures which ensure that they act in a transparent, independent and impartial manner. The designation criteria shall be clear and transparent.

Amendment 122

Proposal for a regulation
Article 32 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. All inspectors shall act in an impartial manner and be independent of any direct or indirect conflicts of interest. Inspectors shall declare such impartiality in writing and such declarations shall be made available on the competent authorities' website.

Amendment 123

Proposal for a regulation
Article 32 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) the inspection techniques and procedures to be followed, including practical exercises;	(a) the inspection techniques and procedures to be followed, including practical exercises ***and conflict of interest rules***;

Amendment 124

Proposal for a regulation
Article 34 a (new)

Text proposed by the Commission	*Amendment*
	Article 34a
	Exchange of information on SoHO availability and continuity of supply
	1. As part of the national plans to ensure the continuity of SoHO supply referred to in Article 62, the competent authorities shall establish a digital communication channel through which they can exchange information on the availability of SoHOs in the national territory in a fast and efficient manner. Through that digital communication channel, the competent authorities may, in specific situations of need, oblige national SoHO entities to provide information on the availability of a certain SoHO. They shall also take into account alerts sent by national SoHO entities concerning the availability of SoHOs and potential shortages. The competent authorities shall ensure that the digital communication channel is available no later than ... [two years after the date of entry into force of this Regulation].
	2. The competent authorities shall monitor the availability of SoHOs at national level through the digital communication channel referred to in paragraph 1. They shall provide guidance to SoHO entities to facilitate the exchange of information on the availability of SoHOs.
	3. The competent authorities shall store and analyse information on the availability of SoHOs and the fluctuations in such availability over time, as well as trends in demand and potential shortages of SoHOs, and shall draw up reports containing that information which may be made available to other Member States through the EU SoHO Platform referred

to in Chapter XI.

Amendment 125

Proposal for a regulation
Article 36 a (new)

Text proposed by the Commission	*Amendment*
	Article 36a
	Authorisation and registry of SoHO clinical studies
	1. Competent authorities shall authorise SoHO clinical studies after granting the approval for the clinical study proposal referred to in Article 41a(5) and verifying that the clinical study has been the subject of a positive recommendation by a relevant ethics committee where necessary.
	2. Competent authorities shall inform, instruct and assist SoHO entities in their Member State with regard to the authorisation and registration processes for SoHO clinical studies. Competent authorities shall provide SoHO entities with guidelines and assistance regarding technical and ethical aspects of SoHO clinical studies.
	3. Competent authorities shall register each authorised SoHO clinical study on the EU SoHO Platform, providing the following information:
	(a) the name or business name and address of the SoHO entity or entities carrying out the clinical study, and the name and contact details of the researchers and a contact person;
	(b) where necessary, a positive recommendation by a relevant ethics committee;
	(c) a summary of the study design;
	(d) date of commencement and completion of the various stages of the

	clinical study;
	(e) not more than one year after the end of the clinical study, a summary of the results and conclusions;
	(f) a summary intended for the general public of the clinical study and the results obtained.
	4. In cases where more than one SoHO entity participates in a SoHO clinical study and those SoHO entities are located in different Member States, the SoHO clinical study shall only require an authorisation by one competent authority of the Union.
	5. Competent authorities shall be responsible for ensuring that the information on SoHO clinical studies in their Member State included on the EU SoHO Platform is consistent and shall introduce any changes on the EU SoHO Platform without undue delay.
	6. SoHO entities responsible for SoHO clinical studies shall report, without undue delay, adverse occurrences detected during the clinical study in accordance with Article 47(1).
	7. The Commission may adopt implementing acts to facilitate the registration of information on the EU SoHO Platform. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

Amendment 126

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	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.	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. ***The SoHO entity shall ensure that the responsible person for release of SoHOs receives adequate and up-to-date training, appropriate to their job and responsibilities, including specific training on those SoHOs that necessitate such training.***

Amendment 127

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. ***For the purposes of this Article, 'substantial modification' means a modification that has an impact on the purpose, quality, safety, efficacy or functionality of a SoHO preparation.***

Amendment 128

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	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***.	circumstances referred to in ***Articles 61 and 61a***.

Amendment 129

Proposal for a regulation
Article 41 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) the results of a risk assessment conducted ***on the combination of SoHO activities performed for the SoHO preparation, together with the intended clinical indication for which it is intended to be applied, taking into account:***	(b) the results of a risk assessment conducted ***in accordance with Article 41a(4);***
(i) whether the SoHO preparation is described in, and aligned with, an EDQM SoHO monograph included in the technical guidelines referred to in Article 59(4), point (a);	
(ii) whether the SoHO preparation meets the defined quality criteria in the EDQM SoHO monograph referred to in point (i) and is intended to be used for the indication and with the mode of application to which that monograph refers, where such details are provided in that monograph;	
(iii) information regarding previous use and authorisation of the SoHO preparation in other SoHO entities, as available in the EU SoHO Platform;	
(iv) evidence generated as part of the process of certification, in accordance with Regulation (EU) 2017/745, of any certified medical device used for the SoHO preparation, where available;	
(v) documentation of a systematic process of identification, quantification and evaluation of any risks to the donor or the recipient arising from the chain of activities performed for the SoHO preparation;	

Amendment 130

Proposal for a regulation
Article 41 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) in cases where the indicated risk is other than negligible, a proposal for clinical outcome monitoring to demonstrate safety, quality and efficacy of the SoHO preparation, in line with the results of the risk assessment;	(c) in cases where the indicated risk is other than negligible, a proposal for clinical outcome monitoring to demonstrate safety, quality and efficacy of the SoHO preparation, in line with the results of the risk assessment***, and as set out in Article 41a(5)***;

Amendment 131

Proposal for a regulation
Article 41 – paragraph 3

Text proposed by the Commission	*Amendment*
3. ***In the proposal referred to in paragraph 2, point (c), the applicant*** shall ***propose a*** clinical outcome monitoring ***plan as follows:***	***deleted***
(a) in cases of low risk, clinical follow-up of a defined number of patients;	
(b) in cases of moderate risk, in addition to point (a), a clinical investigation study of a statistically significant number of patients assessing pre-defined clinical endpoints;	
(c) in cases of high risk, in addition to point (a), a clinical investigation study of a statistically significant number of patients assessing pre-defined clinical endpoints with a comparison to standard therapy.	

