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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Proposal for a Regulation on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC - 4-column table

Delegations will find enclosed the four column table on the above mentioned proposal. This document contains in Annex A the explanations on the layout of the table used in this document and in Annex B the text of the Commission proposal, the amendments voted by the European Parliament on 12 September 2023 and changes to the proposal approved by the Council on 25 October 2023.

ANNEX A

Explanation of the table layout

	Commission proposal	EP amendments voted on 12 September 2023	Text agreed by the Council on 25 October 2023	Tentatively agreed text, compromise proposals and comments
		Plain text in this column is text from the Commission proposal that the European Parliament proposes to maintain. ***Text in blue underlined bold italics in this column is text that the EP proposes to add to the Commission proposal.*** *Text in red italics ~~strikethrough~~ in this column is text that the EP proposes to delete.* When an empty cell in this column is on the same row as a Commission proposal, it means that that text was not changed by the EP.	Plain text in this column is text from the Commission proposal that Council wishes to maintain. **Text in bold** in this column is text that Council has agreed to add. Text in ~~strikethrough~~ in this column is text that Council has agreed to delete.	*This column will contain comments, compromise proposals and tentatively agreed text.*

ANNEX B

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (Text with EEA relevance)

2022/0216(COD)

[Version for Trilogue on November 6, 2023]

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Formula				
1	2022/0216 (COD)		2022/0216 (COD)	
Proposal Title				
2	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on standards of quality and safety		Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on standards of quality and safety	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (Text with EEA relevance)		for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (Text with EEA relevance)	
Formula				
3	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	
Citation 1				
4	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(4), point (a), thereof,		Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(4), point (a), thereof,	
Citation 2				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
5	Having regard to the proposal from the European Commission,		Having regard to the proposal from the European Commission,	
Citation 3				
6	After transmission of the draft legislative act to the national parliaments,		After transmission of the draft legislative act to the national parliaments,	
Citation 4				
7	Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C , , p. .		Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C , , p. .	
Citation 5				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
8	Having regard to the opinion of the Committee of the Regions[1], _____ 1. OJ C , , p. .		Having regard to the opinion of the Committee of the Regions[1], _____ 1. **[1]** OJ C , , p. .	
Citation 6				
9	Acting in accordance with the ordinary legislative procedure,		Acting in accordance with the ordinary legislative procedure,	
Formula				
10				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Whereas:		Whereas:	
Recital 1				
11	(1) In accordance with Article 168(1), first subparagraph, of the Treaty on the Functioning of the European Union (TFEU) and Article 35 of the Charter of Fundamental Rights of the European Union, a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.		(1) In accordance with Article 168(1), first subparagraph, of the Treaty on the Functioning of the European Union (TFEU) and Article 35 of the Charter of Fundamental Rights of the European Union, a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 2				
12	(2) Article 168(4), point (a), TFEU provides that the European Parliament and the Council should adopt measures setting high standards of quality and safety for organs and substances of human origin (SoHOs), blood and blood derivatives. At the same time, Member States cannot be prevented from maintaining or introducing more stringent protective measures. Pursuant to Article 193 TFEU, Member States are to notify the Commission of any such measures. According to Article 168(7) TFEU, the measures adopted pursuant to Article 168(4),		(2) Article 168(4), point (a), TFEU provides that the European Parliament and the Council should adopt measures setting high standards of quality and safety for organs and substances of human origin (~~SoHOs~~**SoHO**), blood and blood derivatives. At the same time, Member States cannot be prevented from maintaining or introducing more stringent protective measures. ~~Pursuant to Article 193 TFEU, Member States are to notify the Commission of any such measures. According to Article 168(7) TFEU, the measures adopted pursuant to Article 168(4),~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	point (a) should not affect national provisions on the donation or medical use of organs and blood.		~~point (a) should not affect national provisions on the donation or medical use of organs and blood.~~	
Recital 2a				
12a			**(2a) According to Article 168(7) TFEU, the Union should respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. Measures adopted pursuant to Article 168(4), point (a) should not affect national provisions on the donation or medical use of organs and blood.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 3				
13	(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	(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	(3) As regards Article 168(4), point (a), TFEU, standards for the safety and quality of organs and ~~SoHOs~~**SoHO**, blood and blood derivatives should ensure a high level of human health protection. Therefore, this Regulation aims at setting high standards ~~by~~**of quality and safety of SoHO and** 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~~**. This Regulation also sets** measures to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	that are critical for the health of patients.	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.***	monitor and support ~~the~~ sufficiency ~~of~~**in** the supply of ~~SoHOs~~**SoHO** that are critical for the health of patients.	
Recital 4				
14	(4) Directives 2002/98/EC[1] and 2004/23/EC[2] of the European Parliament and of the Council constitute the Union's regulatory framework for blood and for tissues and cells, respectively.	(4) Directives 2002/98/EC[1] and 2004/23/EC[2] of the European Parliament and of the Council constitute the Union's regulatory framework for blood and for tissues and cells, respectively.	(4) Directives 2002/98/EC[1] and 2004/23/EC[2] of the European Parliament and of the Council constitute the Union's regulatory framework for blood and for tissues and cells, respectively.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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	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	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~~**has resulted** 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~~**of all SoHO**, enhances legal certainty **for patients and stakeholders**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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. _____ 1. 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).	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. _____ 1. 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	**involved** 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. _____ 1. 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	2. 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).	(OJ L 33, 8.2.2003, p. 30). 2. 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).	(OJ L 33, 8.2.2003, p. 30). 2. 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).	
Recital 5				
15	(5) Directives 2002/98/EC and 2004/23/EC are highly	(5) Directives 2002/98/EC and 2004/23/EC are highly	(5) Directives 2002/98/EC and 2004/23/EC are highly	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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***.	interconnected and contain very similar provisions for oversight and equivalent principles for ~~safety and quality~~**quality and safety** 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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 6				
16	(6) This Regulation should apply to blood and blood components, as regulated by Directive 2002/98/EC, as well as to tissues and cells, including haematopoietic peripheral blood, umbilical-cord blood and bone-marrow stem cells, reproductive cells and tissues, foetal tissues and cells and adult and embryonic stem cells, as regulated by Directive 2004/23/EC. Since donation and human application of SoHOs other than blood, tissues and cells are increasingly common, it is necessary to extend the scope of this Regulation to any SoHO,		(6) This Regulation should apply to blood and blood components, as regulated by Directive 2002/98/EC, as well as to tissues and cells, including haematopoietic peripheral blood, umbilical-cord blood and bone-marrow stem cells, reproductive cells**, tissues and embryos** ~~and tissues~~, foetal tissues and cells and adult and embryonic stem cells, as regulated by Directive 2004/23/EC. Since donation and human application of ~~SoHOs~~**SoHO** other than ~~blood, tissues and cells~~**those regulated by Directives 2002/98/EC and 2004/23/EC** are increasingly	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	regardless of whether it meets the definition of 'blood', 'tissue' or 'cell', to avoid that certain groups of donors or recipients are not protected by an appropriate Union level quality and safety framework. This will, for example, ensure the protection of donors and recipients of human breast milk, intestinal microbiota, blood preparations that are not used for transfusion, and any other SoHO that may be applied to humans in the future.		common, it is necessary to extend the scope of this Regulation to any SoHO, ~~regardless of whether it meets the definition of 'blood', 'tissue' or 'cell', to avoid that certain groups of donors or recipients~~**in order to avoid that certain groups of SoHO donors or SoHO recipients and offspring from medically assisted reproduction** are not protected by an appropriate Union level quality and safety framework. This will, for example, ensure the protection of **SoHO** donors and **SoHO** recipients of human breast milk, intestinal microbiota, blood preparations that are not used for transfusion, and any other SoHO that may be applied to humans in the future.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 7				
17	(7) Solid organs are excluded from the definition of SoHOs for the purposes of this Regulation and, thus, from its scope. Their donation and transplantation are significantly different and are regulated in a dedicated legal framework, set out in Directive 2010/53/EU[1] of the European Parliament and of the Council. Shortcomings have not been raised regarding the existing quality and safety provisions for organs. Nonetheless, when organs are removed from a donor for the		(7) Solid organs are excluded from the definition of ~~SoHOs~~**SoHO** for the purposes of this Regulation and, thus, from its scope. Their donation and transplantation are significantly different**, determined, inter alia, by the effect of ischemia in the organs,** and are regulated in a dedicated legal framework, set out in Directive 2010/53/EU[1] of the European Parliament and of the Council. ~~Shortcomings have not been raised regarding the existing quality and safety provisions~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	purposes of separating tissues or cells for human application, for example heart valves from a heart or pancreatic islets from a pancreas, this Regulation should apply. _____ 1. Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14).		~~for~~**Composite vascular allografts such as hands or faces should be considered to meet the definition of** organs**, as indicated in that Directive**. Nonetheless, when organs are removed from a **SoHO** donor for the ~~purposes~~**purpose** of separating tissues or cells for human application, for example heart valves from a heart or pancreatic islets from a pancreas, this Regulation should apply. _____ 1. Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207,	

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			6.8.2010, p. 14).	
Recital 7a				
17a			**(7a) While the donation and banking of human breast milk should be regulated to prevent disease transmission and ensure safety and quality, the feeding of the own infant with one's own breast milk should not fall within the scope of this Regulation. This includes also personal situations where one's own breast milk is handled or stored in a communal facility, such as a hospital, childcare facility or workplace, since it would be**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			disproportionate to apply the provisions of this Regulation to those settings. However, if one's own breast milk is processed by a specialised SoHO entity, in particular if it is pasteurised, the provisions of this Regulation should apply.	
Recital 8				
18	(8) Ensuring the quality and safety of SoHOs is crucial, especially where such substances interact with the body of the recipient. Hence, this Regulation should not cover the placing of a substance on the body when it does not have any		(8) Ensuring the quality and safety of ~~SoHOs~~**SoHO** is crucial~~,~~ ~~especially where~~ **when** such substances interact with the body of the **SoHO** recipient **or of recipients receiving products manufactured from SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	biological or physiological interaction with that body, such as in the case of wigs made from human hair.		**regulated by other Union legislation**. Hence, this Regulation should not cover the placing of a substance on the body when it does not have any biological ~~or physiological~~ interaction with that body, such as in the case of wigs made from human hair.	
Recital 9				
19	(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	(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	(9) All ~~SoHOs~~**SoHO** that are intended to be applied to humans fall within the scope of this Regulation. ~~SoHOs~~**SoHO** can be prepared and stored in a variety of ways, becoming SoHO preparations, which can be applied	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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[1], on medicinal products, regulated by Directive 2001/83/EC of the European Parliament and of the Council[2] and by Regulation (EC) No 726/2004 of the European Parliament and of the Council[3], including on advanced therapy medicinal products, regulated by	and stored in a variety of ways, becoming SoHO preparations, which can be applied to recipients. In these circumstances, this Regulation should apply to all activities from donor recruitment to human application and outcome monitoring. SoHOs or SoHO preparations can also be used to manufacture products regulated by other Union legislation, or as the starting and raw material thereof, in particular on medical devices, regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council[1], on medicinal products, regulated by Directive 2001/83/EC of the European Parliament and of the Council[2] and by Regulation (EC) No 726/2004 of the European	to **SoHO** recipients. In these circumstances, this Regulation should apply to all activities from **SoHO** donor ~~recruitment~~**registration** to human application and **clinical** outcome monitoring~~. SoHOs or SoHO preparations~~ **registration. SoHO** 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[1], on medicinal products, regulated by Directive 2001/83/EC of the European Parliament and of the Council[2] ~~and by Regulation (EC) No 726/2004 of the European Parliament and of the Council[3],~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Regulation (EC) No 1394/2007 of the European Parliament and of the Council[4], or on food, regulated by Regulation (EC) No 1925/2006 of the European Parliament and of the Council[5]. 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. _____ 1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending	Parliament and of the Council[3], including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007 of the European Parliament and of the Council[4], or on food, regulated by Regulation (EC) No 1925/2006 of the European Parliament and of the Council[5]. 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. _____ 1. Regulation (EU) 2017/745 of	~~including ~~**,** on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007 of the European Parliament and of the Council[4]~~, or on food, regulated by Regulation (EC) No 1925/2006 of the European Parliament and of the Council[5]. The criteria that define when SoHOs or SOHO preparations become~~[3] and investigational medicinal products ~~regulated under other Union legislation are not~~**, as** defined in ~~this~~ Regulation ~~but are defined in those other acts. In addition, ~~**(EU) No 536/2014.** This Regulation should apply without prejudice to Union legislation on genetically modified organisms. _____	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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). 2. 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). 3. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union	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). 2. 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). 3. Regulation (EC) No 726/2004	1. 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). 2. 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).	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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). 4. 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). 5. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of	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). 4. 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).	3. Regulation (EC) ~~No 726/2004~~**No 1394/2007** of the European Parliament and of the Council of ~~31 March 2004 laying down Union procedures for the authorisation and supervision of~~**13 November 2007 on advanced therapy** medicinal products ~~for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1)~~**and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121)**. ~~4. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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).	5. 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).	~~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).~~ ~~5~~. ~~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).~~	
Recital 9a				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
19a			**(9a) Many activities that are carried out, from the moment of the registration of a potential SoHO donor to the use of SoHO in a recipient, or from the moment of collection of SoHO from an individual for application to themselves or from individuals or couples as part of their own current or future medically assisted reproduction treatment, have an impact on safety, quality or effectiveness of SoHO or the safety of SoHO donors.**	
Recital 9b				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
19b			**(9b) Organisations that register prospective SoHO living donors, recording the information needed to identify a match with prospective recipients in the same Member State, or internationally, should be considered as SoHO entities. The registering of individuals that indicate their consent to donate tissues after death, or from whom donation is permitted in accordance with national legislation, should not be considered as SoHO donor registration within this Regulation and should not, therefore, require the organisation carrying out that**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			activity to register as a SoHO entity.	
Recital 9c				
19c			**(9c) The gathering of SoHO donor history and conduct of medical examinations to establish the eligibility of a prospective SoHO donor is an activity that can have an impact on the quality and safety of SoHO and, as such, should be considered a SoHO activity.**	
Recital 9d				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
19d			**(9d) Testing for infectious disease status, or for the purposes of matching a SoHO donor with a specific recipient is an activity with a high degree of impact on the safety of SoHO and, as such, it should be considered a SoHO activity. Hence, laboratories that carry out such testing should also be registered as SoHO entities. While such testing is generally for the purposes of protecting the SoHO recipient, infectious disease testing of individuals prior to the storage of SoHO collected from them, for the purposes of subsequent re-application to them, is important**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			to prevent cross-contamination between such SoHO while in storage. Therefore, this testing should include both the autologous and allogeneic contexts.	
Recital 9e				
19e			**(9e) Collection of SoHO involves risks both to SoHO donors and to individuals from whom SoHO are being collected for subsequent re-application to them or individuals or couples from whom SoHO are collected as part of their own current or future medically assisted**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			reproduction treatment. As such, it should be considered as a SoHO activity. For the purposes of this Regulation and in the interest of ensuring comprehensive SoHO donor protection, the activity should be understood to include the pre-treatment of individuals with hormones, growth factors or other medicinal products, that is required to make the collection possible.	
Recital 9f				
19f			**(9f) SoHO are frequently processed prior to distribution**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			or, in the autologous context, prior to human application. Processing can have objectives such as preservation by, for example, cooling, freezing or freeze-drying; pathogen inactivation, by, for example, washing, antibiotic decontamination or sterilisation; or, physical separation or purification into selected elements by, for example, centrifugation of blood to prepare red cell concentrates, platelet concentrates and plasma as separate components. If not performed correctly and in a consistent manner, processing steps carry risks of contamination or of changing the inherent properties of SoHO in a	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			manner that might reduce their effectiveness. Therefore, they should be considered SoHO activities and any entity performing SoHO processing should be subject to appropriate oversight, including by being authorised for the corresponding SoHO preparation. In cases where a surgical team prepares distributed SoHO for human application, without removal from the surgical field and immediately prior to the application, such preparatory handling should not be considered processing for the purposes of this Regulation. Such preparatory handling might include rinsing or rehydration, in accordance with the instructions	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			provided with the SoHO, or cutting and shaping to render the SoHO suitable for the intended use in the SoHO recipient, for allogenic or autologous use. In addition, in the autologous context, the preparation of SoHO during and for the purpose of application as part of the same surgical intervention in which they were collected and without removal from the surgical field should not be considered as processing for the purposes of this Regulation. **The necessary procedures to be carried out, in accordance with the instructions provided with the preparation, immediately prior to human application, of released and distributed SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			should not be considered as processing for the purposes of this Regulation. Mixing of released human breast milk with medication before human application should also not be considered as processing.	
Recital 9g				
19g			**(9g) Quality control is a key element of a quality management system that is critical for the safe release of SoHO for human application or for distribution or export. As the tests and checks performed as part of quality control are sometimes carried**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			out in dedicated quality control laboratories or departments, the activity should be considered as a SoHO activity and to allow appropriate oversight, such laboratories or departments should be registered as SoHO entities.	
Recital 9h				
19h			**(9h) SoHO are stored in SoHO establishments prior to their release. For the purposes of this Regulation, storage refers to maintaining particular environmental conditions, such as temperature, that were**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			established during the preservation step of processing and that ensure that the quality of SoHO will be maintained. The storage of released and distributed SoHO in a hospital, for example, should also be considered a SoHO activity.	
Recital 9i				
19i			**(9i) As the activity of release is a critical step that allows SoHO to be moved from a 'quarantined' to an 'available for use' status, it should be considered a SoHO activity. Any SoHO entity carrying out release should be**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			authorised as a SoHO establishment. SoHO that are distributed or exported should first have been subjected to a formal release step. In cases where the receiving entity carries out a further processing step on released and distributed SoHO, those SoHO should be subjected to a second release step prior to re-distribution. In the case of autologous, bedside or in-surgery, processing of SoHO without storage, it would be impractical to require a formal release step prior to the re-application of the SoHO preparation to the recipient. In such cases, quality control steps and checks should instead be incorporated in the processing	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			steps that have been authorised. This should allow consistent quality criteria to be achieved without the need for a release activity in these circumstances.	
Recital 9j				
19j			**(9j) SoHO distributed for human application might be intended for an individual SoHO recipient and be distributed on the basis of a medical prescription. Alternatively, SoHO may be distributed in batches to be stored as a local stock to be used, as required, in an entity carrying out**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			application. In such cases, the distributed SoHO should not be released a second time but their provision to individual SoHO recipients, in some cases involving a biological matching step, should be considered as another distribution step.	
Recital 9k				
19k			**(9k) The import of SoHO should include a formal verification that the quality, safety and effectiveness of the imported SoHO are equivalent to those of SoHO provided in the Union in accordance with this Regulation.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			As such, import should be considered a SoHO activity with a significant impact on quality and safety and entities performing import should be authorised as SoHO establishments. Following import, SoHO should be subject to release, prior to distribution within the Union. In certain cases, and in particular in the case of haematopoietic stem cells, national and international donor registries play a key role in the organisation of the import of matching stem cells for individual SoHO recipients in the Union. Such registries verify equivalence of quality and safety to the standards of this Regulation. As such, registries	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			organising import of SoHO should be authorised as importing SoHO establishments. In those cases, it should be possible for the SoHO to be received by the transplanting centres and the steps of physical checking of the imported SoHO and their documentation to be delegated by the authorised registry to the SoHO entity receiving and applying the SoHO to the SoHO recipient.	
Recital 9l				
19l			**(9l) All SoHO being exported from the Union should first**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			require a release to confirm compliance with the quality and safety provisions of this Regulation. Such SoHO activity may have an impact on SoHO supply within the Union. Therefore, organisations exporting SoHO should be authorised as SoHO establishments.	
Recital 9m				
19m			**(9m) In the context of this Regulation, the term effectiveness should be considered to include an expected response in a SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			recipient that is measurable in degree, such as an engraftment of bone marrow cells after transplant, or an expected result in a SoHO recipient that is successful or not, but cannot be measured in degree, such as cornea or bone transplant success or failure, and which is evaluated in accordance with a previously approved clinical monitoring plan, when such a plan is required.	
Recital 9n				
19n			**(9n) Human application of SoHO is an activity that is within**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			the scope of this Regulation with limited associated provisions. Organisations applying SoHO to SoHO recipients are subject to provisions concerning traceability, reporting activity data and notifying adverse reactions or events, where relevant, and monitoring clinical outcomes when applying SoHO in the context of a plan for SoHO preparation authorisation. There are also obligations relating to not applying SoHO unnecessarily and to obtaining recipient consent. However, the clinical decisions relating to SoHO application and the clinical procedures for applying SoHO fall outside the scope of this Regulation and are governed by	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Member State rules on the organisation of their healthcare systems.	
Recital 9o				
19o			**(9o) Most aspects of the monitoring of SoHO recipients, following surgical and other interventions, are outside the scope of this Regulation and fall under healthcare responsibilities. However, certain obligations of this Regulation should apply to SoHO recipient outcome monitoring in the context of the application of SoHO to SoHO recipients as part of a plan to**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			generate evidence for SoHO preparation authorisation. Clinical registries to record the clinical data generated during the clinical outcome monitoring are useful tools that allow for more efficient data collection from aggregated groups of SoHO recipients, applying standardised outcome measurements and reflecting outcomes in the 'real world' setting. Managing such registries should be considered a SoHO activity, as it ensures that data quality and data management procedures are robust and allow the data to be used for the purposes of SoHO preparation authorisation. The transfer of such outcome data from local or national registries	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			to international registries should be promoted as it facilitates the aggregation and analysis of significantly larger data cohorts of SoHO recipients and can contribute to earlier authorisations and access to SoHO therapies.	
Recital 9p				
19p			**(9p) Individuals from whom SoHO are collected for subsequent application as part of their own treatment, or individuals or couples from whom SoHO are collected as part of their own current or**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			future medically assisted reproduction treatment, should not be considered as SoHO donors in the context of this Regulation. The protection of the health of such individuals being treated in the autologous or in-couple settings is the responsibility of the national healthcare system and applying provisions targeted to the protection of SoHO donors, for example monitoring such individuals on SoHO donor registries, would be disproportionate. However, when the SoHO collected from such individuals are processed or stored, their quality and safety should be ensured. In particular, contamination from the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			environment or cross-contamination with infectious pathogens from other SoHO should be prevented and there should be full traceability to avoid mix-ups. Therefore, individuals from whom SoHO are collected in the autologous context or in the medically assisted reproduction context are not addressed in the SoHO donor protection provisions of this Regulation, but are deemed duly protected under the SoHO recipient provisions.	
Recital 10				
20				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(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	(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	(10) When ~~SoHOs~~**SoHO** 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~~**In certain cases, such**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	properties inherent to the substance, and necessary for efficacy in the recipient, also appear. Thus, the requirements for SoHO establishment authorisation should apply.	and effective for the recipient. When autologous SoHOs are collected to be 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.	**as hemodialysis at the bedside, or at home, or red cell salvage during surgery, closed system medical devices are used in autologous context. Where such a closed system medical device has been CE marked for the specific purpose, and has therefore been demonstrated to achieve the intended result, and where the process carried out within the device does not meet the criteria for classification under another regulatory framework, this should be seen as analogous to non-removal from the surgical field and should not be considered as falling within the scope of this Regulation. However, this Regulation should apply** to the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~biological properties inherent to the substance, and necessary for efficacy in the recipient, also appear. Thus, the requirements for SoHO establishment authorisation should apply~~**processing of SoHO at the bedside or in the same surgical procedure by using medical devices for which quality, safety and effectiveness have not been proven as part of the CE marking process for that specific purpose**.	
Recital 10a				
20a			**(10a) When autologous SoHO are collected and processed**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			before being applied again in the same person and without storage, risks associated with the processing should be mitigated. Therefore, there should be an assessment and authorisation of the processes applied to ensure that they are demonstrated to be safe and effective for the SoHO recipient. In such cases, the SoHO preparation authorisation should specify the required quality control checks to be performed during the process, and therefore, no release step should be required before application to the SoHO recipient. Such situation should also apply to the specific case of intra-uterine insemination within couple use, when SoHO are	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			collected and processed from one of the partners before being applied to the other partner, without storage. When autologous SoHO, or SoHO for use within couples, 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 effectiveness in the SoHO recipient, also appear. Thus, the requirements for SoHO release and for SoHO establishment authorisation should apply in those circumstances.	
Recital 11				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
21	(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	(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***	(11) When ~~SoHOs are used~~**SoHO are distributed** 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~~**the provisions laid down in this Regulation that aim to protect SoHO recipients should** contribute~~ to legal clarity and certainty, this Regulation should apply~~**, also,** 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~~**objectives of the legislative measures in those**	

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	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.	***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***	**other frameworks to ensure a high level of protection of recipients of those products manufactured using SoHO. Thus, without prejudice** to Directive 2001/83/EC~~,~~ **and** Regulations (EC) ~~No 726/2004, (EC~~**No 1394/2007, (EU)** ~~No 1925/2006, (EC) No 1394/2007 and (EU) 2017/745, this Regulation should at least apply~~**2017/745 and (EU) No 536/2014 rules laid down in this Regulation shouldapply** to the ~~recruitment and selection of~~**registration and evaluation of SoHO** donors, ~~donation, collection and~~**SoHO** donor testing**, collection** as well as to ~~release,~~ ~~distribution~~**storage, release**, import and export ~~when those~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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).	~~activities concern SoHOs up to the point of their transfer to operators~~**until the SoHO are distributed to a manufacturer** 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.	
Recital 11a				
21a			**(11a) In many Member States, military organisations are active in carrying out SoHO activities,**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			in particular in the collection, processing, storage, testing and distribution of blood and blood components. These organisations and their SoHO activities should be regulated by this framework to ensure equivalent levels of donor and recipient protection as that provided by civil services. However, making public the locations and activities of these organisations is likely to compromise the defence, national security or public security. Therefore, the reporting and oversight provisions of this Regulation should apply to these organisations, but the publication of associated information should not be obligatory.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 12				
22	(12) SoHOs can also be combined with other regulated products before human application. In these circumstances, close interaction between this regulatory framework and other related frameworks is also necessary to ensure a high level of human health protection for all cases where these substances are used.		(12) ~~SoHOs can also~~**SoHO can** be combined with other regulated products before human application. In these circumstances, close interaction between this regulatory framework and other related frameworks is also necessary to ensure a high level of human health protection for all cases where these substances are used.	
Recital 13				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
23	(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	(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. ~~*As different types of*~~	(13) Given the special nature of ~~SoHOs~~**SoHO**, resulting from their human origin, and the increasing demands for these substances for human application**, including through** ~~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 **living SoHO** donors as well as for recipients **and offspring from medically assisted reproduction. SoHO**~~. 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	~~*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*~~***where the*** donation involves ~~*some*~~***significant*** risk to the donor's health ~~*due to*~~***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*** ~~*or a need*~~ for donors to donate ~~*repeatedly. Donations of oocytes, bone marrow, peripheral blood stem cells and plasma*~~***frequently, for example in the case of plasma.***	therefore include principles and technical rules to monitor and protect **living SoHO** donors. As different types of **SoHO** donation imply different risks for **SoHO** donors, with varying levels of significance, the monitoring of **SoHO** donor**'s** health should be proportionate to those levels of risk. This is particularly important when donation involves some risk to the **SoHO** 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~~**repeated collections from the same donor. Collections** of oocytes, bone marrow, peripheral blood stem cells and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		As different types of donation entail different risks for donors, with varying levels of significance, the monitoring of donor health should be ~~*considered to imply a significant*~~***proportionate to those levels of*** risk.	plasma should be considered to imply a ~~significant~~**non-negligible** risk.	
Recital 14				
24	(14) When a harmful genetic condition is detected in the offspring resulting from medically assisted reproduction with third party donation, the transmission of that information enables the prevention of further use of donations affected by that genetic		(14) When a ~~harmful~~**serious** genetic **disorder that might result in a life-threatening, disabling or incapacitating** condition is detected in the offspring resulting from medically assisted reproduction with third party donation, the transmission of that	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	risk. It is thus important that relevant information in such cases is effectively communicated between SoHO entities and acted upon appropriately.		information enables the prevention of further use of donations affected by that genetic risk. It is thus important that relevant information in such cases is effectively communicated between SoHO entities and acted upon appropriately.	
Recital 15				
25	(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.	(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***.	(15) This Regulation does not prevent Member States from maintaining or introducing more stringent protective measures ~~that are compatible with Union law.~~**. If they do so,** Member States should ~~notify the Commission of any such~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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	~~measures~~**make such measures public for the purposes of transparency**. More stringent protective measures put in place by Member States should be ~~evidence-based~~ **compatible with Union law,** 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. **Such measures could include, for**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.***	**instance, the presence of or the access to qualified medical professionals where SoHO collection takes place.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 16				
26	(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	(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*** ~~*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	(16) This Regulation should not interfere with national legislation in the health area with objectives other than quality and safety of ~~SoHOs~~**SoHO,** that is compatible with Union law, in particular legislation concerning **health care organisation or** 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 **SoHO or** particular services that use ~~SoHOs~~**SoHO**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	interfere with decisions of an ethical nature made by Member States***. 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.	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~~**SoHO**, including reproductive ~~cells~~**SoHO** 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. **However, this Regulation does not require a specific use, the distribution or the import, of SoHO where prohibited under national legislation concerning ethical aspects.**	

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

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 18				
28	(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[1], that while financial gain should be avoided, it may also be necessary to ensure that donors are	(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 ~~can~~	(18) **Article 3 of the Charter of Fundamental Rights of the European Union prohibits the making of the human body and its parts, as such, a source of financial gain. The use of financial incentives for SoHO donations can have an impact on the quality and safety of SoHO, posing risks to the health of both SoHO donors and recipients and therefore to the protection of human health. Without affecting national responsibilities on the definition of health policies, the organisation and delivery of health services and medical care,**	

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	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. _____ 1. Council of Europe Committee on Bioethics (DH-BIO). Guide for the implementation of the principle of prohibition of	~~*contribute*~~***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[1], that while financial gain should be avoided, it may also be ~~*necessary*~~***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***	**as well as provisions on**~~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~~**of SoHO, such donation should, as a matter of principle, be voluntary and unpaid, and be founded on the principles of altruism of the donor and solidarity between donor and recipient**. It is ~~also~~**however** recognised, including by the Council of Europe– Committee on	

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	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.	***pose risks, in particular donating*** more frequently than is allowed, ~~*posing risks*~~ 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 ~~*reach such objectives*~~***respect the***	Bioethics[1], that while ~~financial gain should be avoided~~**it is important to avoid financial gain**, it may also be ~~necessary~~**appropriate to take measures** to ensure that donors are not financially disadvantaged**.** **Therefore, the reimbursement of SoHO donors for actual expenses incurred in connection with SoHO donation or the compensation of SoHO donors for losses related to donation are acceptable practices, as long as these measures ensure financial neutrality. For feasibility purposes, it is reasonable that compensation may be provided in the form of a fixed allowance, based on average estimates of losses and expenses. When**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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. _____ 1. 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.	**Member States decide to reimburse or compensate SoHO donors, the conditions for such reimbursement or allowances, including the setting of an upper limit that ensures financial neutrality, should be defined at a Member State** ~~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**.** **Member States may delegate the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			setting of such conditions to independent bodies ~~appropriate in their Member State to reach such objectives~~. _____ ~~1~~. ~~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.~~	
Recital 18a				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
28a		***(18a) As indicated by the Council of Europe Committee on Bioethics[24a], it should be possible to compensate donors for any quantifiable expenses and losses, financial or non-financial, that they incur as a result of a donation. When calculating such compensation, SoHO entities should be able to take into account non-financial variables to determine the appropriate level and form of compensation to be given to donors, as long as such compensation complies with the principle of voluntary and unpaid donation laid down in this Regulation.***	**(18a) SoHO entities should not offer inducements to potential SoHO donors or to those giving consent on their behalf as such an action would be contrary to the principle of voluntary and unpaid donation. Refreshments and small gifts, such as pens or badges, should not be considered as inducements and the practice of offering them to SoHO donors is acceptable as a recognition of their efforts. Rewards or benefits such as payment of funeral expenses, or payment of health insurance unrelated to the SoHO collection should be considered as inducements, and as such contrary to the principle of**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		_____ ***24a. Council of Europe Committee on Bioethics, Guide for the implementation of the principle of prohibition of financial gain with respect to the human body and its parts from living or deceased donors, March 2018. Available at: https://rm.coe.int/guide-financial-gain/16807bfc9a.***	**voluntary unpaid donation and should not be permitted. Additionally, any advertising of SoHO donations by means of a reference to a financial reward should be subject to appropriate restrictions or prohibitions, and recruitment campaigns and promotion and publicity activities should not refer to any compensation.**	
Recital 18b				
28b			**(18b) In order to comply with the principle that the human**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			body and its parts shall not, as such, give rise to financial gain and thus support a donation system that SoHO donors and SoHO recipients can trust, Member States should take measures to ensure that SoHO entities are transparent in the calculation of fees for their services and the financial management of their services. These services refer, among other things, to the cost of testing, processing, storage, distribution, personnel and transportation, infrastructure and administration, and the need to invest in state-of-the-art processes and equipment to ensure the long-term sustainability of the services	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			offered.	
Recital 19				
29	(19) In order to maintain public trust in SoHO donation and use programmes, information that is given to prospective donors, recipients or physicians regarding the likely use and benefits of particular SoHOs or SoHO preparations when applied to recipients should accurately reflect reliable scientific evidence. This should ensure that donors, or their families, are not coerced to donate by exaggerated descriptions of benefits and prospective patients	(19) In order to maintain public trust in SoHO donation and use programmes, information that is given to prospective donors, recipients or physicians regarding the likely use and benefits of particular SoHOs or SoHO preparations when applied to recipients should accurately reflect reliable scientific evidence ***and under no circumstances attribute or imply levels of safety or efficacy that are not supported by scientific methods***. This should ensure that	(19) In order to maintain public trust in SoHO donation and use programmes, information that is given to prospective **SoHO** donors, **SoHO** recipients or physicians regarding the likely use and benefits of particular ~~SoHOs or SoHO preparations~~**SoHO** when applied to **SoHO** recipients should accurately reflect reliable scientific evidence. This should ensure that **SoHO** donors, or their families, are not coerced to donate by exaggerated descriptions of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	donors, or their families, are not coerced to donate by exaggerated descriptions of benefits and prospective ~~*patients*~~***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.	benefits and prospective ~~patients~~**SoHO 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.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 19a				
29a			**(19a) The verification of compliance with this Regulation through SoHO supervisory activities is of fundamental importance to ensure that, across the Union, the objectives of the Regulation are effectively achieved. SoHO competent authorities should monitor and verify, through the organisation of SoHO supervisory activities, that relevant Union requirements are effectively complied with and enforced.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 20				
30	(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	(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	(20) **SoHO** competent authorities should be designated by the Member States for all the areas that fall within the scope of this Regulation. ~~While~~**Since** Member States are best placed to identify the **SoHO** competent authority or authorities for each area, for example by geography, topic or substance, they should also be required to designate a single **SoHO** National Authority that ensures appropriately coordinated communication with other Member States' ~~competent~~**SoHO National**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	National Authority should be considered the same as the designated competent authority in Member States where only one competent authority is designated.	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.***	Authorities and with the Commission**, as well as other tasks pursuant to this Regulation**. The SoHO National Authority should be considered the same as the designated **SoHO** competent authority in Member States where only one **SoHO** competent authority is designated. **The designation of a single SoHO National Authority should not preclude Member States from assigning certain tasks to other SoHO competent authorities of that Member State, in particular for certain tasks where there is a need to ensure an efficient or agile communication with the Commission or other Member States.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 21				
31	(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	(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 ~~*interference*~~***or other actors*** that	(21) For the performance of **SoHO** supervisory activities aimed at verifying the correct application of SoHO legislation, Member States should designate **SoHO** 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, **SoHO** competent authorities should be free from undue political influence and from industry interference that might affect their	

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	impartiality.	might affect their operational impartiality.	operational impartiality.	
Recital 22				
32	(22) For the performance of supervisory activities aimed at verifying the correct application of SoHO legislation, Member States should designate competent authorities that act in the public interest, are appropriately resourced and equipped, and offer guarantees of impartiality, professionalism and transparency. When infringements relate to direct health risks, and the publication of information regarding those		(22) For the performance of **SoHO** supervisory activities aimed at verifying the correct application of SoHO legislation, Member States should designate **SoHO** competent authorities that act in the public interest, are appropriately resourced and equipped, and offer guarantees of impartiality, professionalism and transparency. When infringements relate to ~~direct~~ health risks, and the publication of information regarding those	

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	infringements can contribute to risk mitigation and the protection of donors, recipients or offspring from medically assisted reproduction, competent authorities should, where necessary, be able to prioritise transparency of their enforcement activities over the protection of confidentiality of the party that has infringed the Regulation.		infringements can contribute to risk mitigation and the protection of **SoHO** donors, recipients~~ or~~**,** offspring from medically assisted reproduction **or public health, SoHO** ~~,~~competent authorities should, where necessary, be able to prioritise transparency of their enforcement activities over the protection of confidentiality of the ~~party~~**one** that has infringed the Regulation.	
Recital 22a				
32a			**(22a) In carrying out their SoHO supervisory activities, SoHO competent authorities**	

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			should ensure transparency. Nonetheless, professional and legal rights should be protected by ensuring confidentiality of the information discussed in the course of inspections and other supervisory activities. However, when a serious risk to human health is detected that results in the SoHO competent authorities taking enforcement action, they should give priority to transparency over confidentiality. Circumstances such as the detection of an entity offering services to the public without the required registration, and without complying with standards for SoHO recipient protection such as infectious disease testing,	

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			should be considered as posing a serious risk to human health and should be made available to the public.	
Recital 23				
33	(23) The correct application and enforcement of the rules falling within the scope of this Regulation require an appropriate knowledge of those rules. It is therefore important that the staff performing supervisory activities have an appropriate professional background and are regularly trained, in accordance with their area of competence, on the		(23) The correct application and enforcement of the rules falling within the scope of this Regulation require an appropriate knowledge of those rules. It is therefore important that the staff performing **SoHO** supervisory activities have an appropriate professional background and are regularly trained, in accordance with their area of competence, on the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	obligations resulting from this Regulation.		obligations resulting from this Regulation.	
Recital 24				
34	(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	(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, ***advanced therapies,*** medical devices, organs or food, ***and the SoHO Coordination Board (SCB),*** with the aim of ensuring coherent procedures for	(24) When there is doubt about the regulatory status of a particular substance, product or activity under this Regulation, **SoHO** competent authorities should consult with the relevant authorities responsible for other relevant regulatory frameworks, namely ~~medicinal products,~~ medical devices, ~~organs or food~~**medicinal products or advanced therapy medicinal products**, -with the aim of	

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	inform the SoHO Coordination Board of the outcome of their consultations. When SoHOs or SoHO preparations are used to manufacture products regulated under other Union legislation, or as the starting and raw material thereof, competent authorities should cooperate with the relevant authorities on their territory. This cooperation should aim to reach an agreed approach for any subsequent communications between the authorities responsible for SoHO and for the other relevant sectors, as needed, regarding authorisation and monitoring of the SoHOs or the product manufactured from SoHOs. It should in principle be the responsibility of the Member States	the application of this Regulation ***and other relevant Union legislation***. Competent authorities should inform the ~~*SoHO Coordination Board*~~***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 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	ensuring coherent procedures for the application of this Regulation. **SoHO** competent authorities should inform the SoHO Coordination Board of the outcome of their consultations. When ~~SoHOs or SoHO preparations~~ **SoHO** are used to manufacture products regulated under other Union legislation, ~~or as the starting and raw material thereof,~~**SoHO** 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 **SoHO competent** authorities ~~responsible for SoHO and~~**and the authorities** for the other relevant sectors, as needed~~,~~	

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	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.	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*~~***should respect the SCB's opinion*** on the regulatory status of ~~*a substance, product or activity*~~***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.	~~regarding authorisation and monitoring of the SoHOs or the product manufactured from SoHOs~~. It should ~~in principle be the~~ **be** 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~~ **upon a** duly substantiated request of a Member State, **or may on its own initiative,** decide on the regulatory status of a particular substance, product or activity under this Regulation.	

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Recital 25				
35	(25) Competent authorities should perform supervisory activities regularly, on the basis of a risk assessment and with appropriate frequency, on entities and activities governed by this Regulation. The frequency of supervisory activities and the mode, whether on-site or by remote document review, should be established by the competent authorities, having regard to the need to adjust the control effort to the risk and to the level of compliance expected in the different situations, including the		(25) **SoHO** competent authorities should perform **SoHO** supervisory activities regularly, on the basis of a risk assessment and with appropriate frequency, on **SoHO** entities and activities governed by this Regulation. The frequency of **SoHO** supervisory activities and the mode~~, whether on-site or by remote document review~~ **inspections are carried out**, should be established by the **SoHO** competent authorities, having regard to the need to adjust the ~~control effort~~**degree of control** to	

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	possible violations of this Regulation perpetrated through fraudulent or other illegal practices and previous compliance history. Accordingly, the likelihood of non-compliance with all the areas of this Regulation should be taken into account when scheduling supervisory activities.		the risk and to the level of compliance expected in the different situations, including the possible violations of this Regulation perpetrated through fraudulent or other illegal practices and previous compliance history. Accordingly, the likelihood of non-compliance with all the areas of this Regulation should be taken into account when scheduling **SoHO** supervisory activities.	
Recital 26				
36	(26) Commission experts should be able to perform controls, including audits, in Member States	(26) Commission experts should ***have the necessary experience and knowledge to*** be able to perform	(26) ~~Commission experts~~**The Commission** should be able to perform ~~controls, including audits,~~	

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	to verify the effective application of the relevant requirements of competent authorities and of the supervisory activity systems. Commission controls should also serve to investigate and collect information on enforcement practices or problems, emergencies and new developments in Member States. Official controls should be performed by personnel who are independent, free from any conflict of interest and in particular who are not in a situation which, directly or indirectly, could affect their ability to carry out their professional duties in an impartial manner.	controls, including audits, in Member States to verify the effective application of the relevant requirements of competent authorities and of the supervisory activity systems. Commission controls should also serve to investigate and collect information on enforcement practices or problems, emergencies and new developments in Member States. Official controls should be performed by personnel who are independent, free from any conflict of interest and in particular who are not in a situation which, directly or indirectly, could affect their ability to carry out their professional duties in an impartial manner.	~~in~~**verifications as to the** Member States ~~to verify the~~ **'** effective application of the relevant requirements **systems set out in this Regulation. Such verifications could be organised in different ways, such as audits, visits, surveys, and in collaboration with the Member States so as to limit the administrative burden** ~~of competent authorities and of the supervisory activity systems~~. Commission ~~controls~~**verifications** should also serve to investigate and collect information on enforcement practices or problems, emergencies and new developments in Member States. ~~Official controls~~**Such verifications** should be performed by personnel who are independent,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			free from any conflict of interest and in particular who are not in a situation which, directly or indirectly, could affect their ability to carry out their professional duties in an impartial manner.	
Recital 27				
37	(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	(27) Since SoHO preparations are subjected to a series of SoHO activities prior to their release, ***distribution and issuing*** ~~*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	(27) Since SoHO preparations are subjected to a series of SoHO activities prior to their release and distribution, **SoHO** competent authorities should assess and authorise SoHO preparations to verify that a high level of ~~safety, quality and efficacy~~**quality, safety and effectiveness** is achieved	

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	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	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	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~~ **effectiveness in SoHO** recipients by means of requirements for clinical outcome data collection and review. The extent of such required clinical outcome data **monitoring** 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 **SoHO** recipients (or offspring in the case	

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	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.	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.	of medically assisted reproduction), the vigilance reporting requirements provided for in this Regulation should be adequate to ~~demonstrate safety and quality~~**verify quality and safety**. 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.	
Recital 28				
38	(28) With regard to SoHO preparations that pose a certain level of risk (low, moderate or	(28) ***Applicants requesting authorisation for a SoHO preparation should use the Euro***	(28) With regard to SoHO preparations that pose a ~~certain level of risk (low, moderate or~~	

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	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	***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 &~~*amp;*~~ HealthCare (EDQM, a Directorate of the Council of Europe) should be considered relevant in the design of clinical follow-up studies	~~high)~~**risk other than negligible**, 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 &~~amp;~~ HealthCare (EDQM, a Directorate of the Council of Europe) should be considered relevant in the design of clinical follow-up ~~studies~~**plans** proportionate in extent and complexity to the identified level of risk of the SoHO preparation. In the case of low risk **and a positive benefit-risk assessment**, in addition to the mandatory continuous vigilance reporting, the applicant should organise proactive	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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***	clinical follow-up for a defined number of ~~patients~~**SoHO recipients**. For moderate and ~~high risk~~**a positive benefit-risk assessment**, 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 **and a positive benefit-risk assessment, and cases where risk or benefit are not evaluable due to a lack of scientific and clinical data or knowledge**, these should include a comparison with **a** standard ~~treatments~~**therapy**, ideally in a study with ~~subjects~~**SoHO recipients** allocated to test and control groups in a	

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		(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.	randomised manner. The **SoHO** competent authority should approve the plans before they are implemented and should assess the outcome data as part of a SoHO preparation authorisation.	
Recital 28a				
38a		***(28a) SoHO entities should request approval for SoHO clinical studies from the***		

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		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.		
Recital 29				
39	(29) In the interests of efficiency, it should be permitted to conduct clinical outcome studies using the	(29) In the interests of efficiency, it should be permitted to conduct clinical ~~*outcome*~~ studies using the	(29) In the interests of efficiency, it should be permitted**, without changing the regulatory status of**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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[1], when operators wish to do so. Whilst applicants can choose to record the clinical data generated during the clinical outcome monitoring themselves, they should also be permitted to use existing clinical data registries as a means of such recording when those registries have been verified by the competent authority, or are certified by an external institution, in terms of the reliability of their data management procedures. _____ 1. Regulation (EU) No	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[1], 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 ~~*outcome monitoring*~~***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 competent authority, or are certified by an external institution, in terms of the reliability of their	**the SoHO concerned,** to conduct clinical outcome ~~studies~~**monitoring** 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[1], when ~~operators~~**SoHO entities** 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 **SoHO** competent authority, or are certified by an external institution, in terms of the reliability of their data **quality**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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).	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.*** _____ 1. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for	management procedures. _____ 1. 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).	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).		
Recital 30				
40	(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	(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	(30) In order to facilitate innovation and reduce administrative burden, **SoHO** 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~~**SoHO**	

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	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.	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.***	**recipients**. Such sharing could allow **SoHO competent** authorities to accept previous authorisations granted to other **SoHO** entities, including in other Member States and ~~to~~ thus significantly reduce the requirements to generate evidence.	
Recital 31				
41	(31) A broad range of public and private organisations influence the safety, quality and efficacy of SoHOs, even if they do not		(31) A broad range of public and private organisations influence the ~~safety, quality and efficacy~~**quality, safety and effectiveness** of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	maintain banks of those SoHOs. Many organisations carry out a single SoHO activity, such as collection or donor testing on behalf of one or many organisations that maintain banks of SoHOs. The SoHO entity concept includes this broad range of organisations, from donor registries to physicians that apply SoHOs to recipients or use SoHO processing devices at the recipient's bedside. The registration of all such SoHO entities should ensure that competent authorities have a clear overview of the field and its scale and can take enforcement action when deemed necessary. A SoHO entity registration should refer to the legal entity, regardless of the		SoHOs, even if they do not ~~maintain banks of~~**store** those SoHOs. Many organisations carry out a single SoHO activity, such as collection or **SoHO** donor testing on behalf of one or many organisations that ~~maintain banks of SoHOs~~**store SoHO**. The SoHO entity concept includes this broad range of organisations, from **SoHO** donor registries to ~~physicians that apply SoHOs to~~ **hospitals and clinics where SoHO are applied to SoHO** recipients or ~~use~~ SoHO processing devices **are used** at the recipient's bedside. The registration of all such SoHO entities should ensure that **SoHO** competent authorities have a clear overview of the field and its scale and can take enforcement action	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	number of physical sites associated with the entity.		when deemed necessary. A SoHO entity registration should refer to the legal entity, regardless of the number of physical sites associated with the entity. **Activities performed in a personal context, such as breast feeding or donating breast milk to the infant of a friend or relative, and respecting the principles of voluntary and unpaid donation, should not be considered as SoHO activities. However, if such activities were to be carried out repeatedly as a service for multiple individuals, or for many families, they should be considered as SoHO activities and should fall under the scope of this Regulation.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 32				
42	(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	(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	(32) **SoHO** competent authorities should review the SoHO entities registered in their territory and ensure that those entities that carry out **either** both processing and storage**, or release, or import, or export of SoHO,** ~~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. **SoHO** competent authorities should consider the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	impact on ~~safety, quality and efficacy~~**quality, safety and effectiveness** of the SoHO activities carried out ~~at~~**by** SoHO entities that do not meet the definition of a SoHO establishment and decide whether particular **SoHO** entities should be subject to ~~establishment authorisations~~**authorisation and inspection activities applicable to SoHO establishments** 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.~~**and inspection.**	

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Recital 32a				
42a			**(32a) SoHO entities should keep a record of their activities, including the types and quantities of SoHO, as part of its working procedures and quality management systems, and report data relating to certain SoHO activities; at least the data sets included in the EU SoHO Platform. In cases where national or international registries collect activity data meeting the criteria defined in the SoHO Platform and such registries have been verified by**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			SoHO competent authorities as having in place data quality management procedures that ensure accuracy and completeness of data, Member State should decide if SoHO entities may delegate the submission of the activity data to such registries.	
Recital 33				
43	(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	(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	(33) With regards to standards concerning ~~donor, recipient~~**the protection of SoHO donors, SoHO recipients** and offspring ~~protection~~**from medically assisted reproduction**, this Regulation	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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	technologies change, this hierarchy of rules should facilitate an efficient and responsive uptake of the most up-to-date guidelines ***based on scientific evidence*** for implementing the standards set out in this Regulation. As part of that hierarchy, in the absence of Union legislation describing particular procedures to be applied and followed to meet the standards set out in this Regulation, following the guidelines of the European Centre for Disease Prevention and Control (ECDC) and the EDQM should be considered as a means to demonstrate compliance with the standards laid down in this Regulation***. Member States should be able to decide that SoHO entities should be permitted to***	should provide ~~for a hierarchy of~~ rules for their implementation. As risks and technologies change, ~~this hierarchy of~~**these** 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~~**appropriate** means to demonstrate compliance with ~~the standards laid down in this~~	

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	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.	***follow other recognised guidelines, provided that such guidelines are based on the most up-to-date scientific evidence and achieve the same*** ~~*to ensure high*~~ 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	~~Regulation~~**this Regulation and the standards** to ensure high level of quality, safety and ~~efficacy.~~ **effectiveness. Member States may adopt other guidelines, as reference for** SoHO entities ~~should be permitted to follow other guidelines, provided that it has been demonstrated~~**located in their territory. For such adoption, Member States should demonstrate** that those other guidelines achieve ~~the same level of quality, safety and efficacy~~**compliance with the standards set by this Regulation**. In cases of detailed technical issues for which neither Union legislation nor the ECDC and the EDQM**, nor other guidelines,** have defined a technical guideline or rule,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.***	~~operators~~**SoHO entities** should apply a locally defined rule that is in line with relevant internationally recognised guidelines and **available** scientific evidence and is appropriate to mitigate any risk identified.	
Recital 33a				
43a				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			(33a) When a couple uses their own sperm and oocytes for treatment by medically assisted reproduction, testing for genetic conditions fall outside of the scope of this Regulation as these are associated with particular ethical concerns that fall outside the scope of this Regulation.	
Recital 34				
44	(34) Where evidence demonstrates that specific processing steps reduce or eliminate the risk of transmission of specific infectious or non-infectious disease agents, the quality and safety standards for		(34) Where evidence demonstrates that specific ~~processing steps~~**procedures** reduce or eliminate the risk of transmission of specific infectious or non-infectious disease agents, the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the verification of donor eligibility by means of donor health evaluations, including testing, and the related guidelines for their implementation, should take this evidence into account. Thus, in the case of, for example, plasma for fractionation, that in a subsequent step in the manufacturing process of medicinal products undergoes sterilisation steps, certain donor eligibility criteria used for donation of plasma for transfusion might not be necessary nor appropriate.		quality and safety standards for the verification of **SoHO** donor eligibility by means of **SoHO** donor health evaluations, including testing, and the related guidelines for their implementation, should take this evidence into account. ~~Thus, in the case of, for example, plasma for fractionation, that in a subsequent step in the manufacturing process of medicinal products undergoes sterilisation steps, certain donor eligibility criteria used for donation of plasma for transfusion might not be necessary nor appropriate.~~	
Recital 35				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
45	(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[1], 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	(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[1], 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*~~***also*** member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental	(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[1], 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	

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	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	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,	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~~**quality and safety** of blood, tissues and cells,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance of safety and quality during collection, processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means to implement the technical standards provided for in this Regulation. _____	tissues and cells, should be considered an important contribution to the field of SoHOs in the Union and should be reflected in this Regulation, ***without prejudice to the Union's legal autonomy***. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance of safety and quality during collection, processing, storage and distribution. It should therefore be possible to use those guidelines as one of the means to implement the technical standards provided for in this Regulation.	should be considered an important contribution to the field of ~~SoHOs~~**SoHO** 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 **SoHO** donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance of ~~safety and quality~~**quality and safety** during collection, processing, storage and distribution **or export**. It should therefore be possible to use those **technical** guidelines as one of the means to implement the ~~technical~~ standards provided for in this Regulation.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	1. Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).	***The 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.*** _____ 1. Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on	_____ 1. 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).	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).		
Recital 36				
46	(36) The ECDC, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council[1], 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	(36) The ECDC, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council[1], 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*** ~~*and quality*~~ of SoHOs from a communicable disease threat	(36) The ECDC, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council[1], 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~~**SoHO** from a communicable disease threat perspective, should be considered	

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	an important contribution in the field of SoHOs in the Union and should be reflected in this Regulation. In addition, the ECDC established an expert network for the Microbial Safety of SoHOs, which ensures the implementation of the requirements on the ECDC's relations with the Union Member States and EEA Member States stated in Regulation (EC) No 851/2004, regarding strategic and operational collaboration on technical and scientific issues, surveillance, responses to health threats, scientific opinions, scientific and technical assistance, collection of data, identification of emerging health threats, and public information campaigns related to the safety of SoHOs. This SoHO	perspective, should be considered an important contribution in the field of SoHOs in the Union and should be reflected in this Regulation. In addition, the ECDC established an expert network for the Microbial Safety of SoHOs, which ensures the implementation of the requirements on the ECDC's relations with the Union Member States and EEA Member States stated in Regulation (EC) No 851/2004, regarding ***transparent*** strategic and operational collaboration on technical and scientific issues, surveillance, responses to health threats, scientific opinions, scientific and technical assistance, collection of data, identification of emerging health threats, and public	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~~**SoHO**, which ensures the implementation of the requirements on the ECDC's relations with the Union Member States and EEA Member States stated in Regulation (EC) No 851/2004, regarding strategic and operational collaboration on technical and scientific issues, surveillance, responses to health threats, scientific opinions, scientific and technical assistance, collection of data, identification of emerging health threats, and public information campaigns related to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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. _____ 1. 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).	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. _____ 1. 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	the safety of ~~SoHOs~~**SoHO**. 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 **SoHO** donors and the investigation of serious adverse ~~occurrences~~**reactions and events** involving suspected transmission of a communicable disease. _____ 1. 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).	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		control (OJ L 142, 30.4.2004, p. 1).		
Recital 37				
47	(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,	(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	(37) It is necessary to promote information and awareness campaigns at national and Union level on the importance of ~~SoHOs~~**SoHO donation**. The aim of these campaigns should be to help European citizens to decide whether to become **SoHO** donors during their lifetime and **record or** let their families or legal representatives know their wishes regarding donation **of SoHO** after death. As there is a need to ensure	

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	Member States should promote the donation of SoHOs, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. Member States are also urged to take steps to encourage a strong public and non-profit sector involvement in the provision of SoHO services, in particular for critical SoHOs and the related research and development.	representatives know their wishes regarding donation after death. As there is a need to ensure the availability of ***and 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~~, *including plasma,*~~ of high quality and safety~~, *thereby also*~~ ***with a view to*** increasing ~~*self-sufficiency*~~***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 ~~*involvement*~~**,** in the provision of SoHO services, in particular for	the availability of ~~SoHOs~~**SoHO** for medical treatments, Member States should promote the donation of ~~SoHOs~~**SoHO**, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. **For that purpose, Member States should consider taking measures to ensure availability and accessibility of SoHO within 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~~**SoHO** and the related research and development**, and to take steps to promote affordability of the collected SoHO within the Union**.	