Amendment 132

Proposal for a regulation

Article 41 – paragraph 4

Text proposed by the Commission	*Amendment*
4. SoHO entities shall perform the clinical outcome monitoring once a conditional authorisation has been granted pursuant to Article 21(2), point (c), and submit the results to their competent authorities. In conducting the clinical investigation study as referred to in ***paragraph 3,*** points ***(b)*** and ***(c)***, for the SoHO preparation concerned, the applicant may use an existing clinical registry to record its results provided that their competent authorities have verified that the registry has data quality management procedures in place that ensure accuracy and completeness of data.	4. SoHO entities shall perform the clinical outcome monitoring once a conditional authorisation has been granted pursuant to Article 21(2), point (c), and submit the results ***and the analysis of those results*** to their competent authorities ***at the frequency determined in the authorisation***. In conducting the clinical investigation study as referred to in ***Article 41a(5),*** points ***(a)(ii)*** and ***(a)(iii)***, for the SoHO preparation concerned, the applicant may use an existing clinical registry to record its results provided that their competent authorities have verified that the registry has data quality management procedures in place that ensure accuracy and completeness of data. ***The applicant shall register that study and the results obtained on the EU SoHO Platform in accordance with Article 36a***.

Amendment 133

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. ***For the purposes of this Article, 'substantial change' means a change that has an impact on the purpose, quality, safety, efficacy or functionality of a SoHO preparation.*** SoHO entities shall also inform their competent authorities of changes in the SoHO preparation authorisation holder's details.

Amendment 134

Proposal for a regulation
Article 41 a (new)

Text proposed by the Commission	*Amendment*
	Article 41a
	SoHO clinical studies
	1. When conducting SoHO clinical studies, in the context of the monitoring plans referred to in Article 41(2), point (c), or with the aim of comparing or improving previously authorised treatments, SoHO entities shall comply with the requirements set out in this Regulation.
	2. SoHO clinical studies shall always have the safety and well-being of the participants in the clinical study as a priority and they shall comply with Articles 53, 54, 55, 56, 58 and 59, concerning the protection of donors, recipients and offspring from medically assisted reproduction. SoHO entities intending to start a SoHO clinical study shall seek to obtain robust and reliable data, through collaboration with other SoHO entities, if necessary.
	3. SoHO entities shall submit a request for approval of the SoHO clinical study to competent authorities before starting the clinical study, in accordance with the procedure set out in paragraphs 4 and 5. SoHO entities may request assistance regarding administrative, technical and ethical aspects of the clinical study from the competent authorities, in accordance with Article 36a.
	4. Prior to starting a SoHO clinical study, the applicant shall conduct a risk assesment, on the combination of SoHO activities performed for the SoHO preparation, together with the intended clinical indication, taking into account:
	(a) whether the SoHO preparations are

described in, and aligned with, an EDQM SoHO monograph included in the technical guidelines referred to in Article 59(4), point (a);

(b) whether the SoHO preparations meet the defined quality criteria in the EDQM SoHO monograph referred to in point (a) and are intended to be used for the indication and with the mode of application to which that monograph refers, where such details are provided in that monograph;

(c) information regarding previous use and authorisation of the SoHO preparations in other SoHO entities, as available on the EU SoHO Platform;

(d) evidence generated as part of the process of certification, in accordance with Regulation (EU) 2017/745, of any certified medical device used for the SoHO preparations, where available;

(e) documentation of a systematic process of identification, quantification and evaluation of any risks to the donor or the recipient arising from the chain of activities performed for the SoHO preparations.

5. In line with the results of the risk assessment referred to in paragraph 4, the SoHO entity shall propose a clinical study plan to the competent authorities:

(a) in the context of clinical outcome monitoring for the authorisation of a new SoHO preparation as referred to in Article 41(2), point (c):

(i) in cases of low risk, clinical follow-up of a defined number of patients;

(ii) in cases of moderate risk, in addition to point (i), a clinical investigation study of a statistically significant number of patients assessing pre-defined clinical endpoints;

(iii) in cases of high risk, in addition to point (i), a clinical investigation study of a statistically significant number of patients

	assessing pre-defined clinical endpoints with a comparison to standard therapy;
	(b) in the context of a comparative clinical study with previously authorised SoHO treatments.
	6. When performing a high-risk clinical study, SoHO entities shall apply for a favourable opinion from the relevant ethics committee before starting the clinical study. The Committee shall assess the ethical, legal and methodological aspects of the clinical study, to determine the capacity of the study design to draw robust conclusions, as well as well-being and safety-related aspects of the participants, before issuing a favourable opinion for the clinical study.
	7. The person responsible for the SoHO clinical study shall be adequately trained.

Amendment 135

Proposal for a regulation
Article 43 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The importing SoHO entity authorisation holder shall be based in the Union, and be responsible for the physical reception and visual examination and verification of imported SoHOs prior to their release. The importing SoHO entity shall verify coherence between the SoHO received and the associated documentation and conduct an examination of the integrity of packaging and the compliance of labelling and transport conditions with the relevant standards and technical guidelines as referred to in Articles 57, 58 and 59.	4. The importing SoHO entity authorisation holder shall be based in the Union, and be responsible for the physical reception and visual examination and verification of imported SoHOs prior to their release. The importing SoHO entity shall verify coherence between the SoHO received and the associated documentation and conduct an examination of the integrity of packaging and the compliance of labelling and transport conditions with the relevant standards and technical guidelines as referred to in Articles 57, 58 and 59. ***The importing SoHO entity shall ensure that the imported SoHOs meet safety and quality standards equivalent to those set out in this Regulation.***

Amendment 136

Proposal for a regulation
Article 47 – paragraph 1

Text proposed by the Commission	*Amendment*
1. SoHO entities shall maintain a system for detecting, investigating and recording information concerning adverse occurrences, including adverse occurrences detected during clinical outcome monitoring as part of a SoHO preparation authorisation application as referred to in Article 41.	1. SoHO entities shall maintain a system for detecting, investigating and recording information concerning adverse occurrences, including adverse occurrences detected during clinical outcome monitoring as part of a SoHO preparation authorisation application as referred to in Article 41 ***or as part of a SoHO clinical study as referred to in Article 41a***.

Amendment 137

Proposal for a regulation
Article 47 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Where a SAO notification concerns public health matters, competent authorities shall, without delay, communicate essential information to the general public and to the SCB.

Amendment 138

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.

Amendment 139

Proposal for a regulation
Article 51 – title

Text proposed by the Commission	*Amendment*
Physician	***Physicians***

Amendment 140

Proposal for a regulation
Article 51 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) investigation of suspected adverse occurrences in SoHO donors ***and*** recipients;	(b) investigation of suspected adverse occurrences in SoHO donors***, SoHO*** recipients ***and, where relevant, offspring from medically assisted reproduction***;

Amendment 141

Proposal for a regulation
Article 51 – paragraph 3

Text proposed by the Commission	*Amendment*
3. By derogation from paragraph 2, in the case of SoHO entities that are authorised as SoHO establishments in accordance with Article 25(3), the physician shall be responsible for those tasks that are relevant to the SoHO activities performed by the SoHO entities and that have a direct influence on the health of SoHO donors ***and*** recipients.	3. By derogation from paragraph 2, in the case of SoHO entities that are authorised as SoHO establishments in accordance with Article 25(3), the physician shall be responsible for those tasks that are relevant to the SoHO activities performed by the SoHO entities and that have a direct influence on the health of SoHO donors***, SoHO*** recipients ***and, where relevant, offspring from medically assisted reproduction***.

Amendment 142

Proposal for a regulation

Article 52 – paragraph 2

Text proposed by the Commission	*Amendment*
2. SoHO entities shall protect the health of living donors before, during and after the donation.	2. SoHO entities shall protect the ***physical and, where relevant, mental*** health of living ***SoHO*** donors before, during and after the donation.

Amendment 143

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 SoHO donors before the donation does not pose a disproportionate risk to the donation or to the health of such donors during or after the donation.

Amendment 144

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

Text proposed by the Commission	*Amendment*
(a) meet all applicable consent or authorisation requirements in force in the Member State concerned;	(a) meet all applicable ***informed*** consent or authorisation requirements in force in the Member State concerned;

Amendment 145

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	(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***;	in Article 55 and in a way that ***enables them to give informed consent and request further information if needed***;

Amendment 146

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

Text proposed by the Commission	*Amendment*
(j) verify, by means of ***a registry***, that donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article 56 and demonstrate that their health is not compromised;	(j) verify, by means of ***national registries***, that donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article 56 and demonstrate that their health is not compromised;

Amendment 147

Proposal for a regulation
Article 53 – paragraph 1 – point j a (new)

Text proposed by the Commission	*Amendment*
	(ja) verify, by means of national registries, that donors meet donor eligibility criteria, if required in the case of specific types of donation, on the basis of the latest available scientific evidence and medical expertise;

Amendment 148

Proposal for a regulation
Article 53 – paragraph 1 – point l a (new)

Text proposed by the Commission	*Amendment*
	(la) inform the SoHO recipients of donor anonymity requirements and the possibility of ID release and the implications thereof for medically assisted reproduction with third party donation of

reproductive cells, pursuant to national legislation.

Amendment 149

Proposal for a regulation
Article 53 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. SoHO entities shall not discriminate against SoHO donors on any of the grounds listed in Article 21 of the Charter of Fundamental Rights of the European Union, unless it is necessary to protect the health of the SoHO recipient, of the offspring from medically assisted reproduction or of the SoHO donor. Such discriminatory action shall be based on scientific evidence.

Amendment 150

Proposal for a regulation
Article 53 – paragraph 2

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

evaluations.	procedure and criteria for donor health evaluations.

Amendment 151

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 ***SoHOs that can be donated*** on a frequent and repeated basis, shall register such donors and the results of their donor health evaluations in a cross-entity registry that allows interconnection with other such registries ***at Union level, including cross-border registries***, 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 understood in accordance with the EDQM guidelines referred to in Article 71 for each type of donation.***

Amendment 152

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.

Amendment 153

Proposal for a regulation
Article 54 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States may allow for the compensation or reimbursement from the SoHO entities to donors for losses related to their participation in donations ***through fixed*** rate allowances***. In such case***, Member States shall establish the conditions for such ***allowances*** in national legislation, ***including the setting of an upper limit that ensures that allowances*** are financially neutral and consistent with the standards laid down in this Article. They may delegate the setting of conditions for such ***allowances*** to independent bodies that are established in accordance with national legislation.	2. Member States may allow for the compensation or reimbursement from the SoHO entities to ***living SoHO*** donors for losses ***or expenses*** related to their participation in donations***, in accordance with the principle of voluntary and unpaid donation, and for example taking the form of compensatory leave, tax reductions or flat*** rate allowances ***set at national level. Based on transparent criteria***, Member States shall establish the conditions for such ***forms of compensation or reimbursement*** in national legislation, ***ensuring that they*** are financially neutral and consistent with the standards laid down in this Article. They may ***make compensation or reimbursement subject to the filing of applications by donors and*** delegate the setting of conditions for such ***forms of compensation or reimbursement*** to independent bodies that are established in accordance with national legislation. ***In that regard, the Commission shall support the exchange of best practices between Member States. The donors may also choose not to be compensated for losses or expenses associated with their donation.***

Amendment 154

Proposal for a regulation
Article 54 – paragraph 3

Text proposed by the Commission	*Amendment*

3. SoHO entities may compensate or reimburse donors as provided for by their competent authorities pursuant to paragraph 2.	3. SoHO entities may compensate or reimburse ***living SoHO*** donors as provided for by their competent authorities pursuant to paragraph 2. ***SoHO entities shall report in a transparent manner to the competent authorities on any compensation and reimbursement measures they have in place, and on any changes they make in that respect.***

Amendment 155

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

Text proposed by the Commission	*Amendment*
	3a. Compensation or reimbursement shall not serve as an incentive for donations or engender financial competition, including cross-border competition, between institutions and entities that are seeking donors. It shall not lead to exploitation of vulnerable persons in society.