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		critical SoHOs and the related research and development.		
Recital 37a				
47a		***(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***	**(37a) In the development of national emergency plans, Member States should cooperate with involved stakeholders and should take into account the opinions of the Health Security Committee referred to in Article 4 of Regulation (EU) 2022/2371 and the Health Crisis Board referred to in Article 5 of Council Regulation (EU) 2022/2372, when applicable. Member States should also**	

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		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	**benefit from the supportive role of the appropriate Commission services, such as the Health Emergency Response Authority, the risk assessments and recommendations of ECDC and the guidelines of EDQM in the establishment and operation of national SoHO emergency plans. National emergency plans might include, among preparedness and response measures, stock-piling of certain SoHO where possible and appropriate.**	

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		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. _____		

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		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).		
Recital 37b				
47b		***(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***		

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		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		

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		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		

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		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.		
Recital 37c				
47c				

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		(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		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		products with low profitability, Member States should encourage research and innovation and should ensure that such products continue to be manufactured.		
Recital 38				
48	(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	(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	(38) In order to promote a coordinated application of this Regulation, a SoHO Coordination Board (SCB) should be set up. The Commission **and the Members States** should participate in its activities and ~~chair~~**co-chair** it. The SCB should contribute to ~~a~~ coordinating the application of this Regulation throughout the Union,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHO supervisory activities. The SCB should be composed of persons designated by the Member States based on their role and expertise in their competent authorities, and should also involve experts that are not working for competent authorities, for specific tasks where access to necessary in-depth technical expertise in the field of SoHOs is required. In the latter case, appropriate consideration should be given to the possibility of involving European expert bodies such as the ECDC and the EDQM and existing professional, scientific and donor and patient representative groups at Union level in the field of SoHOs.	helping Member States to conduct SoHO supervisory activities. The SCB should be composed of persons designated by the Member States based on their role and expertise in their competent authorities, and should also involve experts that are not working for competent authorities, for specific tasks where access to necessary in-depth technical expertise in the field of SoHOs is required. In the latter case, appropriate consideration should be given to the possibility of involving European expert ***agencies and*** bodies such as the ECDC and the ***European Medicines Agency (EMA). The European Parliament, the*** EDQM and existing professional, scientific	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 **SoHO** competent authorities, and should also involve experts that are not working for **SoHO** competent authorities, for specific tasks where access to necessary in-depth technical expertise in the field of ~~SoHOs~~**SoHO** is required. In the latter case, appropriate consideration should be given to the possibility of involving European expert bodies such as the ECDC and the EDQM and existing professional, scientific and donor and patient representative groups at Union level in the field of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***.	~~SoHOs~~**SoHO**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 39				
49	(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	(39) Some substances, products or activities have been subject to different legal frameworks with different requirements in the Member States. This ~~causes~~***can sometimes cause*** confusion among operators in the field, and the consequent legal uncertainty ~~is~~***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	(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~~**SoHO**. The SCB should receive relevant information on national decisions made on cases where questions were raised on the regulatory status of ~~SoHOs~~**SoHO**. The SCB should	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	compendium of the opinions issued by the SCB or the competent authorities and of decisions made at Member State level, so that competent authorities considering the regulatory status under this Regulation of a particular substance, product or activity may inform their decision-making process by referring to that compendium. The SCB should also document agreed best practices to support a common Union approach. It should also cooperate with similar Union level bodies established in other Union legislation with a view to facilitating coordinated and coherent application of this Regulation between Member States and across bordering legislative	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 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	keep a **SoHO** compendium of the opinions issued by the SCB or the **SoHO** competent authorities and of decisions made at Member State level, so that **SoHO** 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 **SoHO** 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	frameworks. These measures should promote a coherent cross-sectoral approach and facilitate SoHO innovation.	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.	and across bordering legislative frameworks. **The Commission should support the SCB in its cooperation with similar advisory bodies responsible for deciding on the regulatory status of products under other relevant Union legislation, in particular by organising meetings, at least annually. Such meetings should contribute to promote understanding and to ensure efficiency and scientific consistency with other relevant Union legislation and coherence with the different regulatory status mechanisms established under other Union legislation.** These measures should promote a coherent cross-sectoral approach and facilitate SoHO innovation.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 40				
50	(40) The concept of a plasma master file (PMF) was established in Commission Directive 2003/63/EC[1]. Since that Directive provided for a specific regulatory role for the European Medicines Agency (EMA) in relation to authorisation of plasma for fractionation, the SCB should also collaborate with the relevant EMA expert working groups to exchange experience and good practices so that criteria for the eligibility of donors of plasma for fractionation and of donors of blood for		(40) ~~The concept of a plasma master file (PMF) was established in Commission Directive 2003/63/EC[1]. Since that Directive provided for a specific regulatory role for the European Medicines Agency (EMA) in relation to authorisation of plasma for fractionation, the SCB should also collaborate with the relevant EMA expert working groups to exchange experience and good practices so that criteria for the eligibility of donors of plasma for fractionation and of donors of blood for~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	transfusion are implemented by Member States in a consistent and coherent way. _____ 1. Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 159, 27.6.2003, p. 46).		~~transfusion are implemented by Member States in a consistent and coherent way.~~ _____ ~~1. Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 159, 27.6.2003, p. 46).~~	
Recital 41				
51				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(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*** ~~*as well as improved*~~ 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***	(41) In order to limit administrative burden on **SoHO** competent authorities and the Commission, the latter should establish an online platform (the 'EU SoHO Platform') to facilitate timely submission of data and reports**. The EU SoHO Platform should contribute to improve** ~~as well as improved~~ transparency of ~~national~~ reporting and **SoHO** supervisory activities **and to the exchange of information between relevant parties**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.		
Recital 42				
52	(42) The processing of personal data under this Regulation should be subject to strict guarantees of confidentiality and should comply with the rules on the protection of personal data laid down in Regulation (EU) 2016/679 of the European Parliament and of the		(42) The processing of personal data under this Regulation should be subject to strict guarantees of confidentiality and should comply with the rules on the protection of personal data**, including health data,** laid down in Regulation (EU) 2016/679 of the European	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Council and in Regulation (EU) 2018/1725 of the European Parliament and of the Council .		Parliament and of the Council– and in Regulation (EU) 2018/1725 of the European Parliament and of the Council**.** -	
Recital 43				
53	(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	(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	(43) As the EU SoHO Platform requires the processing of personal data, **including health data,** it will be designed respecting the principles of data protection. Any processing of personal data should be limited to achieving the objectives and **the fulfilment of** obligations of this Regulation. Access to the EU SoHO Platform **by SoHO entities, SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	in this Regulation.	to the extent necessary to carry out supervisory activities provided for in this Regulation.	**competent authorities, Member States or the Commission,** should be limited to the extent necessary to ~~carry out supervisory~~**perform SoHO related** activities ~~provided for~~**laid down** in this Regulation.	
Recital 44				
54	(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	(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***	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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	***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	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 **SoHO** donors, **SoHO** 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 **SoHO** donors or their representatives are informed with regards to the intended use of the donated material, that **SoHO** donor eligibility criteria are based on	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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	scientific evidence, that the use of ~~SoHOs~~**SoHO** in humans is not promoted for commercial purposes or with false or misleading information regarding ~~efficacy~~**effectiveness** so that the **SoHO** donors and **SoHO** recipients can make well-informed and deliberate choices,– that activities are conducted in a transparent manner that prioritises the safety of **SoHO** donors**, recipients and offspring from medically assisted reproduction** ~~and recipients~~, and that allocation and equitable access to ~~SoHOs~~**SoHO** are defined in a transparent manner, on the basis of an objective evaluation of medical needs. This Regulation should therefore be applied accordingly.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		objective evaluation of medical needs. This Regulation should therefore be applied accordingly.		
Recital 44a				
54a		***(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.***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 45				
55	(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	(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	(45) ~~SoHOs~~**SoHO**, 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 **SoHO** 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	for processing of such personal data. With respect to personal data processed by the Commission, this Regulation should provide a legal basis under Article 5 and, where relevant, fulfil the conditions under Article 10(2), point (i), of Regulation (EU) 2018/1725. Data on safety and efficacy of new SoHO preparations in recipients should also be shared, with appropriate protective measures, to allow aggregation at Union level for more robust evidence gathering on the clinical efficacy of SoHO preparations. For all data processing, such processing should be necessary and appropriate with a view to ensuring compliance with this Regulation in order to protect human health. Data on donors,	for processing of such personal data. With respect to personal data processed by the Commission, this Regulation should provide a legal basis under Article 5 and, where relevant, fulfil the conditions under Article 10(2), point (i), of Regulation (EU) 2018/1725. Data on safety and efficacy of new SoHO preparations in recipients should also be shared, with appropriate protective measures, to allow aggregation at Union level for more robust evidence gathering on the clinical efficacy of SoHO preparations. For all data processing, such processing should be necessary and appropriate with a view to ensuring compliance with this Regulation in order to protect human health. Data on donors,	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~~**effectiveness** of new SoHO preparations ~~in recipients~~ should also be shared, with appropriate protective measures, to allow aggregation at Union level for more robust evidence gathering ~~on the clinical efficacy~~ of SoHO preparations. For all data processing, such processing should be **limited to what is** necessary and appropriate with a view to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	ensuring compliance with this Regulation in order to protect human health. Data **collected on SoHO** ~~on~~ donors, **SoHO** recipients and offspring **from medically assisted reproduction** should hence be limited to the minimum necessary and pseudonymised. **SoHO** donors, **SoHO** recipients and offspring **from medically assisted reproduction** should be informed of the processing of their personal data**, including health 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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 46				
56	(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.***	(46) In order to enable better access to health data in the interests of public health, Member States should entrust **SoHO** 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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 47				
57	(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	(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*~~ ***in the optimal timeframe.*** This Regulation~~, *namely to ensure quality and safety of SoHOs and a high level of protection of donors, needs to be achieved at Union*~~	(47) The exchange of ~~SoHOs~~**SoHO** 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~~**SoHO** that need to be matched between the **SoHO** donor and the **SoHO** recipient, such exchanges are essential to allow ~~patients~~**SoHO recipients** to receive the treatment they need. In this context, the objective of this Regulation, namely to ensure quality and safety of ~~SoHOs~~**SoHO** and a high level of protection of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	~~*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*~~ ***should serve to increase coordination between Member States and facilitate the cross-border exchange of SoHOs***.	**SoHO** donors, needs to be achieved at Union level, by establishing high standards of quality and safety for ~~SoHOs~~**SoHO**, 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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 47a				
57a		***(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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.		
Recital 47b				
57b		***(47b) In some cases, such as bone marrow or haematopoietic stem cell transplants, the level of donor/recipient compatibility has***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.		
Recital 48				
58	(48) In order to be able to supplement this Regulation where necessary with additional standards concerning the protection of donors, recipients and offspring from medically assisted reproduction to take into account technical and scientific developments in the field of		(48) In order to ~~be able to~~ supplement this Regulation where necessary with additional standards concerning the protection of **SoHO** donors, **SoHO** recipients and offspring from medically assisted reproduction**, and in order** to take into account **the** technical and scientific	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHOs, and with additional rules on the authorisation of importing SoHO entities, on obligations and procedures for importing SoHO entities, on the organisation of Union training and exchange programmes, on technical specifications concerning the EU SoHO Platform, and on data protection, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13		developments in the field of ~~SoHOs, and with~~ **SoHO, and** additional rules on the authorisation of importing SoHO entities, on obligations and procedures for importing SoHO ~~entities, on the organisation of Union training and exchange programmes, on technical specifications concerning the EU SoHO Platform~~**establishments**, and on data protection, the ~~power to~~**Commission should** adopt **delegated** acts in accordance with Article 290 TFEU ~~should be delegated to the Commission~~. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	April 2016 on Better Law-Making[1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. _____ 1. OJ L 123, 12.5.2016, p. 1.		consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. _____ 1. OJ L 123, 12.5.2016, p. 1.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 49				
59	(49) In order to ensure uniform conditions for the implementation of this Regulation regarding the authorisation system for importing SoHO entities, the application for importing SoHO entity authorisations, the activity data collection and reporting by SoHO entities, the European coding system, the establishment, management and functioning of the SCB, and the general functionalities of the EU SoHO Platform, implementing powers should be conferred on the Commission.		(49) In order to ensure uniform conditions for the implementation of this Regulation regarding the authorisation system for importing SoHO ~~entities~~**establishment**, the application for importing SoHO ~~entity authorisations~~**establishment authorisation**, the activity data collection and reporting by SoHO entities, the **minimum data to ensure traceability, the** European coding system, the establishment, management and functioning of the SCB, and the general functionalities of the EU SoHO Platform, implementing powers should be conferred on the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Commission.	
Recital 50				
60	(50) In order to ensure uniform conditions for the implementation of this Regulation, including the determination of the regulatory status of a substance, product or activity, rules and practical arrangements in respect of the consultation and cooperation with competent authorities of other regulatory sectors, the national registers of SoHO entities, the registration process of SoHO entities, the SoHO preparation authorisation system and the		(50) In order to ensure uniform conditions for the implementation of this Regulation, including the determination of the regulatory status of a substance, product or activity, ~~rules and practical arrangements in respect of the consultation and cooperation with competent authorities of other regulatory sectors, the national registers of SoHO entities, the registration process~~**the data set for SoHO entities to register into the EU SoHO Platform, the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorisation of SoHO preparations, the SoHO establishment authorisation system, the inspections of SoHO establishments, the consultation and coordination related to vigilance, the quality management system for SoHO establishments, the implementation of the standards concerning the protection of donors, recipients and offspring from medically assisted reproduction, the national SoHO emergency plans, the tasks of the SoHO Coordination Board, and the transitional provisions concerning SoHO preparations, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of		**authorisation** of SoHO ~~entities, the SoHO preparation authorisation system and the authorisation of SoHO preparations, the SoHO establishment authorisation system,~~**preparations, common elements for the quality management system of SoHO entities and for** the inspections of SoHO establishments, the consultation and coordination related to vigilance, the ~~quality management system for SoHO establishments, the~~ implementation of the standards concerning the protection of **SoHO** donors, **SoHO** recipients and offspring from medically assisted reproduction, the ~~national SoHO emergency plans, the~~ tasks of the ~~SoHO Coordination Board~~**SCB**, and the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the European Parliament and of the Council[1]. _____ 1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).		transitional provisions concerning SoHO preparations, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1]. _____ 1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 51				
61	(51) Transitional provisions should be laid down in order to ensure a smooth transition from the former regimes for tissues and cells and for blood and blood components to this new Regulation, in particular in order to adapt practices to the new requirements, the changes in SoHO entities, SoHO establishments and SoHO preparations, and to avoid that donated SoHOs are discarded unnecessarily. A transitional regime for establishments already designated, authorised, accredited		(51) Transitional provisions should be laid down in order to ensure a smooth transition from the former regimes for tissues and cells and for blood and blood components to this new Regulation, in particular in order to adapt practices to the new requirements, the changes in SoHO entities, SoHO establishments and SoHO preparations, and to avoid that donated ~~SoHOs~~**SoHO** are discarded unnecessarily. A transitional regime for establishments already designated,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	or licensed before the date of application of this Regulation should be introduced to ensure legal certainty and clarity. In particular, there should be clarity for the establishments concerned as regards their registration and authorisation status as well as their tasks and responsibilities under this Regulation, whilst allowing competent authorities additional time to transfer the relevant information to the systems introduced by this Regulation. To allow for a smooth transition, it is also appropriate that those preparation processes already authorised and lawfully used under the former regimes are still valid, and that SoHOs already collected and stored before the date of		authorised, accredited or licensed before the date of application of this Regulation should be introduced to ensure legal certainty and clarity. In particular, there should be clarity for the establishments concerned as regards their registration and authorisation status as well as their tasks and responsibilities under this Regulation, whilst allowing **SoHO** competent authorities additional time to transfer the relevant information to the systems introduced by this Regulation. To allow for a smooth transition, it is also appropriate that those preparation processes already authorised and lawfully used under the former regimes are still valid, and that ~~SoHOs~~**SoHO** already	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	application of this Regulation may be used for a certain period of time. The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 and delivered an opinion on … [date of the opinion][1], _____ 1. OJ C , , p. .		collected and stored before the date of application of this Regulation may be used for a certain period of time. The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 and delivered an opinion on … [date of the opinion][1], _____ 1. OJ C , , p. .	
Formula				
62				

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	HAVE ADOPTED THIS REGULATION:		HAVE ADOPTED THIS REGULATION:	
CHAPTER I				
63	CHAPTER I GENERAL PROVISIONS		CHAPTER I GENERAL PROVISIONS	
Article 1				
64	Article 1 Subject matter		Article 1 Subject matter	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 1, first paragraph				
65	This Regulation establishes measures setting high standards of quality and safety for all substances of human origin ('SoHOs') intended for human application and for activities related to those substances in order to ensure a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted reproduction. This Regulation is without prejudice to national legislation which establishes rules relating to aspects	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*~~ ***. It ensures*** a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted reproduction ***and serves to strengthen the continuity of supply of SoHOs***. This Regulation is without	This Regulation establishes measures setting high standards of quality and safety for all substances of human origin ('~~SoHOs~~**SoHO**') intended for human application and for activities related to those substances in order to ensure a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted reproduction. ~~This Regulation is without prejudice to national legislation which establishes rules relating to~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	of SoHOs other than their quality and safety and the safety of SoHO donors.	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***.	~~aspects of SoHOs other than their quality and safety and the safety of SoHO donors.~~	
Article 2				
66	Article 2 Scope		Article 2 Scope	
Article 2(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
67	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 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 and recipients, and to the following SoHO activities~~:	
Article 2(1), point (a)				
68	(a) SoHO donor recruitment;	(a) SoHO donor recruitment, ***except if that is the sole SoHO activity of the entity in which case***	(a) SoHO ~~donor recruitment~~**intended for human application and SoHO used to**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		only Article 54(3b) shall apply;	**manufacture products defined in other Union legislation as referred to in paragraph 3 and intended for human application**;	
Article 2(1), point (b)				
69	(b) SoHO donor history review and eligibility assessment;		(b) SoHO ~~donor history review and eligibility assessment~~**donors, SoHO recipients and offspring from medically assisted reproduction**;	
Article 2(1), point (c)				
70				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(c) SoHO testing of donors for eligibility or matching purposes;		(c) SoHO ~~testing of donors for eligibility or matching purposes;~~**activities that have a direct impact on the safety, quality, or effectiveness of SoHO, as follows:**	
Article 2(1), point (c)(i)				
70a			**(i) donor registration;**	
Article 2(1), point (c)(ii)				
70b			**(ii) donor history review and**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			medical examination;	
Article 2(1), point (c)(iii)				
70c			**(iii) testing of SoHO donors or of persons from whom SoHO are collected for autologous use;**	
Article 2(1), point (c)(iv)				
70d			**(iv) collection ;**	
Article 2(1), point (c)(v)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
70e			**(v) processing;**	
Article 2(1), point (c)(vi)				
70f			**(vi) quality control;**	
Article 2(1), point (c)(vii)				
70g			**(vii) storage;**	
Article 2(1), point (c)(viii)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
70h			**(viii) release;**	
Article 2(1), point (c)(ix)				
70i			**(ix) distribution ;**	
Article 2(1), point (c)(x)				
70j			**(x) import;**	
Article 2(1), point (c)(xi)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
70k			**(xi) export;**	
Article 2(1), point (c)(xii)				
70l			**(xii) human application ;**	
Article 2(1), point (c)(xiii)				
70m			**(xiii) clinical outcome registration.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 2(1a)				
70n			**1a. This Regulation shall not apply to:**	
Article 2(1a), point (i)				
70o			**(i) organs intended for transplantation within the meaning of Article 3, points (h) and (q), of Directive 2010/53/EU;**	
Article 2(1a), point (ii)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
70p			**(ii) breast milk when used exclusively for feeding the own child, without any processing carried out by a SoHO entity.**	
Article 2(1b)				
70q			**1b. This Regulation is without prejudice to national legislation which establishes rules relating to aspects of SoHO other than their quality and safety and other than the safety of SoHO donors.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 2(1ba)				
70r			**1ba. By way of derogation, the provisions of this Regulation concerning the publication or communication of information, specifically with regards to obligations in Articles 4(2), 8, 17, 21(3), 31, 33, 39, 44, 62, 63, 66, 77, 81(3b) may not apply when such publication or communication might imply a risk to national security and defence.**	
Article 2(1), point (d)				
71				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(d) collection of SoHOs from donors or patients;		~~(d) collection of SoHOs from donors or patients~~**(iv) collection** ; now incorporated in Article 2.1.C above - as are the following items below	
Article 2(1), point (e)				
72	(e) processing of SoHOs;		~~(e) processing of SoHOs;~~	
Article 2(1), point (f)				
73				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(f) quality control testing of SoHOs;		~~(f)~~**(c)** ~~quality control testing of SoHOs;~~	
Article 2(1), point (g)				
74	(g) storage of SoHOs;		~~(g)~~**(d)** ~~storage of SoHOs;~~	
Article 2(1), point (h)				
75	(h) SoHO release;		~~(h)~~**(e)** ~~SoHO release;~~	
Article 2(1), point (i)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
76	(i) distribution of SoHOs;		~~(i)~~**(f)** ~~distribution of SoHOs;~~	
Article 2(1), point (j)				
77	(j) import of SoHOs;		~~(j)~~**(g)** ~~import of SoHOs;~~	
Article 2(1), point (k)				
78	(k) export of SoHOs;		~~(k)~~**(h)** ~~export of SoHOs;~~	
Article 2(1), point (l)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
79	(l) human application of SoHOs;		~~(l)~~**(i)** ~~human application of SoHOs;~~	
Article 2(1), point (m)				
80	(m) SoHO clinical outcome monitoring.		~~(m)~~**(j)** ~~SoHO clinical outcome monitoring.~~	
Article 2(1), point (ha)				
80a		***(ha) issuing of SoHOs;***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 2(1), point (ma)				
80b		***(ma) SoHO clinical studies.***		
Article 2(1a)				
80c		***1a. Articles 53, 54, 55 and 56 shall apply also to SoHO donations intended for research.***		
Article 2(2)				
81	2. In cases of autologous use of		2. In ~~cases of autologous use of~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHOs where:		~~SoHOs~~**case of SoHO intended for autologous use** where:	
Article 2(2), point (a)				
82	(a) SoHOs are processed and stored before application, this Regulation shall apply in full;		(a) ~~SoHOs~~**SoHO** are processed ~~and~~**or** stored before application, this Regulation shall apply in full;	
Article 2(2), point (b)				
83	(b) SoHOs are processed and not stored before application, only the provisions on vigilance referred to in Article 35, on SoHO rapid alerts		(b) ~~SoHOs are processed and not stored before application, only the provisions on vigilance referred to in Article 35, on SoHO rapid alerts~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	referred to in Article 36, on SoHO entity registration referred to in Article 37, on SoHO preparation authorisation referred to in Article 40, and on activity data collection and reporting referred to in Article 44 shall apply;		~~referred to in Article 36, on SoHO entity registration referred to in Article 37, on SoHO preparation authorisation referred to in Article 40, and on activity data collection and reporting referred to in Article 44 shall apply;~~	
Article 2(2), point (c)				
84	(c) SoHOs are not processed and not stored before application, this Regulation shall not apply.		(c) ~~SoHOs are not~~**SoHO are neither** processed ~~and not~~**nor** stored before application, this Regulation shall not apply.	
Article 2(3), first subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
85	For SoHOs that are used to manufacture products in accordance with Union legislation on medical devices, regulated by Regulation (EU) 2017/745, on medicinal products, regulated by Regulation (EC) No 726/2004 and Directive 2001/83/EC, including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007, or on food, regulated by Regulation (EC) No 1925/2006, or as the starting and raw material thereof, the provisions of this Regulation applicable to the activities of SoHO donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or	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 the activities of SoHO donor	~~For SoHOs that are used to manufacture products in accordance with Union legislation on~~**In case of SoHO that are collected with the purpose of manufacturing,** medical devices, **as** 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~~ **or investigational medicinal products, as defined in** Regulation (~~EC~~**EU**) ~~No 1925/2006, or as the starting and raw material thereof~~**No 536/2014**, the provisions	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, ~~*and*~~ 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.	of this Regulation applicable to the ~~activities of SoHO donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, and collection of SoHOs from donors or patients shall apply~~**SoHO activities referred to in paragraph (1a) point (i), (ii), (iii), (iv) and (viii), shall apply in all cases**. Insofar as the activities of SoHO ~~release, distribution, import and export~~**referred to in paragraph (1a) point (vii), (ix), (x) and (xi)** relate to ~~SoHOs prior to~~**SoHO until** their distribution to ~~an operator~~**a manufacturer** regulated by ~~the~~ other Union legislation referred to in this subparagraph, the provisions of this Regulation shall	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			also apply.	
Article 2(3), second subparagraph				
86	By way of derogation from the first subparagraph, in cases where SoHOs, SoHO preparations, or products manufactured from SoHO, as referred to in that subparagraph, are exclusively for autologous use, only those provisions of this Regulation that concern the collection of SoHOs from patients shall apply.		~~By way of derogation from the first subparagraph, in cases where SoHOs, SoHO preparations, or products manufactured from SoHO, as referred to in that subparagraph, are exclusively for autologous use, only those provisions of this Regulation that concern the collection of SoHOs from patients shall apply.~~	
Article 2(3a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
86a			**3a. By way of derogation from paragraph 3, when SoHO are used to manufacture products under other Union legislation for the exclusive therapeutic use on the person from whom SoHO are collected, the provisions of this Regulation relating to the SoHO activities referred to in Article 2(1c) point (iii) and (iv) shall apply.**	
Article 2(4)				
87	4. Where non-viable SoHOs or their derivatives, as defined in		4. Where non-viable ~~SoHOs~~**SoHO** or their derivatives, as defined in	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 2, point (17), of Regulation (EU) 2017/745, incorporate, as an integral part, a medical device, and where the action of the non-viable SoHOs or their derivatives is principal and not ancillary to that of the device, the non-viable SoHOs or their derivatives shall be governed by this Regulation. If the action of the non-viable SoHOs or their derivatives is ancillary to that of the device and not principal, the provisions of this Regulation, insofar as they concern donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, collection of SoHOs from donors or patients, shall apply.		Article 2, point **(16) and (**17), of Regulation (EU) 2017/745, incorporate, as an integral part, a medical device, and where the action of the non-viable ~~SoHOs~~**SoHO** or their derivatives is principal ~~and not ancillary~~ to that of the device, **this Regulation shall apply in full on** the non-viable ~~SoHOs~~**SoHO** or their derivatives **and the final combination** shall be ~~governed by~~**subject to the provisions of** this Regulation. If the action of the non-viable ~~SoHOs~~**SoHO** or their derivatives is ancillary to that of the device ~~and not principal, the provisions of this Regulation, insofar as they concern donor recruitment, donor history review and eligibility assessment, testing~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~of donors for eligibility or matching purposes, collection of SoHOs from donors or patients, shall apply~~**, this Regulation shall apply for all SoHO activities to which the non-viable SoHO or their derivatives are subjected until distributed for integration into the medical device, and the final combination shall be subject to the provisions of Regulation (EU) 2017/745**.	
Article 2(4a)				
87a		***4a. This Regulation also establishes provisions on:***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		(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.***		
Article 2(4b)				
87b		***4b. This Regulation does not apply to breast milk that is expressed by a mother solely for the purpose of feeding her own child.***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3				
88	Article 3 Definitions		Article 3 Definitions	
Article 3, first paragraph				
89	For the purpose of this Regulation the following definitions shall apply:		For the purpose of this Regulation the following definitions shall apply:	
Article 3, first paragraph, point (1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
90	(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***;	(1) ~~'blood' means the liquid that circulates in arteries and veins carrying oxygen to and carbon dioxide from the tissues of the body;~~	
Article 3, first paragraph, point (2)				
91	(2) 'blood component' means a constituent of blood such as red cells, white cells, platelets and plasma, that can be separated from it;		(2) ~~'blood component' means a constituent of blood such as red cells, white cells, platelets and plasma, that can be separated from it;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (3)				
92	(3) 'cell' means a mass of cytoplasm with or without a nucleus, that is bound externally by a cell membrane. Usually microscopic in size, cells are the smallest structural and functional unit of an organism;		(3) ~~'cell' means a mass of cytoplasm with or without a nucleus, that is bound externally by a cell membrane. Usually microscopic in size, cells are the smallest structural and functional unit of an organism;~~	
Article 3, first paragraph, point (4)				
93	(4) 'tissue' means a group of cells that function together as a unit;		(4) ~~'tissue' means a group of cells that function together as a unit;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (5)				
94	(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***;	(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~~**, including SoHO preparations resulting from the processing of that substance**;	
Article 3, first paragraph, point (6)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
95	(6) 'human application' means inserted, implanted, injected, infused, transfused, transplanted, ingested, transferred (as in transfer to the uterus or fallopian tube of a woman), inseminated or otherwise added to the human body in order to create a biological, mechanical or physiological interaction with that body;		(6) 'human application' means inserted, implanted, injected, infused, transfused, transplanted, ingested, transferred ~~(as in transfer to the uterus or fallopian tube of a woman)~~, inseminated or otherwise added to the human body in order to create a biological~~, mechanical or physiological~~ interaction with that body;	
Article 3, first paragraph, point (6a)				
95a				
Article 3, first paragraph, point (7)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
96	(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*** ~~*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 or efficacy of SoHOs, as listed in Article 2(1);~~	
Article 3, first paragraph, point (7a)				
96a			**(7a) 'effectiveness of SoHO' means the extent to which the use of SoHO reaches the intended biological or clinical outcome in the SoHO recipient;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (7b)				
96b		***(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;***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (8)				
97	(8) 'SoHO donor' means any person who has presented themselves to a SoHO entity with a view to making a donation of SoHOs, whether that donation is successful or not;	(8) 'SoHO donor' means ~~*any person who has presented themselves to a SoHO entity with a view to making a donation of SoHOs, whether that donation is successful or not*~~***a living or deceased SoHO donor***;	(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;~~	
Article 3, first paragraph, point (8a)				
97a			**(8a) living person who has volunteered to a SoHO entity or been presented by a person granting consent on their behalf,**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			in accordance with national legislation, with a view to making a donation of SoHO, for the purpose of use in a person other than themselves, and other than situations of within couple use as defined in point (63); or	
Article 3, first paragraph, point (8b)				
97b			**(8b) deceased person who has been referred to a SoHO entity, and from whom consent has been granted or from whom SoHO collection is permitted, in accordance with national legislation;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (8c)				
97c		***(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;***	**(8c)**	
Article 3, first paragraph, point (8d)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
97d		***(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;***	**(8d)**	
Article 3, first paragraph, point (9)				
98	(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***;	(9) 'SoHO recipient' means the person to whom ~~SoHOs~~**SoHO** are applied **or their application is envisaged, whether**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			by allogeneic or autologous use;	
Article 3, first paragraph, point (9a)				
98a			**(9a) 'recipient'** **means a SoHO recipient or any person receiving a product manufactured from SoHO, regulated under other Union** **legislation, as provided for in Article 2(3);**	
Article 3, first paragraph, point (9b)				
98b				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			(9b) 'consent'means the permission given by:	
Article 3, first paragraph, point (9b)(a)				
98c			**(a) a living SoHO donor or a SoHO recipient for an action affecting them to proceed, or**	
Article 3, first paragraph, point (9b)(b)				
98d			**(b) any person granting consent on behalf of the living SoHO donor or the SoHO recipient who**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			has no capacity to consent, or the authorisation granted by the national law, for an action to proceed in the living SoHO donor or the SoHO recipient, or	
Article 3, first paragraph, point (9b)(c)				
98e			**(c) any person granting consent, or the authorisation granted by national law, for an action to proceed in the case of the deceased SoHO donor in accordance with national legislation.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (10)				
99	(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***;	(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~~**any laboratory or medical intervention, including any preparatory steps, that involves the handling of reproductive SoHO for the purpose of the facilitation of pregnancy or for preservation of fertility**;	
Article 3, first paragraph, point (10a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
99a			**(10a) 'preservation of fertility' means the process of saving or protecting a person's reproductive SoHO** **intended to be used** **later in that person's life.**	
Article 3, first paragraph, point (11)				
100	(11) 'offspring from medically assisted reproduction' means fetuses and children that are born following medically assisted reproduction;	(11) 'offspring from medically assisted reproduction' means ~~*fetuses and*~~ children that are born following medically assisted reproduction;	(11) 'offspring from medically assisted reproduction' means ~~fetuses and~~ children ~~that are~~ born following medically assisted reproduction;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (11a)				
100a		***(11a) 'unborn offspring from medically assisted reproduction' means embryos and foetuses conceived by medically assisted reproduction;***		
Article 3, first paragraph, point (12)				
101	(12) 'SoHO preparation' means a particular type of SoHO that:		(12) 'SoHO preparation' means a ~~particular~~ type of SoHO**,** that:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (12)(a)				
102	(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~~, *including processing,*~~ in accordance with defined quality and safety parameters;	(a) has been subjected to one or more SoHO activities, ~~including processing, in accordance with defined quality and safety parameters~~**as listed in Article 2(1c), one of them being processing**;	
Article 3, first paragraph, point (12)(b)				
103	(b) meets a pre-defined specification; and	(b) meets a pre-defined specification;~~ *and*~~	(b) ~~meets a pre-defined specification~~**has a specific clinical indication**; and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (12)(c)				
104	(c) is intended for application to a recipient for a specific clinical indication or is intended for distribution for manufacture of a product regulated by other Union legislation, or as the starting and raw material thereof;		(c) is intended for application to a ~~recipient for a specific clinical indication~~**SoHO recipient** or is intended for distribution ~~for manufacture of a product regulated by other Union legislation, or as the starting and raw material thereof~~;	
Article 3, first paragraph, point (13)				
105	(13) 'donor recruitment' means	(13) 'donor recruitment' means	(13) ~~'donor recruitment' means~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	any activity aimed at encouraging persons to become SoHO donors;	any activity aimed at ~~*encouraging*~~***informing*** persons ~~*to become SoHO donors*~~***about activities related to SoHO donation or at encouraging them to donate SoHOs***;	~~any activity aimed at encouraging persons to become SoHO donors;~~	
Article 3, first paragraph, point (13a)				
105a			**(13a) 'SoHO donor registration' means recording in a registry, and transferring to other registries where appropriate, the information on a SoHO donor that is essential for identifying a match with a prospective SoHO recipient;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (14)				
106	(14) 'collection' means a process by which SoHOs are removed, procured, excreted, secreted or obtained by any other manner, including any preparatory steps, such as hormone treatment, needed to facilitate the process;		(14) 'collection' means a process by which ~~SoHOs are removed, procured, excreted, secreted or~~ **SoHO are** obtained ~~by any other manner~~**from a person**, including any preparatory steps, such as hormone treatment~~,~~ needed to facilitate the process **at, or under the supervision of, a SoHO entity**;	
Article 3, first paragraph, point (15)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
107	(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;***	(15) 'processing' means any operation involved in the handling of ~~SoHOs, including~~**SoHO including, but not limited to,** washing, shaping, separation, ~~fertilisation,~~ decontamination, sterilisation, preservation and packaging**, except for the preparatory handling of SoHO for immediate application during a surgical intervention, without the SoHO being removed from the surgical field before they are applied**;	
Article 3, first paragraph, point (16)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
108	(16) 'quality control' means several tests or checks to confirm that a SoHO activity or SoHO preparation meets pre-defined quality criteria;		(16) 'quality control~~'~~' means ~~several~~**a pre-defined test, set of** tests or checks to confirm that ~~a SoHO activity or SoHO preparation meets~~ pre-defined quality criteria **are met**;	
Article 3, first paragraph, point (17)				
109	(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***;	(17) 'storage' means the maintenance of ~~SoHOs~~**SoHO** under appropriate controlled conditions ~~until distribution~~;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (18)				
110	(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***;	(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 export** ;	
Article 3, first paragraph, point (18a)				
110a		***(18a) 'issuing' means the provision of SoHOs or SoHO preparations, where relevant following a medical prescription,***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		for application to a specific recipient;		
Article 3, first paragraph, point (19)				
111	(19) 'distribution' means transportation and delivery, within the Union, of released SoHOs or SoHO preparations intended for human application or for the manufacture of products regulated under other Union legislation, or as the starting and raw material thereof, including within the same organisation when SoHOs are delivered from a SoHO entity to a unit responsible for human application;		(19) 'distribution' means ~~transportation and delivery~~**providing**, within the Union, ~~of~~ released ~~SoHOs or SoHO preparations intended for human application or for the manufacture of products regulated under other Union legislation, or as the starting and raw material thereof, including within the same organisation when SoHOs are delivered from a SoHO entity to a unit responsible for human~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~application;~~**SoHO:**	
Article 3, first paragraph, point (19)(a)				
111a			**(a) intended for human application to a specific SoHO recipient in the same or another SoHO entity;**	
Article 3, first paragraph, point (19)(b)				
111b			**(b) intended for human application in general, without the prior identification of a**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			specific recipient, in the same or another SoHO entity;	
Article 3, first paragraph, point (19)(c)				
111c			**(c) intended for the manufacture of products regulated under other Union legislation, as provided for in Article 2(3), to a manufacturer of such products;**	
Article 3, first paragraph, point (20)				
112	(20) 'import' means activities carried out to bring SoHOs or		(20) 'import' means activities carried out to bring ~~SoHOs or~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHO preparations into the Union from a third country, including the organisation of such activities and physical verification of coherence with associated documentation, the appropriateness of transport conditions, the integrity of packaging and the adequacy of labelling before release;		~~SoHO preparations~~ **SoHO** into the Union from a third country~~,~~ ~~including the organisation of such activities and physical verification of coherence with associated documentation, the appropriateness of transport conditions, the integrity of packaging and the adequacy of labelling before~~ **before their** release;	
Article 3, first paragraph, point (20a)				
112a			**(20a) 'third country supplier' means an organisation, located outside the Union, which is contracted to**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			supply SoHO or to perform activities that might influence the quality and safety of the SoHO imported;	
Article 3, first paragraph, point (21)				
113	(21) 'export' means distribution of SoHOs or SoHO preparations to third countries;		(21) 'export' means ~~distribution of SoHOs or SoHO preparations to~~ **activities carried out to send SoHO from the Union to a** third ~~countries;~~**country.**	
Article 3, first paragraph, point (22)				
114				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(22) 'clinical outcome monitoring' means evaluation of the health of a SoHO recipient for the purpose of monitoring the results of a SoHO preparation application, maintaining care and demonstrating safety and efficacy;		(22) 'clinical outcome ~~monitoring~~**registration**' means ~~evaluation of the health of a SoHO recipient for the purpose of~~**the management of a registry where information on the clinical outcome** monitoring**, as referred to in Article 41, including transferring such information to other registries, is recorded** ~~the results of a SoHO preparation application, maintaining care and demonstrating safety and efficacy~~;	
Article 3, first paragraph, point (22a)				
114a			**(22a) 'clinical outcome monitoring plan' means a**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			programme for evaluating the safety and effectiveness of a SoHO preparation;	
Article 3, first paragraph, point (23)				
115	(23) 'autologous use' means collection of SoHO from one individual for subequent application to the same individual, with or without further SoHO activities between collection and application;	(23) 'autologous use' means collection of SoHO from one individual for ~~*subequent*~~***subsequent*** application to the same individual~~*, with or without further SoHO activities between collection and application*~~;	(23) 'autologous use' means ~~collection of SoHO from one individual for subequent applicationapplication~~ **of a SoHO collected from a person** to the same ~~individual, with or without further SoHO activities between collection and applicationperson~~;	
Article 3, first paragraph, point (24)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
116	(24) 'SoHO entity' means an organisation legally established in the Union that carries out one or more of the SoHO activities set out in Article 2(1);		(24) 'SoHO entity' means an organisation legally established in the Union that carries out one or more of the SoHO activities set out in Article ~~2(1)~~**2(1c)**;	
Article 3, first paragraph, point (25)				
117	(25) 'SoHO preparation authorisation' means the formal approval by a competent authority of a SoHO preparation, including the approval of the chain of activities carried out to obtain the SoHO preparation;		(25) ~~'SoHO preparation authorisation' means the formal approval by a competent authority of a SoHO preparation, including the approval of the chain of activities carried out to obtain the SoHO preparation;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (26)				
118	(26) 'vigilance' means a set of organised surveillance and reporting procedures relating to adverse occurrences;		(26) 'vigilance' means a set of organised surveillance and reporting procedures relating to adverse **reactions and adverse events** ~~occurrences~~;	
Article 3, first paragraph, point (27)				
119	(27) 'adverse occurrence' means any incident that caused harm to a living SoHO donor, harm to a SoHO recipient or to offspring	(27) 'adverse occurrence' means any incident ~~*that*~~ ***associated with the donation or human application of SoHOs, which***	(27) 'adverse ~~occurrence~~**reaction**' means any incident **which could be reasonably associated with the quality or safety of SoHO, or its**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	from medically assisted reproduction or that implied a risk of such harm;	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;	**collection or application to a SoHO recipient,** 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;~~**.**	
Article 3, first paragraph, point (27a)				
119a			**(27a) 'adverse event' means any incident or error associated with SoHO activities that may affect the quality or safety of SoHO in such a way that implies a risk of harm to a living SoHO donor, to a SoHO recipient or to offspring from medically assisted**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			reproduction.	
Article 3, first paragraph, point (28)				
120	(28) 'serious adverse occurrence' (SAO) means an adverse occurrence that resulted in, or implied a risk of, any of the following:		(28) 'serious adverse ~~occurrence~~**reaction**' (~~SAO~~**SAR**) means an adverse ~~occurrence that resulted in, or implied a risk of,~~ **reaction that results in** any of the following:	
Article 3, first paragraph, point (28)(a)				
121	(a) death;		(a) death;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (28)(b)				
122	(b) life-threatening, disabling or incapacitating condition, including transmission of a pathogen that might cause such condition;		(b) life-threatening, disabling or incapacitating condition, including transmission of a pathogen**, or a toxic substance** that might cause such condition;	
Article 3, first paragraph, point (28)(c)				
123	(c) transmission of a genetic condition to offspring from medically assisted reproduction with third party donation;		(c) transmission of a genetic **disorder that,** **in the case of medically assisted**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			reproduction with third party donation, **resulted in pregnancy loss or that might result in a life-threatening,** **disabling or incapacitating** condition to offspring from medically assisted reproduction with third party donation**, or, within couple use, as a result of** **a pre-implantation genetic test error**;	
Article 3, first paragraph, point (28)(d)				
124				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(d) hospitalisation or prolongation of hospitalisation;		(d) hospitalisation or prolongation of hospitalisation;	
Article 3, first paragraph, point (28)(e)				
125	(e) the need for a clinical intervention to prevent any of the above;		(e) the need for a **major** clinical intervention to prevent **or reduce the effects** **of** any of the above;	
Article 3, first paragraph, point (28)(f)				
126	(f) loss of a quantity of SoHOs that causes human applications to		(f) ~~loss of a quantity of SoHOs that causes human applications to~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	be postponed or cancelled;		~~be postponed or cancelled;~~	
Article 3, first paragraph, point (28)(g)				
127	(g) loss of highly matched or autologous SoHOs;		(g) ~~loss of highly matched or autologous SoHOs;~~	
Article 3, first paragraph, point (28)(h)				
128	(h) a mix-up of reproductive cells in such a way that an oocyte is fertilised with sperm from an individual other than the intended individual or reproductive cells are inseminated or transferred to the		(h) ~~a mix-up of reproductive cells in such a way that an oocyte is fertilised with sperm from an individual other than the intended individual or reproductive cells are inseminated or transferred to the~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	uterus or fallopian tube of a woman other than the intended recipient;		~~uterus or fallopian tube of a woman other than the intended recipient;~~	
Article 3, first paragraph, point (28)(ha)				
128a		***(ha) the transfer of embryos to a person other than the person intended;***		
Article 3, first paragraph, point (28)(i)				
129	(i) prolonged sub-optimal health of a SoHO donor following single or multiple donations;		(i) prolonged sub-optimal health of a SoHO donor following single or multiple donations;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (28a)				
129a			**(28a) 'serious adverse event' (SAE) means an** **adverse event that implies a risk in any of the following:**	
Article 3, first paragraph, point (28a)(a)				
129b			**(a) inappropriate SoHO distribution;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (28a) (b)				
129c			**(b) a defect implying risk to SoHO recipients or SoHO donors is detected in one SoHO entity that would have implications for other SoHO recipients or SoHO donors because of shared practices, services, supplies or critical equipment;**	
Article 3, first paragraph, point (28a)(c)				
129d			**(c) loss of a quantity of SoHO that causes human applications to be postponed or cancelled;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (28a)(d)				
129e			**(d) loss of highly matched or autologous SoHO;**	
Article 3, first paragraph, point (28a)(e)				
129f			**(e) a mix-up of reproductive SoHO in such a way that an oocyte is fertilised with sperm from an individual other than the intended individual or reproductive SoHO are applied to a recipient other than the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			intended recipient;	
Article 3, first paragraph, point (28a)(f)				
129g			**(f) event resulting in loss of the traceability of SoHO**	
Article 3, first paragraph, point (29)				
130	(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	(29) 'SoHO rapid alert' means a communication regarding ~~*a SAO*~~***an adverse occurrence***, a communicable disease outbreak or other information that might be of relevance to the safety and quality	(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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Member State and is to be transmitted rapidly between competent authorities and the Commission to facilitate the implementation of mitigating measures;	of SoHOs in more than one Member State and is to be transmitted rapidly between competent authorities and the Commission to facilitate the implementation of ***preventing or*** mitigating measures;	~~Member State and is to be transmitted rapidly between competent authorities and the Commission to facilitate the implementation of mitigating measures;~~	
Article 3, first paragraph, point (30)				
131	(30) 'non-viable' means having no potential for metabolism or multiplication;		(30) ~~'non-viable' means having no potential for metabolism or multiplication;~~	
Article 3, first paragraph, point (31)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
132	(31) 'EU SoHO Platform' means the digital platform established by the Commission to exchange information concerning SoHO activities;		(31) ~~'EU SoHO Platform' means the digital platform established by the Commission to exchange information concerning SoHO activities;~~	
Article 3, first paragraph, point (32)				
133	(32) 'SoHO supervisory activity' means any activity as provided for in Chapter III performed by a competent authority or by a delegated body in order to verify and enforce compliance with this Regulation;		(32) ~~'SoHO supervisory activity' means any activity as provided for in Chapter III performed by a competent authority or by a delegated body in order to verify and enforce compliance with this Regulation;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (33)				
134	(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;	(33) 'the **SoHO** compendium' means a list kept up-to-date by the SoHO Coordination Board **(SCB)** of decisions, taken at Member State level, and opinions, issued by **SoHO** competent authorities and by the SCB, on the regulatory status of specific substances, products or activities and published on the EU SoHO platform;	
Article 3, first paragraph, point (34)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
135	(34) 'quality management system' means a formalised system that documents processes, procedures, and responsibilities to support achieving defined quality standards in a consistent manner;		(34) 'quality management system' means a formalised system that documents processes, procedures, and responsibilities to support achieving defined quality standards in a consistent manner;	
Article 3, first paragraph, point (35)				
136	(35) 'delegated body' means a legal body to which the competent authority has delegated certain SoHO supervisory activities in accordance with Article 6;		(35) ~~'delegated body' means a legal body to which the competent authority has delegated certain SoHO supervisory activities in accordance with Article 6~~;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (36)				
137	(36) 'audit' means a systematic and independent examination to determine whether activities and the related results of such activities comply with legislation and planned arrangements and whether these arrangements are applied effectively and are suitable to achieve the objectives;		(36) ~~'audit' means a systematic and independent examination to determine whether activities and the related results of such activities comply with legislation and planned arrangements and whether these arrangements are applied effectively and are suitable to achieve the objectives;~~	
Article 3, first paragraph, point (37)				
138	(37) 'inspection' means a formal and objective control by a		(37) 'inspection' means a formal and objective control by a **SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	competent authority or delegated body to assess compliance with this Regulation and other relevant Union or national legislation and to identify the need for corrective or preventive action to achieve compliance;		competent authority or delegated body to assess compliance with **the requirements of** this Regulation and other relevant Union or national legislation ~~and to identify the need for corrective or preventive action to achieve compliance;~~**;**	
Article 3, first paragraph, point (38)				
139	(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;	(38) ~~'Union training' means activities for the personnel of competent authorities and, where appropriate, for personnel of delegated bodies performing SoHO supervisory activities;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (39)				
140	(39) 'assessors' means personnel performing the assessment of SoHO preparations as referred to in Article 22;		(39) ~~'assessors' means personnel performing the assessment of SoHO preparations as referred to in Article 22;~~	
Article 3, first paragraph, point (40)				
141	(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 ~~both~~***processing and storage or*** processing and ***release or*** storage ***and release*** of SoHOs;	(40) 'SoHO establishment' means a SoHO entity that carries out ~~both processing and storage of SoHOs;~~**any of the following**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			SoHO activities:	
Article 3, first paragraph, point (40)(a)				
141a			**(a) both processing and storage;**	
Article 3, first paragraph, point (40)(b)				
141b			**(b) release;**	
Article 3, first paragraph, point (40)(c)				
141c				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			(c) import;	
Article 3, first paragraph, point (40)(d)				
141d			**(d) export;**	
Article 3, first paragraph, point (41)				
142	(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 ~~*patients*~~***SoHO recipients***;	(41) 'critical SoHO' means a SoHO for which an insufficient supply will result in serious harm or risk of harm to ~~patients;~~**recipients' health or to a serious interruption in the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			manufacture of products defined in other Union legislation, as referred to in Article 2(3), where an insufficient supply of such products will result in serious harm or risk of harm to human health.	
Article 3, first paragraph, point (42)				
143	(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	(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	(42) 'critical SoHO entity' means a SoHO entity that carries out activities contributing to the supply of critical ~~SoHOs~~**SoHO** 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	products for patients;	products for ~~*patients*~~***SoHO recipients***;	substances or products for ~~patients~~ **recipients**;	
Article 3, first paragraph, point (43)				
144	(43) 'conditional authorisation' means the granting of permission by a competent authority to a SoHO entity to perform certain SoHO activities under specific conditions defined by that competent authority;		(43) ~~'conditional authorisation' means the granting of permission by a competent authority to a SoHO entity to perform certain SoHO activities under specific conditions defined by that competent authority;~~	
Article 3, first paragraph, point (44)				
145				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(44) 'on-site inspection' means an inspection carried out at the premises of the SoHO establishment, or other SoHO entity, concerned;		(44) ~~'on-site inspection' means an inspection carried out at the premises of the SoHO establishment, or other SoHO entity, concerned;~~	
Article 3, first paragraph, point (45)				
146	(45) 'technical guidelines' means a description of a series of methodological procedures and parameters that, if followed, achieve a level of quality and safety of a SoHO activity or a SoHO preparation that is considered to be acceptable as a means to comply with regulatory		(45) ~~'technical guidelines' means a description of a series of methodological procedures and parameters that, if followed, achieve a level of quality and safety of a SoHO activity or a SoHO preparation that is considered to be acceptable as a means to comply with regulatory~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	standards;		~~standards;~~	
Article 3, first paragraph, point (46)				
147	(46) 'joint inspection' means an inspection carried out by inspectors from more than one Member State;		(46) ~~'joint inspection' means an inspection carried out by inspectors from more than one Member State;~~	
Article 3, first paragraph, point (47)				
148	(47) 'traceability' means the ability to locate and identify SoHOs during any step from collection through processing and storage to distribution or disposal,	(47) 'traceability' means the ability to locate and identify SoHOs during any step from collection through processing and storage to ~~*distribution*~~***human***	(47) 'traceability' means the ability to locate and identify ~~SoHOs during any step from collection through processing and storage to distribution or disposal,~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	including the ability to:	***application*** or disposal, including the ability to:	~~including the ability to:~~**SoHO from collection to human application, disposal or distribution for the manufacture of products regulated by other Union legislation, as provided for in Article 2(3);**	
Article 3, first paragraph, point (47)(a)				
149	(a) identify the SoHO donor and the SoHO entity processing or storing the SoHOs;		(a) ~~identify the SoHO donor and the SoHO entity processing or storing the SoHOs;~~	
Article 3, first paragraph, point (47)(b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
150	(b) identify the recipient at the SoHO entity applying the SoHOs to the recipient;		(b) ~~identify the recipient at the SoHO entity applying the SoHOs to the recipient;~~	
Article 3, first paragraph, point (47)(c)				
151	(c) locate and identify all relevant data relating to the safety and quality of the SoHOs and any materials coming into contact with those SoHOs;		(c) ~~locate and identify all relevant data relating to the safety and quality of the SoHOs and any materials coming into contact with those SoHOs;~~**;**	
Article 3, first paragraph, point (48)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
152	(48) 'Single European Code' (SEC) means the unique identifier applied to certain SoHOs distributed in the Union;		(48) 'Single European Code' (SEC) means the unique identifier applied to certain SoHOs distributed in the Union;	
Article 3, first paragraph, point (49)				
153	(49) 'SAO notification' means the communication from a SoHO entity, a SoHO establishment or a SoHO donor or recipient to a competent authority, of a serious adverse occurrence or a suspected serious adverse occurrence associated with a SoHO donation or human application;		(49) ~~'SAO notification' means the communication from a SoHO entity, a SoHO establishment or a SoHO donor or recipient to a competent authority, of a serious adverse occurrence or a suspected serious adverse occurrence associated with a SoHO donation or human application;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (50)				
154	(50) 'SAO investigation report' means the report from a SoHO entity or a SoHO establishment to a competent authority on a specific SAO, describing the outcome and including an assessment of the seriousness and the level of imputability, the likely cause and any corrective action taken;		(50) ~~'SAO investigation report' means the report from a SoHO entity or a SoHO establishment to a competent authority on a specific SAO, describing the outcome and including an assessment of the seriousness and the level of imputability, the likely cause and any corrective action taken;~~	
Article 3, first paragraph, point (51)				
155				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(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 ~~*a serious*~~***an*** adverse occurrence, in a SoHO donor, is related to the ~~*donation*~~***collection*** process or, in a ***SoHO*** recipient ***or offspring from medically assisted reproduction***, to the application of the SoHOs;	(51) 'imputability' means the likelihood that ~~a serious adverse occurrence~~**an adverse reaction** , in a SoHO donor, is ~~related to the donation~~**associated with the collection** process or, in a **SoHO** recipient **or offspring from medically assisted reproduction, with**~~, to~~ the application of the ~~SoHOs~~**SoHO**;	
Article 3, first paragraph, point (52)				
156	(52) 'seriousness' means the degree of severity of an adverse occurrence, involving harm to a SoHO donor, recipient or offspring from medically assisted		(52) 'seriousness' means the degree of severity of an adverse ~~occurrence~~**reaction**, involving harm to a **living** SoHO donor, **a SoHO** recipient or offspring from	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	reproduction, at and above which the occurrence shall be notified to a competent authority;		medically assisted reproduction~~, at and above which the occurrence shall be notified to a competent authority~~ **or for public health in general, or an adverse event involving a risk of such harm**;	
Article 3, first paragraph, point (53)				
157	(53) 'self-reporting' means the notification of a SAO by a SoHO recipient or a SoHO donor directly to the competent authorities;		(53) ~~'self-reporting' means the notification of a SAO by a SoHO recipient or a SoHO donor directly to the competent authorities;~~	
Article 3, first paragraph, point (54)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
158	(54) 'Annual SoHO Vigilance Report' means the annual report published by the Commission aggregating the summaries from the SoHO National Authorities on SAO notifications and SAO investigation reports received;		(54) ~~'Annual SoHO Vigilance Report' means the annual report published by the Commission aggregating the summaries from the SoHO National Authorities on SAO notifications and SAO investigation reports received;~~	
Article 3, first paragraph, point (55)				
159	(55) 'deferral' means temporary or permanent suspension of the eligibility of an individual to donate SoHO;		(55) ~~'deferral' means temporary or permanent suspension of the eligibility of an individual to donate SoHO;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (56)				
160	(56) 'responsible person' means the nominated individual in a SoHO entity that has responsibility for SoHO release;		(56) ~~'responsible person' means the nominated individual in a SoHO entity that has responsibility for SoHO release;~~	
Article 3, first paragraph, point (56a)				
160a			**(56a) 'responsible person' means a nominated individual in a SoHO entity that has the responsibility of ensuring compliance with the Regulation;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (57)				
161	(57) 'process validation' means establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce results meeting predetermined specifications and quality attributes;		(57) ~~'process validation' means establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce results meeting predetermined specifications and quality attributes;~~	
Article 3, first paragraph, point (58)				
162	(58) 'equipment qualification' means establishing documented evidence that provides a high		(58) ~~'equipment qualification' means establishing documented evidence that provides a high~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	degree of assurance that a specific piece of equipment will consistently perform to predetermined specifications;		~~degree of assurance that a specific piece of equipment will consistently perform to predetermined specifications~~;	
Article 3, first paragraph, point (59)				
163	(59) 'EDQM SoHO monograph' means a specification of the critical quality parameters of a particular SoHO preparation defined by the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe;		(59) ~~'EDQM SoHO monograph' means a specification of the critical quality parameters of a particular SoHO preparation defined by the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (60)				
164	(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;	(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;~~	
Article 3, first paragraph, point (61)				
165	(61) 'reproductive cells' means all cells intended to be used for the	(61) '~~*reproductive cells*~~***SoHO for reproduction***' means all cells	(61) 'reproductive ~~cells~~**SoHO**' means ~~all cells~~ **human sperm,**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	purpose of medically assisted reproduction;	intended to be used for the purpose of medically assisted reproduction, ***and embryos resulting from fertilisation***;	**oocytes, ovarian and testicular tissue** intended to be used for the purpose of medically assisted reproduction **or restoring endocrine function. For the purposes of this Regulation, embryos are considered reproductive SoHO even though they are** **not collected from the human body**;	
Article 3, first paragraph, point (62)				
166	(62) 'third party donation' means a donation of reproductive cells by a person to a person or a couple with	(62) 'third party donation' means a donation of ~~*reproductive cells*~~***a SoHO for reproduction*** by a	(62) 'third party donation' means a donation of reproductive ~~cells by a person to a person or a~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	whom the donor does not have an intimate physical relationship;	person to a ~~*person*~~***recipient*** or a couple with whom the donor does not have an intimate physical relationship;	~~couple~~**SoHO to be used for a SoHO recipient** with whom the donor does not have an intimate physical relationship;	
Article 3, first paragraph, point (62a)				
166a		***(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;***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (63)				
167	(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 ~~couple~~***relationship*** use' means use of reproductive cells for medically assisted reproduction ~~*from two*~~***between*** persons with an intimate physical relationship, where ~~*one*~~***a*** person ~~*supplies*~~***provides*** their own oocytes and ~~*the other*~~***another*** person supplies their own sperm ***for the human application to a person within the relationship***;	(63) 'within couple use' means use of reproductive ~~cells~~**SoHO** 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~~;	
Article 3, first paragraph, point (64)				
168				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(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;	(64) 'compensation' means making good of any losses associated with donation;	
Article 3, first paragraph, point (64a)				
168a		***(64a) 'financial neutrality of donation' means that no financial gain or loss will be incurred by the donor as a result of the donation;***		
Article 3, first paragraph, point (65)				
169				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(65) 'allogeneic use' means collection of SoHO from one individual for subsequent application to another individual;		(65) 'allogeneic use' means ~~collection of SoHO from one individual for subsequent application to another individual~~**application of a SoHO collected from a person other than** **the SoHO recipient**;	
Article 3, first paragraph, point (66)				
170	(66) 'SoHO supply alert' means a communication regarding a significant interruption to the supply of critical SoHOs that is to be transmitted to a competent authority, and when necessary, by		(66) ~~'SoHO supply alert' means a communication regarding a significant interruption to the supply of critical SoHOs that is to be transmitted to a competent authority, and when necessary, by~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	a SoHO National Authority to the competent authorities of other Member States;		~~a SoHO National Authority to the competent authorities of other Member States;~~	
Article 3, first paragraph, point (67)				
171	(67) 'plasma master file' (PMF) means a compilation of the required scientific data, covering all aspects of the use of plasma, from collection to the creation of a plasma pool, on the quality and safety of human plasma relevant to the medicinal products, medical devices and investigational products that use human plasma in their manufacture;		(67) ~~'plasma master file' (PMF) means a compilation of the required scientific data, covering all aspects of the use of plasma, from collection to the creation of a plasma pool, on the quality and safety of human plasma relevant to the medicinal products, medical devices and investigational products that use human plasma in their manufacture~~;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 3, first paragraph, point (68)				
172	(68) 'plasma for transfusion' means plasma separated from whole blood or collected by apheresis for the purpose of transfusion to a recipient;		(68) ~~'plasma for transfusion' means plasma separated from whole blood or collected by apheresis for the purpose of transfusion to a recipient;~~	
Article 3, first paragraph, point (69)				
173	(69) 'plasma for fractionation' means plasma separated from whole blood or collected by apheresis and used as the starting		(69) ~~'plasma for fractionation' means plasma separated from whole blood or collected by apheresis and used as the starting~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	material for manufacturing of plasma-derived medicinal products;		~~material for manufacturing of plasma-derived medicinal products;~~	
Article 3, first paragraph, point (70)				
174	(70) 'apheresis' means a process by which a specific blood component or type of stem cell is separated from whole blood during the donation, allowing the remaining blood components to be returned immediately to the donor.		(70) ~~'apheresis' means a process by which a specific blood component or type of stem cell is separated from whole blood during the donation, allowing the remaining blood components to be returned immediately to the donor.~~	
Article 3, first paragraph, point (70a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
174a		***(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;***		
Article 3, first paragraph, point (70b)				
174b		***(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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		use;		
Article 3, first paragraph, point (70c)				
174c		***(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;***		
Article 3, first paragraph, point (70d)				
174d		***(70d) 'European autonomy' means the Union's degree of***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		independence from third countries in relation to the collection of SoHOs, the manufacture of SoHO preparations and any other SoHO activities.		
Article 4				
175	Article 4 More stringent Member State measures		Article 4 More stringent Member State measures	
Article 4(1)				
176				