Amendment 156

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

Text proposed by the Commission	*Amendment*
	3b. Member States shall regulate the advertising of the collection of SoHOs. Any advertising of SoHO donations linked to a financial reward shall be prohibited. Recruitment campaigns and advertisements shall not refer to any compensation.

Amendment 157

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

Text proposed by the Commission	*Amendment*
	3c. By ... [two years after the date of entry into force of this Regulation] and every three years thereafter, the Commission shall assess the national conditions for the level of compliance with the principle of voluntary and unpaid donation as set out in this Regulation. That assessment shall determine, inter alia, whether compensation and reimbursement, under any circumstances, harm donor or recipient safety, constitute an incentive or a claim to recruit donors or expose vulnerable people in society to exploitation. Member States shall provide the Commission with the information requested to perform that assessment.
	On the basis of the assessments referred to in the first subparagraph, the Commission shall adopt guidelines for Member States based on best practices in the implementation of compensation schemes and, where appropriate, make recommendations to Member States on how such practices can be improved. Those guidelines and recommendations shall be made available to the public.

Amendment 158

Proposal for a regulation
Article 55 – title

Text proposed by the Commission	*Amendment*
Standards concerning information to be provided prior to consent or authorisation	Standards concerning information to be provided prior to ***informed*** consent or authorisation ***to donate SoHOs***

Amendment 159

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 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.	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***, and ensure that the consent given is informed consent***. 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.

Amendment 160

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 informed*** consent;

Amendment 161

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***;

Amendment 162

Proposal for a regulation
Article 56 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
When the Commission deems it necessary to provide binding rules on the implementation of a particular standard or element of a standard referred to in Articles 53, 54 or 55, in order to ensure convergent and high levels of donor safety, the Commission ***may*** adopt ***implementing acts*** describing particular procedures to be followed and applied to meet such standard, or element thereof.	When the Commission deems it necessary to provide binding rules on the implementation of a particular standard or element of a standard referred to in Articles 53, 54 or 55, in order to ensure convergent and high levels of donor safety, the Commission ***is empowered to*** adopt ***delegated acts in accordance with Article 77 to supplement this Regulation by*** describing particular procedures to be followed and applied to meet such standard, or element thereof.

Amendment 163

Proposal for a regulation
Article 56 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	***deleted***

Amendment 164

Proposal for a regulation
Article 56 – paragraph 2

Text proposed by the Commission	*Amendment*
2***.*** ***On duly justified*** imperative grounds of urgency ***relating to a risk to donor health, the Commission shall adopt immediately applicable implementing acts in accordance with*** the procedure ***referred***	2***.*** ***Where, in the case of a risk to donor health,*** imperative grounds of urgency ***so require,*** the procedure ***provided for*** in Article ***78 shall apply to delegated acts adopted pursuant to this Article.***

to in Article ***79(3).***

Amendment 165

Proposal for a regulation
Article 56 – paragraph 3

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

Amendment 166

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

Text proposed by the Commission	*Amendment*
4. For those standards concerning donor protection or elements thereof for which no ***implementing*** act has been adopted, in order to apply such standards or elements thereof, SoHO entities shall follow:	4. For those standards concerning donor protection or elements thereof for which no ***delegated*** act has been adopted, in order to apply such standards or elements thereof, SoHO entities shall follow ***in order of priority***:

Amendment 167

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

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

EU SoHO Platform referred to in Chapter XI, as follows:

Amendment 168

Proposal for a regulation
Article 56 – paragraph 6

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

Amendment 169

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 ***and their application***. They shall do so by identifying, minimising or eliminating those risks.

Amendment 170

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

Text proposed by the Commission	*Amendment*

	SoHO entities shall not discriminate against SoHO recipients on any of the grounds listed in Article 21 of the Charter of Fundamental Rights of the European Union, unless it is necessary to protect the health of the SoHO recipient or of the SoHO donor. Such discriminatory action shall be based on scientific evidence.

Amendment 171

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***, based on the guidelines referred to in Article 59,*** establish procedures with measures, and, where necessary, combinations of measures, that ensure high levels of safety and quality and demonstrate benefits for SoHO recipients and offspring from medically assisted reproduction that outweigh any risks. They shall, in particular, achieve a high level of assurance that pathogens, toxins or genetic conditions are not transmitted to recipients or offspring from medically assisted reproduction.

Amendment 172

Proposal for a regulation
Article 58 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Where possible, SoHO entities shall use technologies to reduce clinical risks for SoHO recipients and offspring from medically assisted reproduction, and to improve the quality of SoHOs.

Amendment 173

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

Text proposed by the Commission	*Amendment*
(b) testing of donors for communicable diseases using certified and validated testing methods;	(b) testing of donors for communicable diseases using certified and validated testing methods ***or other methods deemed appropriate in EDQM and ECDC guidelines***;

Amendment 174

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

Text proposed by the Commission	*Amendment*
(c) when feasible, using processing technologies that reduce ***or*** eliminate any potential communicable pathogens.	(c) when feasible, using processing technologies that reduce***,*** eliminate ***or inactivate*** any potential communicable pathogens.

Amendment 175

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

Text proposed by the Commission	*Amendment*
	(ca) where possible and appropriate, using methods of detection, inactivation or elimination of microorganisms.

Amendment 176

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

Text proposed by the Commission	*Amendment*

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

Amendment 177

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; ***SoHO entities shall make optimal use of SoHOs, taking into account therapeutic alternatives, and following the most up-to-date scientific guidelines as referred to in Article 59;***

Amendment 178

Proposal for a regulation
Article 58 – paragraph 10 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) prioritise aesthetic uses over therapeutic uses, especially in the event of a possible shortage of SoHOs.

Amendment 179

Proposal for a regulation
Article 58 – paragraph 11 – subparagraph 1

Text proposed by the Commission	*Amendment*

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

Amendment 180

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***, while ensuring that all obligations under Article 53(1), points (e) and (f), and Article 53(2) are met***.