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	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***	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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 4(2)				
177	2. Member States shall make available to the public details of measures put in place in accordance with paragraph 1 without undue delay, including on the internet. The SoHO National Authority shall submit the details of any more stringent measure to the EU SoHO Platform referred to in Chapter XI.		2. Member States shall make available to the public details of ~~measures put in place~~**the more stringent measures adopted** in accordance with paragraph 1 without undue delay, including on the internet. The SoHO National Authority shall submit the details of any **such** more stringent ~~measure~~**measures** to the EU SoHO Platform ~~referred to in Chapter XI~~.	
CHAPTER II				
178				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	CHAPTER II COMPETENT AUTHORITIES		CHAPTER II **MEMBER STATES' SoHO** COMPETENT AUTHORITIES	
Article 5				
179	Article 5 Designation of competent authorities		Article 5 Designation of **SoHO** competent authorities	
Article 5(1)				
180	1. Member States shall designate		1. Member States shall designate	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the competent authority or authorities to which they confer responsibility for the SoHO supervisory activities provided for in Chapter III. The organisation or organisations designated shall be independent from any SoHO entity.		the **SoHO** competent authority or authorities to which ~~they~~ confer responsibility for the SoHO supervisory activities ~~provided for in Chapter III. The organisation or organisations~~**. The authority or authorities** designated shall be independent from any SoHO entity.	
Article 5(2)				
181	2. For the same territory, a Member State may confer responsibilities for SoHO supervisory activities to more than one competent authority, at national, regional or local level.		2. ~~For the same territory,~~ A Member State may confer responsibilities for SoHO supervisory activities ~~-~~ to more than one **SoHO** competent authority, at national, regional or	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			local level.	
Article 5(3)				
182	3. Member States shall ensure that competent authorities:		3. Member States shall ensure that **SoHO** competent authorities:	
Article 5(3), point (a)				
183	(a) have the autonomy to act and make decisions independently and impartially while respecting the internal administrative organisational requirements determined by the Constitutions of	(a) have the autonomy to act and make decisions independently and impartially while respecting the internal administrative organisational requirements determined ~~*by the Constitutions of*~~	(a) have the autonomy to act and make decisions independently and impartially while respecting the ~~internal administrative~~ **constitutional,**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the Member States;	~~*the Member States*~~***in national legislation***;	organisational ~~requirements determined by the Constitutions of the~~**and administrative structure of** Member States;	
Article 5(3), point (b)				
184	(b) have the necessary powers:		(b) have the necessary powers:	
Article 5(3), point (b)(i)				
185	(i) to properly perform their supervisory activities, including access to the premises of, and		(i) to properly perform ~~their~~**the SoHO** supervisory activities **they have been made**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	documents and samples kept by, SoHO entities and any third parties contracted by a SoHO entity;		**responsible for**, including **having** access to the premises of, and documents and samples kept by~~,~~ SoHO entities and any third parties contracted by a SoHO entity;	
Article 5(3), point (b)(ii)				
186	(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***;	(ii) to order the immediate suspension or cessation of a SoHO activity that poses immediate risk to SoHO donors, SoHO recipients**, offspring from medically assisted reproduction** or the general public;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 5(3), point (b)(iii)				
187	(iii) to take decisions on the access and re-use of personal data;		(iii) ~~to take decisions on the access and re-use of personal data;~~	
Article 5(3), point (c)				
188	(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;	(c) have**, or have access to,** sufficient resources, operational capacity, and expertise to achieve the aims of, and fulfil their obligations under, this Regulation;	
Article 5(3), point (d)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
189	(d) are governed by appropriate confidentiality obligations in accordance with Article 75.		(d) are ~~governed by~~ **subject to** appropriate confidentiality obligations in ~~accordance~~**order to comply** with Article 75.	
Article 5(4)				
190	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	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	4. ~~Each~~**When a** Member State **designates only one SoHO competent authority in accordance with paragraph 1, the SoHO competent authority** shall ~~designate a single~~**also be appointed as**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Member States' SoHO National Authorities.	Member States' SoHO National Authorities. ***The Commission shall make publicly available the list of SoHO National Authorities on the EU SoHO Platform.***	**the SoHO National Authority. When a Member State designates more than one SoHO competent authorithies in** **accordance with paragraph 1, it shall appoint one** SoHO National Authority **among them, in accordance with national law. The SoHO National Authority shall be**~~, in conformity with Member States' constitutional requirements,~~ responsible for ~~coordinating exchanges with the Commission and with other~~**activities as referred** **to in Article 9(1a). The designation of a single SoHO National Authority should not preclude the** Member ~~States' SoHO National~~**State from**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			assigning certain tasks to other SoHO competent authorities**, in particular, for the management of rapid alerts to ensure an efficient and agile communication when serious adverse reactions or serious adverse events involve more than one Member State**.	
Article 5(5)				
191	5. Member States shall submit to the EU SoHO Platform referred to in Chapter XI:		5. Member States shall submit to the EU SoHO Platform**,** **and keep updated, information on** ~~referred to in Chapter XI~~:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 5(5), point (a)				
192	(a) the names and contact details of the competent authorities designated pursuant to paragraph 1;		(a) ~~the names and contact details of the competent authorities designated pursuant to paragraph 1;~~	
Article 5(5), point (b)				
193	(b) the names and contact details of their SoHO National Authority referred to in paragraph 4.		(b) the ~~names~~**name** and contact details of ~~their~~**the** SoHO National Authority referred to in paragraph 4~~.~~**;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 5(5), point (ba)				
193a			**(ba) the names and contact details of any SoHO competent authority designated pursuant to paragraph 1, when different from the SoHO National Authority referred to in paragraph 4.**	
Article 5(6)				
194	6. Member States shall update the EU SoHO Platform without undue delay with any changes to the information referred to in		6. ~~Member States shall update the EU SoHO Platform without undue delay with any changes to the information referred to in~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	paragraph 5.		~~paragraph 5.~~	
Article 6				
195	Article 6 Delegation by competent authorities of certain SoHO supervisory activities		Article 6 ~~Delegation by competent authorities of certain SoHO supervisory activities~~	
Article 6(1)				
196	1. Member States or competent authorities may delegate certain SoHO supervisory activities to one		1. ~~Member States or competent authorities may delegate certain SoHO supervisory activities to one~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	or more delegated bodies in accordance with the conditions provided for in Article 10. Member States or competent authorities shall ensure that delegated bodies have the powers needed to effectively perform any activities delegated to them.		~~or more delegated bodies in accordance with the conditions provided for in Article 10. Member States or competent authorities shall ensure that delegated bodies have the powers needed to effectively perform any activities delegated to them.~~	
Article 6(2)				
197	2. Where Member States or competent authorities decide to delegate certain SoHO supervisory activities to one or more delegated bodies, they shall submit information regarding such delegations to the EU SoHO		2. ~~Where Member States or competent authorities decide to delegate certain SoHO supervisory activities to one or more delegated bodies, they shall submit information regarding such delegations to the EU SoHO~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Platform referred to in Chapter XI with details of the delegated supervisory tasks.		~~Platform referred to in Chapter XI with details of the delegated supervisory tasks.~~	
Article 7				
198	Article 7 Independence and impartiality		Article 7 Independence and impartiality	
Article 7(1)				
199	1. Competent authorities shall act independently, in the public interest and free from any external	1. Competent authorities ***and members of the SCB*** shall act independently, in the public	1. **When performing their tasks and excercising their powers, SoHO** competent authorities shall	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	influence.	interest and free from any external influence.	act independently **and impartially**, in the public interest and free from any external **undue** influence.	
Article 7(2)				
200	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***	2. **SoHO** competent authorities shall ensure ~~that their personnel~~**thatpersonnel performing SoHO supervisory activities** have no ~~direct or indirect economic,~~ financial or ~~personal~~**other** 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		interests, which shall be published on the competent authorities' website.	professional conduct.	
Article 7(2a)				
200a		***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.***		
Article 7(3)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
201	3. Paragraphs 1 and 2 shall also apply to delegated bodies.		3. ~~Paragraphs 1 and 2 shall also apply to delegated bodies.~~	
Article 8				
202	Article 8 Transparency		Article 8 Transparency	
Article 8(1)				
203	1. Without prejudice to Article 75, competent authorities shall carry	1. Without prejudice to Article 75, competent authorities ***and***	1. ~~Without prejudice to Article 75,~~ **SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	***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***.	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.~~**:**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 8(1a)				
203a			**(a) carry out the SoHO supervisory activities they have been made responsible for in a transparent manner, at least by complying with the publication requirements provided for in this Regulation; and**	
Article 8(1b)				
203b			**(b) make any enforcement decision, according to Articles 19(1) point d, 21(6)–(8), 27(3)–(5) or 29(9) point (g), and the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			reasons for it, accessible and clear to the public in cases where:	
Article 8(1b)(i)				
203c			**(i) a SoHO entity does not comply with** **the provisions of this Regulation, or**	
Article 8(1b)(ii)				
203d			**(ii) there is a serious risk to the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			safety of SoHO donors, recipients, offspring from medically assisted reproduction or public health.	
Article 8(2)				
204	2. Paragraph 1 shall not affect national legislation on access to information.		2. Paragraph 1 shall ~~not affect~~**be without prejudice to Article 75 and to** national legislation on access to information.	
Article 8(3)				
205	3. Competent authorities shall lay		3. **SoHO** competent authorities	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	down practical arrangements for implementing the transparency rules referred to in paragraph 1 in their internal rules.		shall lay down **in their internal rules** practical arrangements for implementing the transparency rules referred to in paragraph 1 ~~in their internal rules~~.	
Article 8(4)				
206	4. Paragraphs 1, 2 and 3 shall also apply to delegated bodies.		4. ~~Paragraphs 1, 2 and 3 shall also apply to delegated bodies.~~	
Article 9				
207	Article 9		Article 9	

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	General responsibilities and obligations		General responsibilities and obligations **of** **SoHO competent authorities**	
Article 9(1)				
208	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.	1. **SoHO** competent authorities shall be responsible for the SoHO supervisory activities ~~referred to in Chapter III~~ in order to verify the effective compliance ~~of~~**by** SoHO entities ~~in~~**on** their territory with the requirements set out in this Regulation.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 9(1a)				
208a			**1a. The SoHO National Authority appointed in accordance with Article 5(4) shall be responsible for coordinating the information exchanges with the Commission and with other Member States' SoHO National Authorities, as well as other tasks, provided for in Articles 4(2), 13(4), 14(1), (2) and (3), 18(1), 33(3), 35(10a) and (11),** **36(2), -62, 63(3), 64(2) and (3), and 67(2) and (4). The SoHO National** **Authority may also be**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			responsible for the task provided for in Article 13(1).	
Article 9(2)				
209	2. Competent authorities shall have in place:		2. **SoHO** competent authorities shall ~~have in place~~:	
Article 9(2), point (a)				
210	(a) a sufficient number of suitably qualified personnel to carry out the supervisory functions provided for in this Regulation;	(a) ~~*a sufficient number of suitably qualified personnel*~~***human and financial resources, operational capacity, and expertise, including***	(a) **have, or have access to,** a sufficient number of suitably qualified **and experienced** personnel to carry out the **SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		technical expertise, to carry out the supervisory functions provided for in this Regulation;	supervisory ~~functions provided for in this Regulation~~**activities they have been made responsible for, efficiently and** **effectively**;	
Article 9(2), point (aa)				
210a			**(aa) have procedures in place to ensure compliance with the confidentiality obligations set out in Article 75;**	
Article 9(2), point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
211	(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;	(b) ~~procedures to~~ ensure the independence, impartiality, effectiveness, quality, suitability for purpose and consistency of their SoHO supervisory activities;	
Article 9(2), point (c)				
212	(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;	(c) **have** appropriate and properly maintained ~~facilities~~**premises** and equipment to ensure that **the** personnel can perform their SoHO supervisory activities efficiently and effectively;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 9(2), point (d)				
213	(d) a quality management system for their SoHO supervisory activities that includes a plan for continuity of their activities in case of exceptional circumstances.		(d) **have** a quality management system **or standardised documented procedures in place for the**~~for their~~ SoHO supervisory activities **they have been made responsible for** that includes a plan for continuity of their activities in case of **crisis situations** **that impede the normal performance of their tasks;** ~~exceptional circumstances.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 9(2), point (da)				
213a			**(da) develop and implement, or provide access to, training programmes to ensure that personnel performing SoHO supervisory activities receive, for their area of competence, appropriate training;**	
Article 9(2), point (db)				
213b			**(db) provide opportunities for their personnel to participate in the Union training referred to in Article 69 where such training is**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			available and relevant.	
Article 9(3)				
214	3. Paragraphs 1 and 2 shall also apply to delegated bodies.		3. ~~Paragraphs 1 and 2 shall also apply to delegated bodies.~~	
Article 10				
215	Article 10 Conditions for delegating certain SoHO supervisory activities to delegated bodies		Article 10 ~~Conditions for delegating~~**Delegation of** certain SoHO supervisory activities to ~~delegated~~**other** bodies	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 10(1a)				
215a			**-1a. Member States may empower a SoHO competent authority responsible for any of the SoHO supervisory activities as referred to in Articles 22, 23, 29, 30, 31, 33(1), 34(1), 35(1a),(2), (3) point (a), (4), (5), (6), (6a), (7), (9) and (10) to delegate that SoHO supervisory activity to one or more other bodies.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 10(1)				
216	1. Member States and competent authorities that delegate certain SoHO supervisory activities to a delegated body referred to in Article 6 shall conclude a written agreement on the delegation.		1. Member States **shall ensure that the delegated bodies have the powers needed to effectively perform the activities delegated to them and fulfil the requirements in Article 11. SoHO** ~~and~~ competent authorities that delegate ~~certain~~ SoHO supervisory activities ~~to a delegated body referred to in Article 6~~**in accordance with paragraph -1a to a delegated body** shall ~~conclude~~**have in place** a written agreement ~~on the delegation~~**with that delegated**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			body.	
Article 10(2)				
217	2. Competent authorities shall ensure that the agreement referred to in paragraph 1 includes the following:		2. **The delegating SOHO** competent authorities shall ensure that ~~the~~ **the** **written** agreement **includes at least** ~~referred to in paragraph 1 includes~~ the following:	
Article 10(2), point (a)				
218	(a) a precise description of the		(a) a precise description of the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHO supervisory activities that the delegated body is expected to perform, and the conditions under which those activities are expected to be performed;		SoHO supervisory activities that the delegated body is expected to perform, and the conditions under which those activities are expected to be performed;	
Article 10(2), point (b)				
219	(b) the conditions to be met by the delegated body, including that the delegated body:		(b) the ~~conditions to be met by~~**condition that** the delegated body**:** **participates in certification or other schemes at Union level, when available, to ensure the uniform application of principles of good practices required for their relevant sector;**~~, including~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~that the delegated body:~~	
Article 10(2), point (b)(i)				
220	(i) has the expertise, equipment and infrastructure required to perform those SoHO supervisory activities delegated to it;		(i) ~~has the expertise, equipment and infrastructure required to perform those SoHO supervisory activities delegated to it;~~	
Article 10(2), point (b)(ii)				
221	(ii) has a sufficient number of suitably qualified and experienced staff;		(ii) ~~has a sufficient number of suitably qualified and experienced staff;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 10(2), point (b)(iii)				
222	(iii) participates in certification or other schemes at Union level, when available, to ensure the uniform application of principles of good practices required for their relevant sector;		(iii) ~~participates in certification or other schemes at Union level, when available, to ensure the uniform application of principles of good practices required for their relevant sector;~~	
Article 10(2), point (b)(iv)				
223	(iv) has sufficient powers to perform the SoHO supervisory activities delegated to it;		(iv) ~~has sufficient powers to perform the SoHO supervisory activities delegated to it;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 10(2), point (c)				
224	(c) a precise description of arrangements ensuring an efficient and effective coordination between the delegating competent authorities and the delegated body;		(c) a precise description of **the** arrangements ensuring an efficient and effective coordination between the delegating **SoHO** competent ~~authorities~~**authority** and the delegated body;	
Article 10(2), point (d)				
225	(d) provisions for the fulfilment of the obligations of the delegated body as set out in Articles 11 and		(d) provisions ~~for~~**on** the fulfilment of the obligations ~~of the delegated body~~ as set out in Articles 11 and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	12.		12.;	
Article 10(2), point (da)				
225a			**(da) provisions on its termination in the case of withdrawal of the delegation pursuant to Article 12.**	
Article 10(2a)				
225b			**2a. SoHO competent authorities having delegated SoHO supervisory activities pursuant to paragraph -1a shall submit to the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			EU SoHO Platform the names and contact details of the delegated bodies, together with the details concerning the delegated SoHO supervisory activities.	
Article 11				
226	Article 11 Obligations of the delegated bodies		Article 11 Obligations of the delegated bodies	
Article 11, first paragraph				
227				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Delegated bodies to which certain SoHO supervisory activities have been delegated in accordance with Article 6 shall:		**1.** Delegated bodies to which ~~certain~~ SoHO supervisory activities ~~have been~~**are** delegated in accordance with Article ~~6~~**10** shall:	
Article 11, first paragraph, point (-aa)				
227a			**(-a) meet the requirements specified in Article 9(2);**	
Article 11, first paragraph, point (a)				
228	(a) communicate to the delegating competent authorities, on a regular		(a) ~~communicate to~~**inform** the delegating **SoHO** competent	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	basis and whenever those competent authorities so request, the outcome of the SoHO supervisory activities performed by them;		authorities, on a regular basis and whenever those **delegating SoHO** competent authorities so request, **of** the outcome of the SoHO supervisory activities performed by them;	
Article 11, first paragraph, point (b)				
229	(b) immediately inform the delegating competent authorities whenever the outcome of the delegated SoHO supervisory activities indicates non-compliance or points to the likelihood of non-compliance, unless specific arrangements established between those competent authorities and the		(b) immediately inform the delegating **SoHO** competent authorities whenever the outcome of the delegated SoHO supervisory activities indicates non-compliance or points to the likelihood of non-compliance, unless specific **written** arrangements established between those **delegating**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	delegated bodies provide otherwise; and		**SoHO** competent authorities and the delegated bodies provide otherwise; and	
Article 11, first paragraph, point (c)				
230	(c) cooperate with the delegating competent authorities, including by providing access to their premises and facilities.		(c) **fully** cooperate with the delegating **SoHO** competent authorities, including by providing access to their premises and ~~facilities~~**documentation,** **including IT systems**.	
Article 11 (2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
230a			**2. Delegated bodies shall be subject to the provisions of Articles 7, 15 and 75 in full and, where relevant, to the provisions of** **Articles 24 and 32.**	
Article 12				
231	Article 12 Obligations of the delegating competent authorities		Article 12 Obligations of the delegating **SoHO** competent authorities	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 12, first paragraph				
232	Competent authorities that have delegated certain SoHO supervisory activities to delegated bodies in accordance with Article 6 shall:		**SoHO** competent authorities that have delegated certain SoHO supervisory activities to delegated bodies in accordance with Article ~~6~~ **10** shall:	
Article 12, first paragraph, point (a)				
233	(a) organise audits or inspections of such bodies, as necessary and taking into account participation of such bodies in certification or other schemes referred to in Article 10(2), point (b)(iii);		(a) ~~organise~~**conduct regularly** audits ~~or inspections of such bodies, as necessary and~~**of the delegated bodies . The interval between such audits shall be determined by the delegating**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			SoHO competent authority, taking into account **the** participation of ~~such~~**the delegated** bodies in certification or other schemes referred to in Article ~~10(2)~~**10(1)**, point (b)~~(iii)~~**, as well as the scope and the impact of the delegated SoHO supervisory activities on the quality and safety of SoHO**;	
Article 12, first paragraph, point (b)				
234	(b) fully or partly withdraw the delegation without delay in particular in cases where:		(b) fully or partly withdraw the delegation without delay **when necessary, and** in particular in cases where:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 12, first paragraph, point (b)(i)				
235	(i) there is evidence that such delegated bodies are failing to properly perform the activities delegated to them;		(i) there is evidence that ~~such~~**the** delegated bodies are failing to properly perform the **SoHO supervisory** activities delegated to them;	
Article 12, first paragraph, point (b)(ii)				
236	(ii) the delegated bodies fail to take appropriate and timely action to remedy the shortcomings identified; or		(ii) the delegated bodies ~~fail~~**have failed** to take appropriate and timely action to remedy ~~the shortcomings~~**such performance**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			failures identified; or	
Article 12, first paragraph, point (b)(iii)				
237	(iii) the independence or impartiality of the delegated bodies has been shown to be compromised.		(iii) **there is evidence that** the independence or impartiality of the delegated bodies has been ~~shown to be~~ compromised.	
Article 13				
238	Article 13 Communication and coordination between SoHO competent		Article 13 Communication and coordination between SoHO competent	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorities		authorities	
Article 13(1)				
239	1. Where more than one authority is competent to perform SoHO supervisory activities in a Member State pursuant to Article 5(2), the Member State shall ensure efficient and effective coordination between all SoHO competent authorities involved, to ensure consistency and effectiveness of SoHO supervisory activities as set by this Regulation across its territory.		1. Where more than one authority is competent to perform SoHO supervisory activities in a Member State pursuant to Article 5(2), the Member State **or the SoHO National Authority** shall ensure efficient and effective coordination between all **the** SoHO competent authorities ~~involved, to ensure~~**concerned in order to guarantee** consistency and effectiveness of **the** SoHO supervisory activities ~~as set by this Regulation across~~**performed on** its	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			territory.	
Article 13(2)				
240	2. Competent authorities shall cooperate with each other and with the Commission. They shall communicate information to each other and, in particular, to the SoHO National Authority as necessary for the effective implementation of the supervisory functions provided for in this Regulation.		2. **Within a Member State, SoHO** competent authorities shall cooperate with each other ~~and with the Commission~~. They shall communicate information to each other and, in particular, to the SoHO National Authority as necessary for the effective implementation of the **SoHO** supervisory ~~functions provided for in this Regulation~~**activities including the activities of the SoHO National Authority as referred to in Article 9(1a)**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 13(3)				
241	3. In cases where competent authorities provide an opinion to a SoHO entity on the applicability of this Regulation to a particular substance or activity within their territory, those competent authorities shall notify the SoHO National Authority, which, in turn, shall notify the SoHO Coordination Board ('SCB') of the opinion given to the SoHO entity.		3. In cases where **a SoHO** competent ~~authorities provide~~**authority issues** an opinion to a SoHO entity on the applicability of this Regulation to a particular substance**, product** or activity ~~within their~~**on its** territory, ~~those~~**that SoHO** competent ~~authorities~~**authority** shall notify the SoHO National Authority **of that opinion issued**, which, in turn, shall notify the ~~SoHO Coordination Board ('SCB') of the opinion given to the SoHO entity~~**SCB**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 13(4)				
242	4. Following a reasoned request from a competent authority of another Member State, the competent authority shall without undue delay inform the requesting competent authority of the outcome of supervisory activities concerning a SoHO entity on its territory, and, as necessary and proportionate, provide the records referred to in Articles 29 and 30.		4. Following a ~~reasoned~~**duly substantiated** request from ~~a competent~~**the SoHO National** Authority of another Member State, the ~~competent~~**SoHO National** Authority shall without undue delay**, and ensuring consideration of aspects of confidentiality as set out in Article 75,** inform the requesting ~~competent~~**SoHO National** Authority of the outcome of **the SoHO** supervisory activities concerning a SoHO entity on its territory, and, as necessary and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			proportionate, provide the ~~records~~**requesting SoHO National Authority with the relevant documentation related to activities** referred to in Articles 29 and 30.	
Article 14				
243	Article 14 Obligations to consult and cooperate with authorities of other regulatory sectors		Article 14 ~~Obligations to consult and cooperate~~**Consultation and cooperation** with authorities of other regulatory sectors	
Article 14(-1a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
243a			**-1a. Member States shall ensure that the SoHO National Authority has appropriate mechanisms to communicate with the competent authorities for organs designated under Directive 2010/53/EU and any competent authorities designated under other Union legislation referred to in Article 2(3) within that Member State.**	
Article 14(1)				
244	1. In all cases where questions arise as to the regulatory status of a	1. In all cases where questions arise as to the regulatory status of a	1. In all cases where questions arise as to the regulatory status of a	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	substance, product or activity, competent authorities shall consult with authorities established in other relevant Union legislation referred to in Article 2(3), as relevant. In such cases, competent authorities shall also consult the compendium referred to Article 3 point (33).	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 relevant~~.~~ In such cases, competent authorities shall also consult the compendium referred to Article 3**,** point (33).	substance, product or activity, **the SoHO** competent authorities shall**, in addition to what is set out in Article 13(2) of this Regulation,** consult**, via the SoHO National Authority, with the competent authorities** ~~with authorities established in other relevant Union legislation~~ referred to in ~~Article 2(3), as relevant~~**paragraph -1a, as appropriate, with a view to reaching a decision on the regulatory status**. In such cases, **SoHO** competent authorities **involved in the consultation** shall also consult the **SoHO** compendium**, and consider any relevant regulatory status decision and take into account any relevant opinion included therein** ~~referred to Article 3 point~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~(33)~~.	
Article 14(2), first subparagraph				
245	In the course of the consultation referred to in paragraph 1, the competent authorities may also submit a request to the SCB for its opinion on the regulatory status of the substance, product or activity under this Regulation and shall do so in all cases where the competent authorities, after the consultations referred to in paragraph 1, are not in a position to take a decision in that respect.		**2.** In the course of the consultation referred to in paragraph 1, the **SoHO** competent authorities **involved in such consultation** may also**, via the SoHO National Authority,** submit a request to the SCB for ~~its~~**an** opinion on the regulatory status of the substance, product or activity under this Regulation**. The SoHO competent authorities** ~~and~~ shall do so in all cases where the ~~competent authorities, after the~~ consultations referred to in paragraph 1, ~~are not~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~in a position to take a decision in that respect~~**have not lead to a decision on the regulatory status of such substance, product or activity in the Member State concerned. The SoHO competent authorities involved in the consultation shall take into account the opinion issued by the SCB following such a request**.	
Article 14(2), second subparagraph				
246	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	***If the SCB deems it necessary, it shall consult***~~*The competent authorities may also indicate that they consider there is a need that the SCB consults*~~, in accordance	The **SoHO** competent authorities **involved in the consultations referred to in paragraph 1** may also**, via their SoHO National Authority,** indicate ~~that~~**if** they	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	advisory bodies established in other relevant Union legislation referred to in Article 2(3).	with Article 68(1), point (b), with the equivalent advisory bodies established in other relevant Union legislation referred to in Article 2(3).	consider **that** there is a need ~~that~~**for** the SCB ~~consults,~~ **to consult, before issuing its opinion and** in accordance with Article 68(1), point (b), with the **relevant** equivalent advisory bodies established in other relevant Union legislation referred to in Article 2(3).	
Article 14(3)				
247	3. The competent authorities shall inform the SCB of the subsequent decision taken in their Member State, following the consultations referred to in paragraph 1 of this Article, regarding the regulatory		3. ~~The competent authorities shall inform the SCB of the subsequent decision taken in their Member State~~**When a consultation referred to in paragraph 1 leads to a decision**, ~~following the~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	status of the substance, product or activity concerned under this Regulation and on any consensus reached as a result of those consultations for publication in the compendium by the SCB.		~~consultations referred to in paragraph 1 of this Article, regarding the regulatory status~~ **the SoHO National Authority shall inform the SCB** of the ~~substance, product or activity concerned under this Regulation and on any consensus reached as a result of those consultations for publication~~**regulatory status decision taken in its Member State and the reasons for it, with a view to the publication thereof by the SCB** in the **SoHO** compendium**, pursuant to Article 68(1) point (d)** ~~by the SCB~~.	
Article 14(2a), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
247a		***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.***		
Article 14(2b)				
247b		*deleted*		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 14(4), first subparagraph				
248	The Commission may, upon a duly substantiated request of a Member State following the consultation referred to in paragraph 1, or on its own initiative, by means of implementing acts, determine the regulatory status of a substance, product or activity under this Regulation, in case questions arise in that respect, notably when these questions cannot be resolved at the Member State level, or in discussions between the SCB and the advisory bodies established in other relevant Union legislation, in accordance with Article 68(1), point (b).		**4.** The Commission ~~may~~**shall**, upon a duly substantiated request ~~of~~**from** a Member State following the consultation referred to in paragraph 1, or **may** on its own initiative, by means of implementing acts, determine the regulatory status of a substance, product or activity under this Regulation, in case **this is needed to avoid risks to the safety of SoHO donors, recipients or offspring from medically assisted reproduction, or of a compromised access of recipients to safe and effective treatment.** **A request from a Member State,**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			as referred to in the first subparagraph, is to be considered duly substantiated when questions arise in ~~that respect~~**respect to the regulatory status of a substance, product or activity under this Regulation**, notably when these questions cannot be resolved at the Member State level, or in ~~discussions~~**consultations conducted in accordance with Article 68(1), point (b)** between the SCB and the advisory bodies established ~~in~~**under** other relevant Union legislation~~, in accordance with Article 68(1), point (b)~~ **as referred to in Article 2(3)**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 14(4), second subparagraph				
249	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	
Article 14(5)				
250	5. For SoHOs that are intended to be subsequently used to manufacture products under other Union legislation, or as the starting and raw material thereof, as referred to in Article 2(3), or SoHOs that are intended to be		5. ~~For SoHOs that are intended to be subsequently used to manufacture products under other Union legislation, or as the starting and raw material thereof,~~**In the case of SoHO** as referred to in Article 2(3)~~, or SoHOs that are~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	combined with medical devices, as referred to in Article 2(4), the competent authority shall cooperate with the authorities responsible for the supervisory activities under the relevant Union legislation, with a view to ensuring coherent oversight. During the process, the competent authorities may seek the assistance of the SCB.		~~intended to be combined with medical devices, as referred to in~~ **or** Article 2(4), the **SoHO** competent authority shall cooperate with the authorities responsible for the supervisory activities under ~~the~~**other** relevant Union legislation **as referred to in Article 2(3)**, with a view to ensuring coherent oversight. During ~~the~~**that** process, the **SoHO** competent authorities may seek**, via their SoHO National Authority,** the assistance **and advice** of the SCB **concerning, inter alia, good cooperation practices that ensure coherent oversight when SoHO change regulatory status**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 14(6)				
251	6. The consultation and cooperation referred to in paragraphs 1, 2 and 5 may also be initiated on the basis of a request for advice from a SoHO entity, as referred to in Article 40.		6. The consultation and cooperation referred to in paragraphs 1, 2 and 5 may also be initiated on the basis of a request ~~for advice~~ from a SoHO entity~~, as referred to in Article 40~~ **for an opinion**.	
Article 14(6a)				
251a			**6a. In case a SoHO competent authority takes any enforcement decision concerning a SoHO entity that also performs**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			activities regulated under other Union legislation as referred to in Article 2(3) and overseen by competent authorities as referred to in paragraph -1a, the SoHO competent authority shall, without undue delay, via the SoHO National Authority, inform the relevant competent authority designated under that other Union legislation, of its decision.	
Article 14(7), first subparagraph				
252	The Commission may, by means of implementing acts, lay down rules concerning procedures for		~~The Commission may, by means of implementing acts, lay down rules concerning procedures for~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	consultation referred to in paragraph 1 and cooperation referred to in paragraph 5 by the competent authorities when they consult the authorities established in other relevant Union legislation referred to in Article 2(3).		~~consultation referred to in paragraph 1 and cooperation referred to in paragraph 5 by the competent authorities when they consult the authorities established in other relevant Union legislation referred to in Article 2(3).~~	
Article 14(7), second subparagraph				
253	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).		~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).~~	
Article 15				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
254	Article 15 Right of appeal		Article 15 Right of appeal	
Article 15(1)				
255	1. Where decisions are taken by competent authorities concerning natural or legal persons, those decisions shall be subject to such persons' right of appeal in accordance with national legislation.		1. Where decisions are taken by **SoHO** competent authorities concerning natural or legal persons, those decisions shall be subject to such persons' right of appeal in accordance with national legislation.	
Article 15(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
256	2. The right of appeal shall not affect the obligation of competent authorities to take prompt action to eliminate or contain the risks to human health in accordance with this Regulation.		2. ~~The right of appeal shall not affect the obligation of competent authorities to take prompt action to eliminate or contain the risks to human health in accordance with this Regulation.~~	
Article 15(3)				
257	3. Paragraphs 1 and 2 shall also apply to delegated bodies.		3. ~~Paragraphs 1 and 2 shall also apply to delegated bodies.~~	
Article 16				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
258	Article 16 General obligations concerning the personnel of competent authorities		Article 16 ~~General obligations concerning the personnel of competent authorities~~	
Article 16(1)				
259	1. Competent authorities shall:		1. ~~Competent authorities shall:~~	
Article 16(1), point (a)				
260	(a) have, or have access to, a sufficient number of personnel so		(a) ~~have, or have access to, a sufficient number of personnel so~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	that SoHO supervisory activities can be performed efficiently and effectively;		~~that SoHO supervisory activities can be performed efficiently and effectively;~~	
Article 16(1), point (aa)				
260a		***(aa) make the declarations of interest referred to in Article 7(2) publicly available on their website;***		
Article 16(1), point (b)				
261	(b) ensure that the personnel performing SoHO supervisory		(b) ~~ensure that the personnel performing SoHO supervisory~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	activities are suitably qualified and experienced;		~~activities are suitably qualified and experienced;~~	
Article 16(1), point (c)				
262	(c) have procedures or arrangements in place to ensure that personnel performing SoHO supervisory activities are free from any conflict of interest;		(c) ~~have procedures or arrangements in place to ensure that personnel performing SoHO supervisory activities are free from any conflict of interest;~~	
Article 16(1), point (d)				
263	(d) have procedures in place to ensure confidentiality and maintain		(d) ~~have procedures in place to ensure confidentiality and maintain~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	professional secrecy.		~~professional secrecy.~~	
Article 16(2)				
264	2. Personnel performing SoHO supervisory activities shall:		2. ~~Personnel performing SoHO supervisory activities shall:~~	
Article 16(2), point (a)				
265	(a) declare in writing any direct or indirect interests referred to in Article 7(2) and update that declaration yearly and whenever the declared information changes		(a) ~~declare in writing any direct or indirect interests referred to in Article 7(2) and update that declaration yearly and whenever the declared information changes~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	or any new interest arises;		~~or any new interest arises;~~	
Article 16(2), point (b)				
266	(b) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and in a consistent manner;		(b) ~~receive, for their area of competence, appropriate training enabling them to undertake their duties competently and in a consistent manner;~~	
Article 16(2), point (c)				
267	(c) keep up-to-date in their area of competence and receive regular		(c) ~~keep up-to-date in their area of competence and receive regular~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	additional training as necessary;		~~additional training as necessary;~~	
Article 16(2), point (d)				
268	(d) participate in training in the subject matter and on the obligations of competent authorities resulting from this Regulation, as referred to in paragraph 3.		(d) ~~participate in training in the subject matter and on the obligations of competent authorities resulting from this Regulation, as referred to in paragraph 3.~~	
Article 16(3)				
269	3. Competent authorities, in cooperation with delegated bodies		3. ~~Competent authorities, in cooperation with delegated bodies~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	as necessary, shall develop and implement training programmes for the purpose of ensuring that personnel performing SoHO supervisory activities receive the training referred to in paragraph 2, points (b), (c) and (d). Competent authorities shall maintain records of the training undertaken by their personnel. Competent authorities shall provide opportunities for their personnel to participate in the Union training referred to in Article 69 where such Union training is available and appropriate.		~~as necessary, shall develop and implement training programmes for the purpose of ensuring that personnel performing SoHO supervisory activities receive the training referred to in paragraph 2, points (b), (c) and (d). Competent authorities shall maintain records of the training undertaken by their personnel. Competent authorities shall provide opportunities for their personnel to participate in the Union training referred to in Article 69 where such Union training is available and appropriate.~~	
Article 16(4)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
270	4. Paragraphs 1, 2 and 3 shall also apply to delegated bodies.		4. ~~Paragraphs 1, 2 and 3 shall also apply to delegated bodies.~~	
Article 17				
271	Article 17 Obligations as regards Commission controls		Article 17 Obligations as regards Commission ~~controls~~**verifications**	
Article 17, first paragraph				
272	Competent authorities and		**SoHO** competent authorities and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	delegated bodies shall cooperate with the Commission for the performance of Commission controls referred to in Article 70. In particular, they shall:		delegated bodies shall cooperate with the Commission for the performance of Commission ~~controls~~**verifications** referred to in Article 70. In particular, they shall:	*deleted*
Article 17, first paragraph, point (a)				
273	*(a)* take appropriate follow-up measures to remedy the shortcomings identified through the controls provided for in Article 70;		(a) take appropriate follow-up measures to remedy the shortcomings identified through ~~the controls provided for in Article 70~~**such verifications**;	*deleted*
Article 17, first paragraph, point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
274	*(b)* give the necessary technical assistance and provide the available documentation, upon justified request, and other technical support that Commission experts request to enable them to perform controls efficiently and effectively; and		(b) ~~give~~**provide** the necessary technical assistance and ~~provide~~ the available documentation, upon justified request, ~~and other technical~~**as well as other** support that **the** Commission ~~experts request~~**requests** to enable them to perform ~~controls~~**verifications** efficiently and effectively~~; and~~**, including facilitating access to all premises or part of premises, and to documentation, including IT systems, of the SoHO competent authority or delegated body relevant for the execution of their duties.**	*deleted*