Amendment 181

Proposal for a regulation
Article 59 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
4. For those standards or elements of standards concerning recipient and offspring protection for which no implementing act has been adopted, in order to apply such standards or elements thereof, SoHO entities shall follow:	4. For those standards or elements of standards concerning recipient and offspring protection for which no implementing act has been adopted, in order to apply such standards or elements thereof, SoHO entities shall follow ***in order of priority***:

Amendment 182

Proposal for a regulation
Article 59 – paragraph 6

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

Amendment 183

Proposal for a regulation
Article 61 a (new)

Text proposed by the Commission	*Amendment*
	Article 61a
	Derogation from the obligations to authorise SoHO preparations in emergency situations or in situations where there is no therapeutic alternative
	1. By way of derogation from Article 21, competent authorities may permit, at the request of a SoHO entity and where duly justified by a health emergency, the distribution or preparation for immediate application of SoHO preparations within their territory in cases where the procedures referred to in that Article have not been carried out, provided that the use of those SoHO preparations is in the interest of public health. Competent authorities shall indicate the period of time for which the permission is granted or shall define conditions that make it possible to clearly establish that period of time.

	2. Competent authorities may furthermore grant, on an exceptional basis, a conditional and temporary authorisation for SoHO preparations at the request of a prescribing physician within a SoHO entity, in situations where there is no therapeutic alternative, provided that:
	(a) provision has been made for the use of such preparations for a given patient, in the event that treatment cannot be postponed or when the patient's vital interests so require;
	(b) the preparations can be deemed to be safe and effective on the basis of the available clinical data.
	3. Competent authorities shall immediately inform the SoHO National Authority of any exceptional authorisation and, without undue delay, enter information on any conditional authorisation of SoHO preparations on the EU SoHO Platform referred to in Chapter XI.
	4. After receiving conditional and temporary authorisation for a SoHO preparation in accordance with paragraph 2 of this Article, the SoHO entity shall, in parallel, initiate a regular authorisation procedure for that SoHO preparation in accordance with Article 21.

Amendment 184

Proposal for a regulation
Article 62 – title

Text proposed by the Commission	*Amendment*
Establishment of national SoHO emergency plans	Establishment of national SoHO emergency plans ***and of plans to ensure continuity of supply of SoHOs***

Amendment 185

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 plans ***to strive for sufficiency of*** supply ***of*** critical SoHOs ***and contribute to European autonomy in the context of a resilient supply chain.*** ***The national plans shall in particular include measures to ensure that the donor base is resilient, actions to make a more efficient use of SoHOs, monitoring of trends in the supply of critical SoHOs as well as measures for cases where national SoHO stocks exceed the national demand and SoHOs are exported to other countries with SoHO shortages***. ***When drawing up and reviewing their national plans, Member States shall take into account the recommendations issued by the Commission in accordance with Article 62a and best practices documented by the SCB in accordance with Article 68.***

Amendment 186

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 doing, they shall ***encourage the*** collection ***of SoHO*** with a strong public and non-	2. Member States shall make all reasonable efforts***, in line with the principle of voluntary and unpaid donation,*** 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***, among***

profit sector involvement**.**	***other measures:***
	(a) include all relevant stakeholders in the drawing up of their national plans;
	(b) ensure that there is an adequate number of SoHO collection ***entities,*** with a strong public and non-profit sector involvement***, and of SoHO establishments as well as adequate opening times;***
	(c) ensure appropriate working conditions and adequate training are provided for relevant SoHO professions;
	(d) ensure that critical SoHO donor recruitment and retainment strategies are put in place, including communication campaigns and education programmes;
	(e) establish quantitative collection targets for critical SoHOs.

Amendment 187

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

Text proposed by the Commission	*Amendment*
	2a. SoHO entities shall report to the competent authorities on potential shortages of SoHOs or upon request from the competent authorities in accordance with Article 34a. The competent authorities shall be responsible for monitoring the availability of SoHOs at national level.

Amendment 188

Proposal for a regulation
Article 62 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall ***specify the following in the plans referred to in***	3. ***In cases where the availability of SoHOs or products derived from them***

paragraph 1:	***depends on potential commercial interests, each Member State shall ensure that those SoHO entities, within the limit of their responsibilities, provide an appropriate and continuous supply of SoHOs, or their derivatives, to patients in their territory .*** Member States shall ***negotiate fair and transparent prices for SoHO-derived products that are based on altruistic and unpaid donations. Member States shall also ensure that affordable products are available to patients and that there is continuous investment in research and innovation in relation to those products.***
(a) potential risks to the supply of critical SoHOs;	
(b) the critical SoHO entities to be involved;	
(c) the powers and responsibilities of competent authorities;	
(d) channels and procedures for sharing information between competent authorities including competent authorities of other Member States and other parties concerned, as appropriate;	
(e) a procedure for the development of preparedness plans for specific identified risks, in particular those concerning communicable disease outbreaks;	
(f) a procedure for the assessment and authorisation, when justified, of requests from SoHO entities for derogations to the standards defined in Chapters VI and VII.	

Amendment 189

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

Text proposed by the Commission	*Amendment*
	3a. By ... [2 years after the date of entry into force of this Regulation], Member States shall submit their national plans to

	the Commission and the SCB. They shall review their national plans every two years, and inform the Commission and the SCB of any substantial change to those plans.

Amendment 190

Proposal for a regulation
Article 62 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall ***ensure that any derogation granted in accordance with*** paragraph ***3, point (f), is time-limited and is justified insofar as it implies*** risks ***that are lower than the risk of shortage of the*** specific ***SoHO***.	4. ***In order to be able to deal with emergency situations that arise, when the supply situation for critical SoHOs presents or is likely to present a serious risk to human health,*** Member States shall ***specify the following in the plans referred to in*** paragraph ***1:***
	(a) potential risks ***to the supply of critical SoHOs and measures that impact the demand for SoHOs;***
	(b) the critical SoHO entities to be involved;
	(c) the powers and responsibilities of competent authorities;
	(d) channels and procedures for sharing information between competent authorities, including competent authorities of other Member States and other parties concerned, as appropriate;
	(e) a procedure for the development of preparedness plans for specific ***identified risks, in particular those concerning communicable disease outbreaks;***
	(f) a procedure for the assessment and authorisation, when justified, of requests from SoHO entities for derogations from the standards defined in Chapters VI and VII;
	(g) actions to prioritise therapeutic uses of critical SoHOs and certain patients in the event of shortages.

Amendment 191

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 ***ensure that any derogation granted in accordance with paragraph 4, point (f), is time-limited and is justified insofar as it implies risks that are lower than the risk of shortage*** of the ***specific SoHO***.

Amendment 192

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 take into account ***the guidance of the ECDC, for emergencies related to epidemiological outbreaks, in particular to ensure pandemic prevention and preparedness, and the guidelines published by the EDQM, for emergency planning in general***.

Amendment 193

Proposal for a regulation
Article 62 – paragraph 7 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The Commission ***may*** adopt ***implementing acts*** describing:	The Commission ***is empowered to*** adopt ***delegated acts in accordance with Article 77 to supplement this Regulation by*** describing:

Amendment 194

Proposal for a regulation
Article 62 – paragraph 7 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) rules for the establishment of the national ***SoHO emergency*** plans provided for in paragraph 1 to the extent necessary to ensure the consistent and effective management of supply interruptions;	(a) rules for the establishment of the national plans provided for in paragraph 1 to the extent necessary to ensure the consistent and effective management of supply interruptions;

Amendment 195

Proposal for a regulation
Article 62 – paragraph 7 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the role of stakeholders and the supportive role of the ECDC in the establishment and operation of national ***SoHO emergency*** plans***.***	(b) the role of stakeholders and the supportive role of the ECDC ***and the EDQM*** in the establishment and operation of national plans***;***

Amendment 196

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

Text proposed by the Commission	*Amendment*
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	***deleted***

Amendment 197

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 autonomy

1. By ... [two years after the date of entry into force of this Regulation], the Commission shall publish a strategy for the promotion of European SoHO supply autonomy. That strategy shall set out a roadmap with ambitious targets for each critical SoHO, laid down by the Commission in coordination with national competent authorities, the SCB, the ECDC, the European Parliament, scientists from professional associations and patient associations, as well as with all other relevant stakeholders. Without prejudice to Articles 53 and 54, the strategy shall promote actions to:

(a) support and coordinate communication campaigns at European and national level on the various types of SoHO donations that are available;

(b) support, through relevant programmes, the training of healthcare workers in hospital and healthcare facilities, to raise awareness concerning SoHO donations;

(c) coordinate the exchange of best practices linked to optimisation of the use of critical SoHOs.

2. The strategy referred to in paragraph 1 shall include actions to establish a Union list of critical SoHOs.

3. The strategy referred to in paragraph 1 shall include actions to ensure that the reports referred to in Article 34a are regularly monitored via the EU SoHO Platform referred to in Chapter XI. Such monitoring shall be aimed at identifying at Union level any actual or potential shortages which would endanger patient health.

4. The strategy for promoting European SoHO supply autonomy shall be revised by the Commission every five

	years from 2030. Where necessary, national plans set up in accordance with Article 62 shall be reviewed accordingly within no more than two years of the publication of the revised strategy.

Amendment 198

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.

Amendment 199

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

Amendment 200

Proposal for a regulation
Article 63 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The SoHO National Authorities ***may***	3. The SoHO National Authorities

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)***.	***shall, without undue delay,*** submit to the EU SoHO Platform the SoHO supply alert received.

Amendment 201

Proposal for a regulation
Article 64

Text proposed by the Commission	*Amendment*
Article 64	***deleted***
Derogation from the obligations to authorise SoHO preparations in emergency situations	
1. By way of derogation from Article 21, competent authorities may permit, on a request from a SoHO entity duly justified by a health emergency, the distribution or preparation for immediate application of SoHO preparations within their territory in cases where the procedures referred to in that Article have not been carried out, provided that the use of those SoHO preparations is in the interest of public health. Competent authorities shall indicate the period of time for which the permission is granted or shall define conditions enabling to clearly establish that period of time.	
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.	

Amendment 202

Proposal for a regulation
Article 65 – title

Text proposed by the Commission	*Amendment*
Additional emergency measures by Member States	Additional emergency ***and supply*** measures by Member States

Amendment 203

Proposal for a regulation
Article 65 – paragraph 1

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

Amendment 204

Proposal for a regulation
Article 66 – title

Text proposed by the Commission	*Amendment*
SoHO entity emergency plans	SoHO entity emergency ***and continuity of supply*** plans

Amendment 205

Proposal for a regulation
Article 66 – paragraph 1

Text proposed by the Commission	*Amendment*
Each SoHO entity carrying out SoHO activities that concern critical SoHOs shall have a SoHO entity emergency plan ***that supports*** the implementation of the national SoHO emergency ***plan*** as referred to in Article 62.	Each SoHO entity carrying out SoHO activities that concern critical SoHOs shall have a ***continuity of supply plan and a*** SoHO entity emergency plan***. Those plans shall support*** the implementation of the national ***continuity of supply and*** SoHO emergency ***plans*** as referred to in Article 62.

Amendment 206

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. ***Such experts and stakeholders may include consumers, patients, health professionals and researchers.*** Other ***relevant*** Union institutions, bodies, offices and agencies ***or services*** shall have an observer role. ***The European Parliament shall designate a technical representative to participate in the SCB as an observer.***

Amendment 207

Proposal for a regulation
Article 67 – paragraph 3

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

Amendment 208

Proposal for a regulation
Article 67 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The Commission shall make publicly available the rules of procedure and guidance of the SCB, as well as the agendas and the minutes of the meetings of the SCB on the EU SoHO Platform, unless such publication undermines the protection of a public or private interest, as referred to in Article 4 of Regulation (EC) No 1049/2001 of the European Parliament and of the Council[1a].
	[1a] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

Amendment 209

Proposal for a regulation
Article 67 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission shall ***chair the***	4. ***The SCB shall be co-chaired by a***

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

Amendment 210

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

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

Amendment 211

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

Text proposed by the Commission	*Amendment*
	(***ka) make available to the public a summary of the topics discussed at the meetings.***

Amendment 212

Proposal for a regulation
Article 67 – paragraph 7

Text proposed by the Commission	*Amendment*
7. The Commission shall***, by means of implementing acts,*** adopt the necessary measures for the establishment, management and functioning of the SCB.	7. The Commission shall adopt ***delegated acts in accordance with Article 77 to supplement this Regulation by setting out*** the necessary measures for the establishment, management and functioning of the SCB.
Those implementing acts shall be adopted	

in accordance with the examination procedure referred to in Article 79(2).