Article 17, first paragraph, point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
275	*(c)* give the necessary assistance to ensure that the Commission experts have access to all premises or part of premises, and to information, including IT systems, relevant for the execution of their duties.		(c) ~~give the necessary assistance to ensure that the Commission experts have access to all premises or part of premises, and to information, including IT systems, relevant for the execution of their duties.~~	*deleted*
CHAPTER III				
276	CHAPTER III SoHO SUPERVISORY ACTIVITIES		CHAPTER III SoHO SUPERVISORY ACTIVITIES	
Article 18				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
277	Article 18 Register of SoHO entities		Article 18 Register of SoHO entities	
Article 18(1)				
278	1. SoHO National Authorities shall establish and maintain a register of SoHO entities on their territory.		1. SoHO National Authorities shall establish and maintain a register of SoHO entities on their territory. **In carrying out this task, SoHO National Authorities may make use of the EU SoHO Platform, in accordance with Article 74(1). In such case, the SoHO National Authority shall instruct SoHO competent**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			authorities, where necessary, and SoHO entities to register directly on the EU SoHO Platform.	
Article 18(2)				
279	2. Instead of establishing a register of SoHO entities, as referred to in paragraph 1, a SoHO National Authority may use the EU SoHO Platform as referred to in Chapter XI. In this case, the SoHO National Authority shall instruct competent authorities, where necessary, and SoHO entities to register directly on the EU SoHO Platform.		2. ~~Instead of establishing a register of SoHO entities, as referred to in paragraph 1, a SoHO National Authority may use the EU SoHO Platform as referred to in Chapter XI. In this case, the SoHO National Authority shall instruct competent authorities, where necessary, and SoHO entities to register directly on the EU SoHO Platform.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 18(3)				
280	3. Competent authorities shall verify that each registered SoHO entity has provided the following information:		3. ~~Competent authorities shall verify that each registered SoHO entity has provided the following information:~~	
Article 18(3), point (a)				
281	(a) name or business name and address of the SoHO entity, and name and contact details of a contact person;		(a) ~~name or business name and address of the SoHO entity, and name and contact details of a contact person;~~	
Article 18(3), point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
282	(b) a declaration that the SoHO entity complies with the obligations and requirements on SoHO entities set out in this Regulation, in particular Articles 44, 47, 56 and 59, as relevant;		(b) ~~a declaration that the SoHO entity complies with the obligations and requirements on SoHO entities set out in this Regulation, in particular Articles 44, 47, 56 and 59, as relevant;~~	
Article 18(3), point (c)				
283	(c) a statement from the SoHO entity that it accepts to be inspected as provided for in this Regulation;		(c) ~~a statement from the SoHO entity that it accepts to be inspected as provided for in this Regulation;~~	
Article 18(3), point (d)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
284	(d) a list of the SoHO activities that the SoHO entity is carrying out;		(d) ~~a list of the SoHO activities that the SoHO entity is carrying out;~~	
Article 18(3), point (e)				
285	(e) the name and curriculum vitae of the responsible person for release of SoHOs as referred to in Article 38, if the SoHO entity releases SoHOs or SoHO preparations.		(e) ~~the name and curriculum vitae of the responsible person for release of SoHOs as referred to in Article 38, if the SoHO entity releases SoHOs or SoHO preparations.~~	
Article 18(4)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
286	4. In cases where SoHO National Authorities establish their own registries of SoHO entities as referred to in paragraph 1, they shall submit the information included in the registries to the EU SoHO Platform as referred to in Chapter XI. Competent authorities shall be responsible for ensuring that the information regarding the SoHO entities on their territory pursuant to this Article and to Article 19 is congruent in the register of SoHO entities and in the EU SoHO Platform, and shall submit any changes to the EU SoHO Platform without undue delay.		4. In cases where SoHO National Authorities establish ~~their own~~ registries of SoHO entities ~~as referred to in paragraph 1, they~~**outside the EU SoHO Platform, the SoHO competent authorities** shall submit the information included in ~~the~~**such** registries to the EU SoHO Platform ~~as referred to in Chapter XI~~. **SoHO** competent authorities shall be responsible for ensuring that the information regarding the SoHO entities on their territory pursuant to ~~this Article and to~~ Article 19 is congruent in the register of SoHO entities and in the EU SoHO Platform, and shall submit any changes to the EU SoHO Platform	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			without undue delay.	
Article 18(5), first subparagraph				
287	The Commission may adopt implementing acts concerning the compatibility and comparability of the registers of SoHO entities for facilitating the submission to the EU SoHO Platform.		**5.** The Commission may adopt implementing acts concerning the ~~compatibility and comparability of the registers of~~**set of data to be published for registered** SoHO entities**, to facilitate the transfer of information from national registries** ~~for facilitating the submission~~ to the EU SoHO Platform.	
Article 18(5), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
288	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	
Article 19				
289	Article 19 Registration of SoHO entities		Article 19 Registration of SoHO entities	
Article 19(1)				
290				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	1. Competent authorities shall have procedures in place for the registration of SoHO entities in accordance with Article 37.		1. **SoHO** competent authorities shall have procedures in place for the registration of SoHO entities in accordance with Article 37.	
Article 19(1a)				
290a			**1a. SoHO competent authorities shall verify that each registered SoHO entity on a national registry or the EU SoHO Platform has provided the information pursuant to Article 37(1) before publication on the EU SoHO Platform. In cases where national registries are in place and following such verification the SoHO competent**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			authority shall submit the information on the registration to the EU SoHO Platform.	
Article 19(1b)				
290b			**1b. SoHO competent auhorities shall verify whether an authorisation is required under Articles 21, 27 or 28 for a registered SoHO entity taking into account the declaration as referred in Article 37(1b).**	
Article 19(1c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
290c			**1c. SoHO competent authorities shall identify whether the SoHO entity is a critical SoHO entity, according to the criteria agreed by the SCB taking into account the self-assessment done by the SoHO entity, where applicable as referred to in Article 37(1). SoHO competent authorities shall update the registration information accordingly.**	
Article 19(1d)				
290d			**1d. Where on the basis of the information submitted, an**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			organisation does not meet the definition of a SoHO entity, pursuant to Article 37, the SoHO competent authority shall remove the registration from the EU SoHO Platform and, if applicable from the national registry, and inform the organisation without undue delay.	
Article 19(2)				
291	2. Competent authorities shall:		2. **SoHO** competent authorities shall:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 19(2), point (a)				
292	(a) acknowledge receipt of the registration within 14 working days of its submission;		(a) acknowledge receipt of the registration ~~within 14 working days of its submission;~~**without undue delay;**	
Article 19(2), point (b)				
293	(b) request the SoHO entity to provide supplementary information, if needed;		(b) request the SoHO entity to provide supplementary information, **in accordance with Article 37(1),** if needed;	
Article 19(2), point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
294	(c) inform the SoHO entity in cases where the registration indicates that an authorisation pursuant to Articles 21, 27 or 28 is required;		(c) ~~inform the SoHO entity in cases where the registration indicates that~~**provide instructions on the procedures to follow to apply for** an authorisation~~ pursuant to Articles 21, 27 or 28 is required~~**, when relevant**;	
Article 19(2), point (d)				
295	(d) identify whether the entity is a critical SoHO entity, and inform the entity in cases where it is considered a critical SoHO entity;		(d) ~~identify whether the~~**inform the SoHO** entity **in cases where it is considered**~~is~~ a critical SoHO entity~~, and inform the entity in cases where it is considered a critical SoHO entity~~ **and the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			related obligations pursuant to Articles 63 and 66;	
Article 19(2), point (e)				
296	(e) submit any additional information on the registration as necessary, including the requirement for an authorisation pursuant to point (c), and whether the SoHO entity is a critical SoHO entity to the EU SoHO Platform referred to in Chapter XI.		(e) ~~submit any additional information on the registration as necessary, including the requirement for an authorisation pursuant to point (c), and whether the SoHO entity is a critical SoHO entity to~~**inform the SoHO entity that its registration has been verified and published in** the EU SoHO Platform~~ referred to in Chapter XI~~.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 19(2a)				
296a			**2a. In case of changes in the registration submitted by the SoHO entity in accordance with Article 37(3), SoHO competent authorities shall verify those changes and publish the updated registration in the EU SoHO Platform without undue delay, including in case of cessation of activities.**	
Article 19(3), first subparagraph				
297	The Commission may adopt		~~The Commission may adopt~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	implementing acts concerning the registration process to facilitate the compatibility of the registers of SoHO entities with the EU SoHO Platform.		~~implementing acts concerning the registration process to facilitate the compatibility of the registers of SoHO entities with the EU SoHO Platform.~~	
Article 19(3), second subparagraph				
298	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).		~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).~~	
Article 20				
299				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 20 SoHO preparation authorisation system		Article 20 SoHO preparation authorisation system	
Article 20(1)				
300	1. Competent authorities shall establish and maintain a system for receiving and processing requests for the authorisation of SoHO preparations. The system shall allow for the suspension or withdrawal of authorisations.		1. **SoHO** competent authorities shall establish and maintain a system for ~~receiving~~**granting authorisation of SoHO preparations to SoHO entities located in their territory. The system shall include the reception** and processing **of** requests ~~for the authorisation of SoHO preparations. The system~~**and the approval of**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			clinical outcome monitoring plans for the generation of evidence required for authorisation, where necessary, and shall allow for the suspension or withdrawal of authorisations.	
Article 20(2)				
301	2. Competent authorities shall authorise SoHO preparations pursuant to Articles 21, 22 and, where applicable, Article 23.		2. **SoHO** competent authorities shall authorise SoHO preparations pursuant to Articles 21, 22**, 22a** and, where applicable, Article 23.	
Article 20(2a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
301a			**2a. The SoHO preparation authorisation is waived for SoHO that are intended to be distributed for the manufacture of products regulated by other Union legislation, as referred to in Article 2(3).**	
Article 20(3)				
302	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	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	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,~~**pursuant**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.***	**to Article 21 (2), point (d)** or until ~~a~~**the SoHO** 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~~ **until the SoHO entity authorised for the SoHO preparation has demonstrated to that Member State the compliance with that** more stringent measure ~~has been met~~.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 20(4), first subparagraph				
303	The Commission may adopt implementing acts concerning the compatibility and comparability of the SoHO preparation authorisation system.		~~The Commission may adopt implementing acts concerning the compatibility and comparability of the SoHO preparation authorisation system.~~	
Article 20(4), second subparagraph				
304	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).		~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 21				
305	Article 21 Authorisation of SoHO preparations		Article 21 Authorisation of SoHO preparations	
Article 21(1)				
306	1. Competent authorities shall have procedures in place to allow that applications for the authorisation of SoHO preparations are submitted in accordance with Article 41. They shall provide guidelines and templates for the submission of applications for		1. **SoHO** competent authorities shall ~~have procedures in place to allow that applications~~**provide guidelines and templates** for the ~~authorisation of SoHO preparations are submitted~~**submission of applications for SoHO preparation authorisation,** in	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHO preparation authorisation. 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). Competent authorities may establish simplified procedures for applications concerning modifications to previously authorised SoHO preparations.		accordance with Article 41~~. They shall provide guidelines and templates~~**, and** for the ~~submission of applications for SoHO preparation authorisation~~**design of clinical outcome monitoring plans, in accordance with Article 22a**. When developing these guidelines and templates, **SoHO** competent authorities shall ~~consult~~**use the templates and shall take into account** the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c). **SoHO** competent authorities may establish simplified procedures for applications concerning modifications to previously authorised SoHO preparations. **SoHO competent authorities may**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			use the secure communication channel on the EU SoHO Platform for the exchange, with the SoHO entity, of documents relating to the application and authorisation of SoHO preparations.	
Article 21(2)				
307	2. Upon receipt of an application for the authorisation of a SoHO preparation, competent authorities shall:		2. Upon receipt of an application for the authorisation of a SoHO preparation, **SoHO** competent authorities shall:	
Article 21(1a), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
307a		***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.***		
Article 21(2), point (a)				
308	(a) acknowledge receipt of the application within 14 working days;		(a) acknowledge receipt of the application ~~within 14 working days~~**without undue delay**;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 21(2), point (b)				
309	(b) assess the SoHO preparation pursuant to Article 22 and examine agreements between the applicant SoHO entity and any third parties contracted by that SoHO entity concerning SoHO activities, where applicable;		(b) assess the SoHO preparation pursuant to Article 22 and examine agreements between the applicant ~~SoHO entity and any third parties~~**and other SoHO entities** contracted ~~by that SoHO entity concerning SoHO activities~~**to perform SoHO activities or other third parties, in relation to the SoHO preparation**, where applicable;	
Article 21(2), point (c)				
310				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(c) grant a conditional authorisation for the use of the SoHO preparation in all cases where clinical outcome data is required for authorisation, pursuant to Article 22(4), points (d) and (e);		(c) grant ~~a conditional authorisation for the use of the SoHO preparation in all cases where clinical outcome data is required for authorisation, pursuant to Article 22(4), points (d) and (e)~~**or refuse the approval for clinical outcome monitoring plans, as appropriate, pursuant to Article 22(4), points (d) and (e); and indicate a time limit for the applicant to submit the results of the approved clinical outcome monitoring**;	
Article 21(2), point (d)				
311	(d) grant or refuse the		(d) **on the basis of the assessment**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorisation for the SoHO preparation, as appropriate.		**performed in point (b), and the results of the clinical outcome monitoring referred to in point (c), when applicable,** grant or refuse the authorisation for the SoHO preparation **and, if any, indicating which conditions apply**~~, as appropriate~~.	
Article 21(2), point (ba)				
311a			**(ba) request the applicant to provide supplementary information, if needed;**	
Article 21(3)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
312	3. Competent authorities shall submit information regarding SoHO preparation authorisations, including a summary of the evidence used to authorise each SoHO preparation, to the EU SoHO Platform referred to in Chapter XI, and, for each SoHO preparation, amend accordingly the authorisation status of the SoHO entity to which the SoHO preparation is linked to in the EU SoHO Platform, including the name and contact details of the SoHO preparation authorisation holder.		3. **SoHO** competent authorities shall submit information regarding **the authorisation of the** SoHO preparation ~~authorisations,~~ including a summary of the evidence used to authorise each SoHO preparation, to the EU SoHO Platform ~~referred to in Chapter XI,~~ and, for each SoHO preparation, amend accordingly the authorisation ~~status~~ **information** of the SoHO entity ~~to which the SoHO preparation is linked to in the EU SoHO Platform, including the name and contact details of the SoHO preparation authorisation holder.~~**concerned.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 21(4)				
313	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***.	4. **SoHO** 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).~~**the time limit set out in accordance with national legislation or taking into account best practices agreed and documented by the SCB as referred to in Article 68(1), point**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			(c). The time limit foreseen for the authorisation may be extended for:	
Article 21(4), point (a)				
313a			**(a) the duration of the consultation processes referred to in Article 14(1), (2) and (3);**	
Article 21(4), point (b)				
313b			**(b) the time needed to perform a request for additional**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			information to the SoHO entity;	
Article 21(4), point c				
313c			**(c) the time needed to perform clinical outcome monitoring; or**	
Article 21(4), point d				
313d			**(d) the performance of additional validation or the generation of additional quality and safety data as requested by the SoHO competent authority.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 21(4a)				
313e			**4a. For SoHO preparations that incorporate a medical device as an integral part, as referred to in Regulation (EU) 2017/745 Annex IX (5) (3) (1), and where the medical device has an action that is ancillary to that of the SoHO preparation, SoHO competent authorities shall verify that the medical device has been certified by the notified body under that framework.**	
Article 21(5)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
314	5. Upon receipt of a request for an opinion in course of the conformity assessment procedure pursuant to Article 52 of Regulation (EU) 2017/745, the competent authorities receiving the request shall follow the relevant procedure of that Regulation, and inform the SCB of the opinion provided.		5. Upon receipt of a request for an opinion in course of the conformity assessment procedure pursuant to Article 52 of Regulation (EU) 2017/745, **of a medical device that incorporates a SoHO preparation as an integral part, and where the medical device has an action that is principal, the SoHO** ~~the~~ competent authorities receiving the request shall ~~follow the relevant procedure of that~~**provide an opinion regarding compliance of the SoHO preparation part with the provisions of this** Regulation, **in accordance with Annex IX (5) (3)(1) of Regulation (EU) 2017/745 ,** and inform the SCB of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			the opinion provided.	
Article 21(6), first subparagraph				
315	Competent authorities may, in accordance with national legislation, suspend the authorisation of a SoHO preparation if SoHO supervisory activities demonstrate or give reasonable ground for suspecting that:		**6. SoHO** competent authorities may, in accordance with national legislation, suspend the authorisation of a SoHO preparation**, or the implementation of its clinical monitoring outcome plan, in circumstances where** ~~if~~ SoHO supervisory activities demonstrate or give reasonable ground for suspecting that **such SoHO preparation, or any activities performed for that preparation**:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 21(6), first subparagraph, point (a)				
316	(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; ~~and~~***or***	(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~~**;**	
Article 21(6), first subparagraph, point (b)				
317	(b) that non-compliance implies a risk to the safety of SoHO donors, recipients or offspring from		(b) ~~that non-compliance implies a risk to the safety of SoHO donors, recipients or offspring from~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	medically assisted reproduction.		~~medically assisted reproduction.~~ **do not comply with the provisions of this Regulation; or**	
Article 21(6), first subparagraph, point (c)				
317a			**(c) a risk to the safety of SoHO donors, recipients or offspring from medically assisted reproduction, or a risk of unnecessary wastage of SoHO is identified.**	
Article 21(6), second subparagraph				
318				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Competent authorities shall specify a period of time for the investigation of the suspected non-compliance and for SoHO entities to rectify a confirmed non-compliance, during which the suspension will remain in place.		**SoHO** competent authorities shall specify a period of time for the investigation of the suspected non-compliance and for SoHO entities to rectify a confirmed non-compliance, during which the suspension will remain in place.	
Article 21(7)				
319	7. In cases where SoHO entities are not able to rectify confirmed non-compliances referred to in paragraph 6 in the specified time period, competent authorities shall, in accordance with national legislation, withdraw the authorisation of the SoHO		7. In cases where SoHO ~~entities are not able to rectify~~**competent authorities have** confirmed non-compliances referred to in paragraph 6 **and SoHO entities are not able to rectify** in the specified time period, **SoHO** competent authorities shall, in	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	preparation concerned.		accordance with national legislation, withdraw the authorisation of the SoHO preparation **from the SoHO entities** concerned.	
Article 21(8)				
320	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	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*~~	8. **SoHO** 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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	failed to comply with the conditions of its authorisation.	failed to comply with the conditions of its authorisation.	~~failed to comply with the conditions of its authorisation~~**a suspension, as described in paragraph 6, is not sufficient to resolve the identified shortcomings**.	
Article 21(9)				
321	9. In cases of authorisation suspension or withdrawal, as referred to in paragraphs 6, 7 and 8, competent authorities shall, without undue delay, amend accordingly the authorisation status of the SoHO entity concerned in the EU SoHO Platform as referred to in Chapter XI.		9. In cases of authorisation suspension or withdrawal, as referred to in paragraphs 6, 7 and 8, **SoHO** competent authorities shall, without undue delay, amend accordingly the authorisation ~~status~~**information of the SoHO preparation** of the SoHO entity concerned in the EU SoHO	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Platform. ~~as referred to in Chapter XI.~~	
Article 21(9a)				
321a			**9a. SoHO competent authorities may exceptionally authorise, at the request of the SoHO entity responsible for that application, the application of a SoHO preparation to a specific SoHO recipient within their territory in cases where the procedures referred to in this Article have not been carried out, provided that:**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 21(9a), first subparagraph, point (a)				
321b			**(a) the use of the SoHO preparation is foreseen for a specific SoHO recipient, in cases where the SoHO recipient has no therapeutic alternative, where treatment cannot be postponed or where the SoHO recipient's prognosis is life-threatening;**	
Article 21(9a), first subparagraph, point (b)				
321c			**(b) the safety and effectiveness of the SoHO preparation can reasonably be assumed on the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			basis of the available clinical data; and	
Article 21(9a), first subparagraph, point (c)				
321d			**(c) the SoHO recipient concerned is informed that the SoHO preparation in question has not been authorised according to the provisions of this Regulation.**	
Article 21(9a), second subparagraph				
321e			**9a. SoHO competent authorities**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			shall inform the SoHO National Authority of that exceptional authorisation.	
Article 21(10)				
322	10. Competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).		10. ~~Competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).~~	
Article 21(11), first subparagraph				
323	The Commission may adopt		**11.** The Commission may adopt	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	implementing acts concerning the procedures to authorise SoHO preparations pursuant to this Article.		implementing acts concerning the procedures to authorise SoHO preparations pursuant to this Article.	
Article 21(11), second subparagraph				
324	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	
Article 22				
325				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 22 Assessment of SoHO preparations		Article 22 Assessment of SoHO preparations	
Article 22(1)				
326	1. The assessment of a SoHO preparation, shall include a review of all SoHO activities that are performed for that SoHO preparation and that might influence the safety, quality and efficacy of the SoHO preparation.		1. The assessment of a SoHO preparation~~,~~ shall include a review of all SoHO activities that are performed for that SoHO preparation and that might influence the ~~safety, quality and efficacy~~**quality, safety and effectiveness** of the SoHO preparation.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 22(2)				
327	2. The assessment of SoHO preparations shall be carried out by assessors meeting the requirements set out in Article 24.		2. The assessment of SoHO preparations shall be carried out by **SoHO preparation** assessors meeting the requirements set out in Article 24.	
Article 22(3)				
328	3. In cases where the SoHO preparation subject to the application for authorisation pursuant to Article 21 has been duly authorised in another SoHO entity in the same or in another		3. In cases where the SoHO preparation**,** subject to the application for authorisation pursuant to Article 21**,** has been duly authorised in another SoHO entity in the same or in another	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Member State, competent authorities may authorise that SoHO preparation in the applicant SoHO entity, provided that the competent authorities have verified that the SoHO activities performed for the SoHO preparation are carried out by the applicant SoHO entity in a manner such that the safety, quality and efficacy results will be equivalent to those demonstrated in the SoHO entity where the SoHO preparation was first authorised.		Member State, **SoHO** competent authorities may authorise that SoHO preparation ~~in the applicant SoHO entity~~, provided that the **SoHO** competent authorities have verified**, with the consent of SoHO entities implied,** that the SoHO activities performed **and the steps of the processing applied** for the SoHO preparation are carried out by the applicant ~~SoHO entity~~ in a manner such that the ~~safety, quality and efficacy~~**quality, safety and effectiveness** results **of the SoHO preparation** will be equivalent to those demonstrated in the SoHO entity where the SoHO preparation was first authorised.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 22(4)				
329	4. In cases where the SoHO preparation, subject to the application for authorisation pursuant to Article 21, has not been duly authorised in another SoHO entity, competent authorities:		4. In cases where the SoHO preparation, subject to the application for authorisation pursuant to Article 21, has not been ~~duly~~ authorised in another SoHO entity, **or the SoHO competent authority chooses not to take SoHO preparation authorisation in another Member State into account, SoHO** competent authorities **shall**:	
Article 22(4), point (a)				
330				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(a) shall assess all the information provided by the applicant pursuant to Article 41;		(a) ~~shall~~ assess ~~all~~**the adequacy of** the information provided by the applicant pursuant to Article ~~41~~**41(2) point (a)**;	
Article 22(4), point (b)				
331	(b) shall review the SoHO preparation dossier referred to in Article 41(2), point (a);		(b) ~~shall review the SoHO preparation dossier referred to in Article 41(2), point (a);~~	
Article 22(4), point (c)				
332	(c) shall initiate the consultation		(c) ~~shall~~ initiate the consultation	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	described in Article 14(1), if during the review of the SoHO preparation dossier referred to in point (b), questions arise as to whether the SoHO preparation falls, in part or fully, within the scope of this Regulation or other Union legislation, taking into account the activities performed for the SoHO preparation and the intended human application;		described in Article ~~14(1)~~**14**, if during the review of the ~~SoHO preparation dossier~~**information** referred to in point ~~(b)~~**(a)**, questions arise as to whether the SoHO preparation falls, in part or fully, within the scope of this Regulation or other Union legislation, taking into account the activities performed for the SoHO preparation and the intended human application;	
Article 22(4), point (d)				
333	(d) shall review and evaluate the risk assessment performed by the applicant as pursuant to Article		(d) ~~shall review and~~ evaluate the ~~risk~~**benefit-risk** assessment ~~performed~~**carried out** by the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	41(2), point (b);		applicant as pursuant to Article 41(2), point (b) **including the scientific evidence and clinical data provided regarding the expected benefit and risk**;	
Article 22(4), point (e)				
334	(e) shall evaluate the plan for clinical outcome monitoring and its proportionality to the level of risk of the SoHO preparation as referred to in Article 41(3), points (a), (b) and (c), as applicable;		(e) ~~shall~~ evaluate the plan for clinical outcome monitoring**,** and its proportionality to the level of risk **and expected benefit** of the SoHO preparation ~~as referred to in~~ **according to** Article ~~41(3), points (a), (b) and (c), as applicable;~~**22a, where relevant;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 22(4), point (f)				
335	(f) may consult the SCB, pursuant to Article 68(1) on the evidence necessary and sufficient for the authorisation of a particular SoHO preparation;		(f) ~~may~~ consult the SCB, pursuant to Article 68(1) on the evidence necessary and sufficient for the authorisation of a particular SoHO preparation **where the guidance referred to in paragraph 7 is not sufficient**;	
Article 22(4), point (g)				
336	(g) shall assess, in the case of a conditional authorisation pursuant to Article 21(2), point (c), the results of the clinical outcome		(g) ~~shall~~ assess, in the case of a ~~conditional authorisation~~**previously approved clinical outcome monitoring plan**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	monitoring.		pursuant to Article 21(2), point (c), the results of the clinical outcome monitoring **upon completion and submission by the applicant**.	
Article 22(5)				
337	5. When assessing the SoHO preparation pursuant to paragraph 4, points (e) and (g), competent authorities shall consider, in the cases where the applicant has proposed to record, and recorded, the results of the clinical outcome monitoring in an existing clinical registry, that this is an acceptable method, provided that those competent authorities have verified		5. When assessing the SoHO preparation pursuant to paragraph 4, points (e) and (g), **SoHO** competent authorities shall ~~consider~~**verify**, in the cases where the applicant has proposed to record, and recorded, the results of the clinical outcome monitoring in an existing clinical registry, that this ~~is an acceptable method, provided that those competent~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	that the registry has data quality management procedures in place that ensure accuracy and completeness of data.		~~authorities have verified that the~~ registry has data quality management procedures in place that ensure **adequate** accuracy and completeness of data.	
Article 22(6)				
338	6. Competent authorities shall conduct the assessment steps referred to in paragraphs 3 and 4 of this Article by means of a remote document review. Competent authorities may also, as part of the SoHO preparation assessment, carry out inspections pursuant to Articles 29, 30 and 31.		6. **SoHO** competent authorities shall conduct the assessment ~~steps~~ referred to in paragraphs 3 and 4 of this Article by means of a remote document review. **SoHO** competent authorities may also, as part of the SoHO preparation assessment, carry out inspections pursuant to Articles 29, 30 and 31. **Member States shall ensure**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			communication and cooperation between SoHO preparation assessors and inspectors pursuant to Article 13.	
Article 22(7)				
339	7. When conducting the assessment steps referred to in paragraph 4 of this Article, competent authorities shall consult the best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).		7. When conducting the assessment steps referred to in paragraph 4 of this Article, **SoHO** competent authorities shall ~~consult~~**take into account** the best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 22a				
339a			**Article 22a** **Clinical outcome monitoring plans**	
Article 22a(1)				
339b			**1. As a basis for the assessment of an authorisation for a new SoHO preparation, a clinical outcome monitoring plan from the applicant shall be approved by the SoHO competent authority in cases where scientific and clinical evidence**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			provided as part of the assessment carried out by the applicant, as referred to in Article 22(4)(d), are not sufficient or the risk is more than negligible. The approved clinical outcome monitoring plan shall be implemented, and the results of the monitoring assessed, before the SoHO preparation authorisation is granted pursuant to Article 21.	