Amendment 213

Proposal for a regulation
Article 67 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7a. Members of the SCB shall not have financial or other interests in related industries which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests which could relate to this industry shall be entered in a register held by the Commission which is accessible to the public, on request, at the Commission's offices.
	The SCB's code of conduct shall make reference to the implementation of this Article, in particular in relation to the acceptance of gifts.

Amendment 214

Proposal for a regulation
Article 67 – paragraph 7 b (new)

Text proposed by the Commission	*Amendment*
	7b. Members of the SCB, experts and observers shall declare, at each meeting, any specific interests which could be considered to be prejudicial to their independence with respect to the items on the agenda. Such declarations shall be made available to the public.

Amendment 215

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) ***in collaboration with other authorities designated pursuant to other relevant Union legislation,*** preparing opinions at the request of competent authorities in accordance with Article ***14(1) and (2),*** on the regulatory status under this Regulation of a substance, product or activity and transmitting its opinions to the compendium;

Amendment 216

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 ***within their respective areas of expertise***, and with the EMA on authorisations and supervisory activities concerning the implementation of the PMF certification pursuant to Directive 2003/63/EC, to support the harmonised implementation of standards and technical guidelines;

Amendment 217

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

Text proposed by the Commission	*Amendment*
	(fa) ensuring coordination regarding continuity and sufficiency of supply of critical SoHOs;

Amendment 218

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

Text proposed by the Commission	*Amendment*
	(ga) in the event of a SoHO-related health emergency or for the purpose of preventing potential threats, collaborate with the Commission, the Advisory Committee on Public Health Emergencies and the ECDC, as established in Regulation (EU) 2022/2371.

Amendment 219

Proposal for a regulation
Article 69 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Commission shall organise Union training in cooperation with the Member States ***concerned***.	The Commission shall organise Union training in cooperation with the Member States.

Amendment 220

Proposal for a regulation
Article 71 – paragraph 1

Text proposed by the Commission	*Amendment*
The Commission shall establish and maintain cooperation with the EDQM in relation to the guidelines published by the EDQM.	The Commission shall establish and maintain cooperation with the EDQM in relation to the guidelines published by the EDQM. ***Such cooperation shall be based on the highest scientific standards, be proactive in identifying future needs and be transparent, involving the relevant stakeholders in consultations related to the development of the guidelines. Such cooperation shall be without prejudice to Union law and shall take into account***

Union principles on transparency and stakeholder participation.

Amendment 221

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

Text proposed by the Commission	*Amendment*
	In the event that the guidelines referred to in the first paragraph diverge from the interests of the Union and the Member States, the Commission may adopt complementary guidance for Member States on how and when to apply those guidelines.

Amendment 222

Proposal for a regulation
Article 73 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall establish, manage and maintain the EU SoHO Platform to facilitate effective and efficient exchange of information concerning SoHO activities in the Union, as provided for in this Regulation.	1. The Commission shall establish, manage and maintain the EU SoHO Platform to facilitate effective and efficient exchange***, registration and storage*** of information concerning SoHO activities ***and supply of critical SoHOs*** in the Union, as provided for in this Regulation.

Amendment 223

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	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***.	anonymised formats. The EU SoHO Platform shall provide a channel for restricted exchange of information and data between competent authorities.

Amendment 224

Proposal for a regulation
Article 73 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission shall adopt delegated acts in accordance with Article 77 supplementing this Regulation by laying down technical specifications regarding the establishment, management and maintenance of the EU SoHO Platform.	4. The Commission shall adopt delegated acts in accordance with Article 77 supplementing this Regulation by laying down technical specifications regarding the establishment, management and maintenance of the EU SoHO Platform***, and establishing access rights for national competent authorities and Union bodies and agencies to carry out their tasks, and minimum categories of information to be shared pursuant to paragraph 2 of this Article***.

Amendment 225

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 Article 13 of Regulation (EU) 2022/123 of the European Parliament and of the Council [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).

Amendment 226

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 Directorates General of the*** Commission, in particular in relation to SAO***,*** rapid alerts ***and SoHO supply alerts, and between competent authorities and the SCB, 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.

Amendment 227

Proposal for a regulation
Article 74 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The EU SoHO Platform shall also be the main intermediary for reporting SoHO shortages, for cross-border requests for SoHOs and for import and export of SoHOs. National authorities shall issue and receive alerts concerning shortages that cannot be resolved at

Member State level, as well as SoHO cross-border requests and shall be able to respond to them. National authorities, aware of the national availability of SoHOs, as referred to in Article 34a, shall use the EU SoHO Platform to report any SoHO shortages that may lead to a public health emergency or severe occurrence.

Amendment 228

Proposal for a regulation
Article 74 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. In the event of a SoHO-related health emergency or for the purpose of preventing potential threats, alerts issued through the EU SoHO Platform shall enable the Commission, competent authorities and other relevant bodies to rapidly develop awareness of such emergency or of potential threats so that action can be taken as soon as possible in accordance with Regulation (EU) 2022/2371.

Amendment 229

Proposal for a regulation
Article 74 – paragraph 2 c (new)

Text proposed by the Commission	*Amendment*
	2c. The EU SoHO Platform shall contain a record of SoHO clinical studies and their results, as referred to in Article 36a.

Amendment 230

Proposal for a regulation

Article 74 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall adopt ***implementing*** acts laying down technical specifications for the EU SoHO Platform, including its functions, the roles and responsibilities of each of the parties listed in paragraph 1, the retention periods for personal data and the technical and organisational measures to ensure the safety and security of personal data processed.	3. The Commission shall adopt ***delegated*** acts ***in accordance with Article 77 to supplement this Regulation and to ensure uniformity, compatibility and comparability of data exchanged through the platform by*** laying down technical specifications for the EU SoHO Platform, including its functions, the roles and responsibilities of each of the parties listed in paragraph 1, the retention periods for personal data and the technical and organisational measures to ensure the safety and security of personal data processed.
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	

Amendment 231

Proposal for a regulation
Article 75 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) personal data in accordance with Article 76;	(a) ***natural persons with regard to the processing of*** personal data in accordance with Article 76;

Amendment 232

Proposal for a regulation
Article 75 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and competent authorities with regard to the exchange of information and the	3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and competent authorities with regard to the exchange of information and the

dissemination of alerts, nor the obligations of persons to provide information under national criminal law.	dissemination of alerts, nor the obligations of persons to provide information under national criminal law ***or other applicable law, including on access to information***.

Amendment 233

Proposal for a regulation
Article 75 – paragraph 6 – point b

Text proposed by the Commission	*Amendment*
(b) the information or data made available to the public does not unnecessarily undermine the protection of commercial interests of a SoHO entity or any other natural or legal person;	(b) the information or data made available to the public does not unnecessarily undermine the protection of commercial interests of a SoHO entity or any other natural or legal person ***any other natural or legal person***;

Amendment 234

Proposal for a regulation
Article 76 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Personal data, including data concerning health, required for the application of Articles 35, 36, 41 and 47, Article 53(1), points (f) and (g), Article 53(3), and Article 58(11), (13) and (14), shall only be processed for the purpose of ensuring safety and quality of SoHOs and protecting the concerned SoHO donors, SoHO recipients and offspring from medically assisted reproduction. Those data shall be directly related to the performance of the supervisory activities and SoHO activities concerned and be limited to the extent necessary and proportionate for that purpose.	3. Personal data, including data concerning health, required for the application of Articles 35, 36, 41 and 47, Article 53(1), points (f) and (g), Article 53(3), and Article 58(11), (13) and (14), shall only be processed for the purpose of ensuring safety and quality of SoHOs and protecting the concerned SoHO donors, SoHO recipients and offspring from medically assisted reproduction. Those data shall be directly related to the performance of the supervisory activities and SoHO activities concerned and be limited to the extent necessary and proportionate for that purpose. ***The Commission may adopt implementing acts laying down categories of personal data necessary for such processing.*** ***Those implementing acts shall be adopted***

	in accordance with the examination procedure referred to in Article 79(2).

Amendment 235

Proposal for a regulation
Article 76 – paragraph 6

Text proposed by the Commission	*Amendment*
6. In relation to their responsibilities to process personal data to comply with the obligations of this Regulation, the SoHO entities and competent authorities of the Member States shall be regarded as controllers as defined in Article 4, point (7), of Regulation (EU) 2016/679 and they are bound by the rules of that Regulation.	6. In relation to their responsibilities to process personal data to comply with the obligations of this Regulation, the SoHO entities and competent authorities of the Member States shall be regarded as controllers as defined in Article 4, point (7), of Regulation (EU) 2016/679 and they are bound by the rules of that Regulation. ***The same provisions shall apply to any third party contracted by a SoHO entity for the processing of personal data. Such third party shall be considered to be a processor as defined in Article 4, point (8), of Regulation (EU) 2016/679.***

Amendment 236

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 ***Article*** 28(10), ***Article*** 42(3), ***Article*** 53(6), ***Article 56(1), Article*** 58(15), ***Article 62(7), Article 67(7), Article*** 69(6), ***Article*** 73(4), ***Article 74(3)*** and ***Article*** 76(8) shall be conferred on the Commission for an indeterminate period of time from … [OP please insert the date = date of entry into force of this Regulation].

Amendment 237

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 ***Article*** 28(10), ***Article*** 42(3), ***Article*** 53(6), ***Article 56(1), Article*** 58(15), ***Article 62(7), Article 67(7), Article*** 69(6), ***Article*** 73(4), ***Article 74(3)*** and ***Article*** 76(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment 238

Proposal for a regulation
Article 84 – paragraph 1

Text proposed by the Commission	*Amendment*
Without prejudice to the dates of application referred to in Article 87 and the transitional provisions provided for in this Chapter, the Commission is empowered to adopt the delegated acts referred to in ***Articles*** 42(3) ***and*** 73(4) and the implementing acts referred to in ***Articles*** 26(4), 43(6), 44(3)***,*** 46(3)***, 67(7) and 74(3)*** as from … [OP please insert the date = one day after the date of entry into force of this Regulation]. Such acts shall apply from the date of application in accordance with Article 87(1), second subparagraph, without prejudice to any transitional rules provided for in this Chapter.	Without prejudice to the dates of application referred to in Article 87 and the transitional provisions provided for in this Chapter, the Commission is empowered to adopt the delegated acts referred to in ***Article*** 42(3), ***Article 67(7), Article*** 73(4) ***and Article 74(3)*** and the implementing acts referred to in ***Article*** 26(4), ***Article*** 43(6), ***Article*** 44(3) ***and Article*** 46(3) as from … [OP please insert the date = one day after the date of entry into force of this Regulation]. Such acts shall apply from the date of application in accordance with Article 87(1), second subparagraph, without prejudice to any transitional rules provided for in this Chapter.

Amendment 239

Proposal for a regulation
Article 86 – paragraph 1

Text proposed by the Commission	*Amendment*
The Commission shall, by … [OP please insert the date = five years after the date of application of this Regulation] assess the application of this Regulation, produce an evaluation report on the progress towards achievement of the objectives of this Regulation and present the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.	The Commission shall, by … [OP please insert the date = five years after the date of application of this Regulation] assess the application of this Regulation, produce an evaluation report on the progress towards achievement of the objectives of this Regulation and present the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions. ***In that report, the Commission shall also consider the feasibility of and the need for establishing a central register for SoHO donations.***

Amendment 240

Proposal for a regulation
Article 86 – paragraph 3

Text proposed by the Commission	*Amendment*
Member States shall provide the Commission with additional information necessary and proportionate for the preparation of the evaluation report.	Member States shall provide the Commission with additional information necessary and proportionate for the preparation of the evaluation report. ***The evaluation report shall, where appropriate, be accompanied by a legislative proposal to amend this Regulation.***