Article 22a(2)				
339c			**2. Clinical outcome monitoring plans shall not be approved in cases where scientific and clinical**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			data provided as part of the benefit-risk assessment indicate a relevant level of risk without a significant expected benefit.	
Article 22a(3)				
339d			**3. The design of the clinical outcome monitoring plan referred to in paragraph 1, shall be proportionate to the level of risk assessed by the applicant, together with the expected benefit, and shall take into account the guidance and templates provided by their SoHO competent authority, in accordance with Article 21(1).**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 22a(4)				
339e			**4. The clinical outcome monitoring plan shall include the clinical outcome monitoring as follows:**	
Article 22a(4), point (a)				
339f			**(a) in cases of low risk, and an expected positive benefit-risk assessment, pro-active clinical follow-up of a defined number of SoHO recipients;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 22a(4), point (b)				
339g			**(b) in cases of moderate risk, and an expected positive benefit-risk assessment, in addition to point (a), a clinical study of a pre-specified number of SoHO recipients required to be able to assess pre-defined clinical endpoints;**	
Article 22a(4), point (c)				
339h			**(c) in cases of high risk, and an**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			expected positive benefit-risk assessment, and cases where risk or benefit are not evaluable due to a lack of scientific and clinical data or knowledge, in addition to point (a), a clinical study of a pre-specified number of SoHO recipients required to be able to assess pre-defined clinical endpoints with a comparison to standard therapy.	
Article 22a(5)				
339i			**5. The applicant remains responsible for collecting the data and must be able to have these data available upon request**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			from the SoHO competent authority.	
Article 22a(6)				
339j			**6. In case where SoHO supervisory activities indicate a risk for SoHO donors, SoHO recipients or offspring from medically assisted reproduction, SoHO competent authorities may stop clinical outcome monitoring and withdraw the previous approval of the clinical outcome monitoring plan.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 23				
340	Article 23 Joint SoHO preparation assessments		Article 23 Joint SoHO preparation assessments	
Article 23(1)				
341	1. At the request of one or more competent authorities, SoHO preparation assessments as referred to in Article 22 may be carried out by competent authorities from more than one Member State, as a joint SoHO preparation		1. At the request of one or more **SoHO** competent authorities, **via their SoHO National Authority to another SoHO National Authority,** SoHO preparation assessments as referred to in Article 22 may be carried out by ~~competent authorities from~~**SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	assessment.		**preparation assessors assigned by** more than one Member State, as a joint SoHO preparation assessment.	
Article 23(2)				
342	2. The competent authority receiving a request for a joint SoHO preparation assessment may accept such a request, and coordinate and support that assessment, where that competent authority agrees that there are reasonable grounds for conducting a joint assessment.		2. ~~The competent authority receiving a request for a joint SoHO preparation assessment may accept such~~**With the previous consent of the SoHO National Authority, the SoHO competent authority receiving** a request~~, and coordinate and support that~~ **for a joint SoHO preparation** assessment~~, where that competent authority agrees that there are~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~reasonable grounds for conducting a joint assessment~~ **shall make all reasonable efforts to accept such request, taking into account their available resources**.	
Article 23(3)				
343	3. Competent authorities participating in a joint assessment shall conclude a prior written agreement on the joint assessment. The agreement shall at least defines the following:		3. **The SoHO** competent authorities participating in a joint **SoHO preparation** assessment shall conclude a prior written agreement ~~on~~**to carry out** the joint assessment. ~~The~~**Such written** agreement shall **specify** at least ~~defines~~ the following:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 23(3), point (a)				
344	(a) the scope of the joint assessment;		(a) the scope of the joint assessment;	
Article 23(3), point (b)				
345	(b) the roles of the participating assessors during and following the assessment, including the designation of an authority leading the assessment;		(b) the roles of the participating assessors during and following the assessment~~, including the designation of an authority leading the assessment;~~**;**	
Article 23(3), point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
346	(c) the powers and responsibilities of each of the authorities.		(c) the powers and responsibilities of each of the **SoHO competent** authorities **involved**.	
Article 23(3), second paragraph				
346a			**3. The SoHO competent authorities participating in the joint SoHO preparation assessments shall commit themselves in that agreement to jointly accept the results of that assessment.** **The agreement shall be signed by all the participating SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			competent authorities, including the respective SoHO National Authorities, according to the requirements developed by the SCB.	
Article 23(4)				
347	4. Member States may set up joint assessment programmes to facilitate frequent or routine joint assessments. In such cases, competent authorities may sign a single written agreement provided that agreement meets the requirements in paragraph 3.		4. Member States may set up joint **SoHO preparation** assessment programmes to facilitate frequent or routine joint assessments. ~~In such cases, competent authorities may sign~~**Member States may operate such programmes under** a single written agreement ~~provided that agreement meets the requirements~~ **as referred to** in	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			paragraph 3.	
Article 23(4a)				
347a			**4a. For the purposes of coordinating and performing joint SoHO preparation assessments, as referred to in this Article, SoHO competent authorities shall take into account the relevant best practices agreed and documented by the SCB, as referred to in Article 68(1), point(c).**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 23(5)				
348	5. On completion of a joint SoHO preparation authorisation, the competent authority in the territory where the SoHO preparation authorisation holder is based shall submit the information, as pursuant to Article 21(3), regarding the new authorised SoHO preparation in the EU SoHO Platform.		5. ~~On completion of a joint SoHO preparation authorisation, the competent authority in the territory where the SoHO preparation authorisation holder is based shall submit the information, as pursuant to Article 21(3), regarding the new authorised SoHO preparation in the EU SoHO Platform.~~	
Article 24				
349	Article 24 Specific obligations concerning		Article 24 Specific obligations concerning	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHO preparation assessors		SoHO preparation assessors	
Article 24(1)				
350	1. Assessors shall:		1. **SoHO preparation** assessors shall:	
Article 24(1), point (a)				
351	(a) possess 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		(a) ~~possess~~**be in possession of** a diploma, certificate or other evidence of formal qualifications in the field of medical**, pharmaceutical or life** ~~or biological~~ sciences, awarded on	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	course recognised as equivalent by the Member State concerned;		completion of a university course of study or a course **qualification** recognised as equivalent by the Member State concerned;	
Article 24(1), point (b)				
352	(b) have expertise in the processes being assessed and the human applications for which the SoHO preparations will be used.		(b) have expertise in the processes being assessed ~~and~~**or** the human applications for which the SoHO preparations will be used.	
Article 24(2)				
353	2. The assessment of SoHO		2. The assessment of SoHO	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	preparations as referred to in Article 22 may be done jointly by a team of persons which collectively have the qualifications and experience set out in paragraph 1.		preparations as referred to in Article 22 may be done jointly by a team of persons which collectively have the qualifications and experience set out in paragraph 1.	
Article 24(3)				
354	3. In exceptional cases, competent authorities may consider that a person's considerable and relevant experience may exempt this person from the requirements set out in paragraph 1.		3. In exceptional cases, **SoHO** competent authorities may consider that a person's considerable and relevant experience may exempt this person from the requirements set out in paragraph 1.	
Article 24(4)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
355	4. Before assessors take up their duties, competent authorities shall provide assessors with a specific induction training on the procedures to be followed for the assessment of SoHO preparations in accordance with Article 22.		4. Before **SoHO preparation** assessors take up their duties, **SoHO** competent authorities shall provide **SoHO preparation** assessors with a specific induction training on the procedures to be followed for the assessment of SoHO preparations in accordance with Article 22.	
Article 24(5)				
356	5. Competent authorities shall ensure that the specific induction training is complemented by specialised training for assessment		5. **SoHO** competent authorities shall ensure that the specific induction training is complemented by specialised training for	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	of processing methods and technologies used for specific types of SoHO preparations and by continuous training, as appropriate, throughout the career of the assessors. Competent authorities shall make all reasonable efforts to ensure that assessors that participate in joint assessments have completed the relevant Union training referred to in Article 69(1) and are included in the list referred to in Article 69(5).		assessment of processing methods and technologies used for specific types of SoHO preparations and by continuous training, as appropriate, throughout the career of the **SoHO preparation** assessors. **SoHO** competent authorities shall make all reasonable efforts to ensure that **SoHO preparation** assessors that participate in joint **SoHO preparation** assessments have completed the relevant Union training referred to in Article 69(1) and are included in the list referred to in Article 69(5).	
Article 24(6)				
357				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	6. Assessors may be assisted by technical experts provided that competent authorities ensure that those experts comply with the requirements of this Regulation, in particular with the obligations set out in Articles 7 and 76.		6. **SoHO preparation** assessors may be assisted by technical experts provided that **SoHO** competent authorities ensure that those experts comply with the requirements of this Regulation, in particular with the obligations set out in Articles 7**, 75** and 76.	
Article 25				
358	Article 25 SoHO establishment authorisation system		Article 25 SoHO establishment authorisation system	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 25(1)				
359	1. Competent authorities shall establish and maintain a system for receiving and processing requests for the authorisation of SoHO establishments.		1. **SoHO** competent authorities shall establish and maintain a system for receiving and processing requests for the authorisation of SoHO establishments **in their territory. The system shall allow for the suspension and withdrawal of authorisations**.	
Article 25(2)				
360	2. Competent authorities shall authorise as SoHO establishments		2. **SoHO** competent authorities shall authorise as SoHO	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the SoHO entities that both process and store SoHOs in accordance with Article 27.		establishments the SoHO entities that ~~both process and store SoHOs~~**meet the definition in Article 3(40),** in accordance with Article 27.	
Article 25(2a)				
360a			**2a. SoHO competent authorities shall include all SoHO activities carried out by a SoHO establishment in the authorisation granted, including those SoHO activities carried out outside of the premises of the SoHO establishment.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 25(3)				
361	3. Competent authorities may decide that certain SoHO entities that do not process and store SoHO also need to be authorised as SoHO establishments, in particular SoHO entities that:		3. **SoHO** Competent authorities may decide that certain SoHO entities that do not ~~process and store SoHO~~**meet the SoHO establishment definition,** also need to be authorised as ~~SoHO establishments~~**such** , in particular SoHO entities that:	
Article 25(3), point (a)				
362	(a) have significant influence on the safety and quality of SoHOs due to the scale, criticality or		(a) have significant influence on the safety and quality of SoHOs due to the scale, criticality or	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	complexity of the SoHO activities they perform; or		complexity of the SoHO activities they perform; or	
Article 25(3), point (b)				
363	(b) carry out SoHO activities in connection with multiple SoHO establishments.		(b) carry out SoHO activities in connection with multiple SoHO establishments.	
Article 25(3), last paragraph				
363a			**3. SoHO competent authorities shall inform the SoHO entity of such decision and of the resulting obligation to comply with all**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			provisions for SoHO establishments, including the submission of an application for SoHO establishment authorisation.	
Article 25(4)				
364	4. Paragraph 3 shall not apply to SoHO entities that import SoHO.		4. ~~Paragraph 3 shall not apply to SoHO entities that import SoHO.~~	
Article 25(5)				
365	5. SoHO establishment authorisations shall be valid		5. SoHO establishment authorisations shall be valid	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	throughout the Union for the period defined in the terms of the authorisation, when such a time period has been defined, or until a competent authority has suspended or withdrawn the authorisation or the establishment has ceased to conduct SoHO activities. Where a Member State has adopted a more stringent measure, in accordance with Article 4, which relates to a specific SoHO establishment authorisation, that Member State may decline to recognise the validity of the SoHO establishment authorisation of another Member State pending verification that the more stringent measure has been met.		throughout the Union for the period defined in the terms of the authorisation, when such a time period has been defined, or until a **SoHO** competent authority has suspended or withdrawn the authorisation or the establishment has ceased to conduct SoHO activities. Where a Member State has adopted a more stringent measure, in accordance with Article 4, which relates to a specific SoHO establishment authorisation, that Member State may decline to recognise the validity of the SoHO establishment authorisation of another Member State ~~pending verification that~~**until it has verified compliance with** the more stringent measure ~~has been met~~.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 25(6), first subparagraph				
366	The Commission may adopt implementing acts to specify uniform procedures and working methods for establishing and maintaining a SoHO establishment authorisation system.		~~The Commission may adopt implementing acts to specify uniform procedures and working methods for establishing and maintaining a SoHO establishment authorisation system.~~	
Article 25(6), second subparagraph				
367	Those implementing acts shall be adopted in accordance with the examination procedure referred to		~~Those implementing acts shall be adopted in accordance with the examination procedure referred to~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	in Article 79(2).		~~in Article 79(2).~~	
Article 26				
368	Article 26 Importing SoHO entity authorisation system		Article 26 ~~Importing SoHO entity authorisation system~~	
Article 26(1)				
369	1. Competent authorities shall establish and maintain a system for receiving and processing requests for the authorisation of importing		1. ~~Competent authorities shall establish and maintain a system for receiving and processing requests for the authorisation of importing~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHO entities.		~~SoHO entities.~~	
Article 26(2)				
370	2. Competent authorities shall authorise as importing SoHO entities the SoHO entities that import SoHOs pursuant to Article 28.		2. ~~Competent authorities shall authorise as importing SoHO entities the SoHO entities that import SoHOs pursuant to Article 28.~~	
Article 26(3)				
371	3. Importing SoHO entity authorisations shall be valid throughout the Union for the		3. ~~Importing SoHO entity authorisations shall be valid throughout the Union for the~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	period defined in the terms of the authorisation, when such a time period has been defined, or until a competent authority has suspended or withdrawn the authorisation or the entity has ceased to conduct SoHO activities. Where a Member State has adopted a more stringent measure, in accordance with Article 4, which relates to a specific importing SoHO entity authorisation, that Member State may decline to recognise the validity of the importing SoHO entity authorisation of another Member State pending verification that the more stringent measure has been met.		~~period defined in the terms of the authorisation, when such a time period has been defined, or until a competent authority has suspended or withdrawn the authorisation or the entity has ceased to conduct SoHO activities. Where a Member State has adopted a more stringent measure, in accordance with Article 4, which relates to a specific importing SoHO entity authorisation, that Member State may decline to recognise the validity of the importing SoHO entity authorisation of another Member State pending verification that the more stringent measure has been met.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 26(4), first subparagraph				
372	The Commission shall adopt implementing acts to specify uniform procedures and working methods for establishing and maintaining an importing SoHO entity authorisation system.		~~The Commission shall adopt implementing acts to specify uniform procedures and working methods for establishing and maintaining an importing SoHO entity authorisation system.~~	
Article 26(4), second subparagraph				
373	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).		~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 27				
374	Article 27 Authorisation of SoHO establishments		Article 27 Authorisation of SoHO establishments	
Article 27(1)				
375	1. Competent authorities shall provide guidelines and templates to allow that applications from SoHO entities for their authorisation as SoHO establishments are	1. Competent authorities shall provide guidelines and templates to allow that applications from SoHO entities for their authorisation as SoHO establishments are	1. **SoHO** competent authorities shall provide guidelines and templates to allow that applications ~~from SoHO entities for their~~**for the** authorisation ~~as~~**of** SoHO	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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).	submitted in accordance with Article 49. When developing ~~*these*~~***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).	establishments are submitted in accordance with Article 49. When developing these guidelines and templates, **SoHO** competent authorities shall ~~consult~~**take into account** the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c). **SoHO competent authorities may use the secure communication channel on the EU SoHO Platform for the exchange, with the SoHO establishment, of documents relating to the application for an authorisation.**	
Article 27(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
376	2. Upon receipt of an application for the authorisation of a SoHO establishment, competent authorities shall:		2. Upon receipt of an application for the authorisation of a SoHO establishment, **SoHO** competent authorities shall:	
Article 27(2), point (a)				
377	(a) acknowledge receipt of the application within 14 working days;		(a) acknowledge receipt of the application ~~within 14 working days~~**without undue delay**;	
Article 27(2), point (b)				
378				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(b) assess the application;		(b) assess the application;	
Article 27(2), point (c)				
379	(c) examine agreements between the applicant SoHO establishment and any third parties contracted by that SoHO establishment to perform SoHO activities;		(c) examine agreements between the applicant SoHO establishment and any ~~third parties~~**SoHO entities** contracted by that SoHO establishment to perform SoHO activities;	
Article 27(2), point (d)				
380	(d) request that the applicant		(d) request that the applicant	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHO establishment provides supplementary information, if needed;		SoHO establishment provides supplementary information, if needed;	
Article 27(2), point (e)				
381	(e) carry out an on-site system inspection of the applicant SoHO establishment and, where applicable, of third parties contracted by the SoHO establishment to perform SoHO activities, pursuant to Article 29;		(e) carry out an on-site ~~system~~ inspection of the applicant SoHO establishment **pursuant to Article 29,** and, where applicable,**of SoHO entities or** ~~of~~ third parties contracted by the SoHO establishment ~~to perform SoHO activities,~~ pursuant to Article ~~29~~**30**;	
Article 27(2), point (f)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
382	(f) inform the applicant, without undue delay, of the outcome of the assessment and inspections referred to in points (b), (c), (d) when relevant and (e) and of the decision on the authorisation;		(f) inform the applicant, without undue delay, of the outcome of the assessment and inspections referred to in points (b), (c), (d) when relevant**,** and (e)~~ and of the decision on the authorisation~~;	
Article 27(2), point (g)				
383	(g) grant or refuse the authorisation of the applicant SoHO establishment as a SoHO establishment, as appropriate, and indicate which SoHO activities are covered by the authorisation and which conditions apply, if any;		(g) grant or refuse the authorisation of the applicant SoHO establishment as a SoHO establishment, as appropriate, and indicate which SoHO **and which SoHO** activities **for each SoHO** are covered by the authorisation	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			and which conditions apply, if any;	
Article 27(2), point (h)				
384	(h) assess and, as appropriate, approve subsequent changes made by the SoHO establishment to the information provided in the application and communicated to them according to Article 49(2);		(h) ~~assess and, as appropriate, approve subsequent changes made by the SoHO establishment to the information provided in the application and communicated to them according to Article 49(2);~~	
Article 27(2), point (i)				
385	(i) submit information regarding the authorisation by amending		(i) submit information regarding the ~~authorisation by amending~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	accordingly the status of the SoHO entity concerned, and including the name and contact details of the SoHO establishment authorisation holder, in the EU SoHO Platform as referred to in Chapter XI without undue delay.		~~accordingly the status~~**granted authorisation** of the SoHO ~~entity concerned, and including the name and contact details~~**establishment, by amending the status** of the SoHO ~~establishment authorisation holder,~~**entity to SoHO establishment** in the EU SoHO Platform ~~as referred to in Chapter XI~~ without undue delay.	
Article 27(2), point (j)				
385a			**(j) assess and, as appropriate, authorise any significant changes made by the SoHO establishment to the information provided in the application and**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			communicated to them according to Article 49(2), and update the information in the EU SoHO Platform.	
Article 27(3), first subparagraph				
386	Competent authorities may suspend the authorisation of a SoHO establishment, or of certain SoHO activities the establishment is authorised to perform, if SoHO supervisory activities demonstrate or give reasonable grounds for suspecting, that the SoHO establishment in question:		**SoHO** competent authorities may**, in accordance with national legislation,** suspend the authorisation of a SoHO establishment, or of certain SoHO activities the establishment is authorised to perform, if SoHO supervisory activities demonstrate or give reasonable grounds for suspecting, that the SoHO establishment in question:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 27(3), first subparagraph, point (a)				
387	(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; ~~and~~*or*	(a) does not comply with the conditions of its authorisation ~~or the provisions of this Regulation; and~~;	
Article 27(3), first subparagraph, point (aa)				
387a		***(aa) does not take corrective or preventive action following an inspection by national authorities pursuant to Article 29(14); and***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 27(3), first subparagraph, point (b)				
388	(b) that non-compliance, or suspected non-compliance, implies a risk to the safety of SoHO donors or recipients or offspring from medically assisted reproduction.		(b) ~~that non-compliance, or suspected non-compliance, implies a risk to the safety of SoHO donors or recipients or offspring from medically assisted reproduction.~~ **does not comply with the provisions of this Regulation; or**	
Article 27(3), first subparagraph, point (c)				
388a			**(c) a risk to the safety of SoHO donors, recipients or offspring**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			from medically assisted reproduction, or a risk of unnecessary wastage of SoHO, is identified.	
Article 27(3), second subparagraph				
389	Competent authorities shall specify a period of time for the investigation of a suspected non-compliance and for the SoHO establishment to rectify a confirmed non-compliance, during which the suspension will remain in place.		**SoHO** competent authorities shall specify a period of time for the investigation of a suspected non-compliance and for the SoHO establishment to rectify a confirmed non-compliance, during which the suspension will remain in place.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 27(4)				
390	4. In cases where competent authorities have confirmed non-compliances referred to in paragraph 3 and SoHO establishments are not able to rectify them in the specified time period, competent authorities shall, in accordance with national legislation, withdraw the authorisation of a SoHO establishment.		4. In cases where **SoHO** competent authorities have confirmed non-compliances referred to in paragraph 3 and SoHO establishments are not able to rectify them in the specified time period, **SoHO** competent authorities shall, in accordance with national legislation, withdraw the authorisation of a SoHO establishment.	
Article 27(5)				
391				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 ~~*repeatedly*~~ failed to comply with the conditions of its authorisation.	5. **SoHO** 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 authorisationa~~ **a suspension, as described in paragraph 3, is not sufficient to resolve the identified shortcomings**.	
Article 27(6)				
392				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	6. In cases of authorisation suspension or withdrawal, as referred to in paragraphs 3, 4 and 5, competent authorities shall amend accordingly the authorisation status of the SoHO establishment concerned in the EU SoHO Platform as referred to in Chapter XI without undue delay.		6. In cases of authorisation suspension or withdrawal, as referred to in paragraphs 3, 4 and 5, **SoHO** competent authorities shall amend accordingly the authorisation status of the SoHO establishment concerned in the EU SoHO Platform ~~as referred to in Chapter XI~~ without undue delay.	
Article 28				
393	Article 28 Authorisation of importing SoHO entities		Article 28 Authorisation of importing SoHO ~~entities~~**establishments**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 28(1)				
394	1. Competent authorities shall provide guidelines and templates to allow that applications from SoHO entities for their authorisation as importing SoHO entities are submitted in accordance with Article 43. In 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. **SoHO** competent authorities shall ~~provide guidelines and templates to allow that applications from SoHO entities for their authorisation as importing~~**authorise as SoHO establishments those** SoHO entities ~~are submitted in accordance with Article 43. In developing these guidelines and templates, competent authorities shall consult the relevant best practices agreed and documented by the SCB~~ **that import SoHO,** as referred to in Article ~~68(1), point (c)~~**25(2)**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 28(1a)				
394a			**1a. Articles 25(1), 25(5), 25(6) and 27 shall apply, mutatis mutandis, to the authorisation of importing SoHO establishments.**	
Article 28(2)				
395	2. Upon receipt of an application for the authorisation of an importing SoHO entity, competent authorities shall:		2. Upon receipt of an application for ~~the~~**an importing SoHO establishment** authorisation**, SoHO competent authorities shall act in accordance with Article 27(2). SoHO** ~~of an importing SoHO entity,~~ competent	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			authorities shall~~:~~ **also assess the procedures in place at the applicant importing SoHO establishment to ensure that the imported SoHOs are equivalent, in terms of quality, safety and effectiveness, to SoHOs preparations authorised according to the provisions of this Regulation.**	
Article 28(2), point (a)				
396	(a) acknowledge receipt of the application within 14 working days;		(a) ~~acknowledge receipt of the application within 14 working days;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 28(2), point (b)				
397	(b) assess the application;		(b) ~~assess the application;~~	
Article 28(2), point (c)				
398	(c) examine agreements between the applicant SoHO entity and any third parties contracted by that SoHO entity to perform SoHO activities;		(c) ~~examine agreements between the applicant SoHO entity and any third parties contracted by that SoHO entity to perform SoHO activities;~~	
Article 28(2), point (d)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
399	(d) request that the applicant provides supplementary information, if needed;		(d) ~~request that the applicant provides supplementary information, if needed;~~	
Article 28(2), point (e)				
400	(e) inform the applicant, without undue delay, of the outcome of the assessment and examinations referred to in points (b), (c) and (d) where relevant, and of the decision on the authorisation;		(e) ~~inform the applicant, without undue delay, of the outcome of the assessment and examinations referred to in points (b), (c) and (d) where relevant, and of the decision on the authorisation;~~	
Article 28(2), point (f)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
401	(f) grant or refuse the authorisation of the applicant as an importing SoHO entity, as appropriate, and indicate which SoHOs are covered by the authorisation and which conditions apply, if any;		(f) ~~grant or refuse the authorisation of the applicant as an importing SoHO entity, as appropriate, and indicate which SoHOs are covered by the authorisation and which conditions apply, if any;~~	
Article 28(2), point (g)				
402	(g) assess and, as appropriate, approve subsequent changes made by the SoHO importing entity and communicated to them as referred to in Article 43(3);		(g) ~~assess and, as appropriate, approve subsequent changes made by the SoHO importing entity and communicated to them as referred to in Article 43(3);~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 28(2), point (h)				
403	(h) submit information regarding the authorisation, by amending accordingly the status of the SoHO entity concerned, and including the name and contact details of the importing SoHO entity authorisation holder, in the EU SoHO Platform as referred to in Chapter XI, without undue delay.		(h) ~~submit information regarding the authorisation, by amending accordingly the status of the SoHO entity concerned, and including the name and contact details of the importing SoHO entity authorisation holder, in the EU SoHO Platform as referred to in Chapter XI, without undue delay.~~	
Article 28(2a)				
403a			**2a. With regards to Article 27(2)(e), and in cases where the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			imported SoHO are not physically received by the importing SoHO establishment but are directly sent to the SoHO entity for application to a specific SoHO recipient or to an operator for manufacturing a product under other Union legislation, as referred to in Article 2(3), SoHO competent authorities may choose to carry out only a document review-based inspection.	
Article 28(3)				
404	3. In cases where the applicant intends to distribute the imported		3. ~~In cases where the applicant intends to distribute the imported~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHOs to other Member States, competent authorities may perform the actions set out in paragraph 2, points (b), (c) and (d), in consultation with the SoHO National Authorities of the Member States concerned.		~~SoHOs to other Member States, competent authorities may perform the actions set out in paragraph 2, points (b), (c) and (d), in consultation with the SoHO National Authorities of the Member States concerned.~~	
Article 28(4)				
405	4. Competent authorities may require to inspect any party in a third country supplying SoHOs to the applicant prior to granting or refusing the importing SoHO entity authorisation, in particular in cases where the application concerns regular and repeated import of		4. **SoHO** competent authorities may require to inspect any ~~party in a~~ third country ~~supplying SoHOs~~**supplier** to the applicant prior to granting or refusing the importing SoHO ~~entity~~**establishment** authorisation, in particular in cases where the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHOs from the same party.		application concerns regular and repeated import of ~~SoHOs~~**SoHO** from the same ~~party~~**third country supplier**.	
Article 28(5)				
406	5. Competent authorities may suspend the authorisation of an importing SoHO entity if SoHO supervisory activities demonstrate or give reasonable grounds to suspect:		5. ~~Competent authorities may suspend the authorisation of an importing SoHO entity if SoHO supervisory activities demonstrate or give reasonable grounds to suspect:~~	
Article 28(5), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
407	(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; ~~and~~***or***	(a) ~~that the SoHO entity in question does not comply with the conditions of the authorisation or the provisions of this Regulation; and~~	
Article 28(5), point (b)				
408	(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.	(b) ~~that this non-compliance, or suspected non-compliance, implies a risk to the safety of recipients or offspring from medically assisted reproduction.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 28(6)				
409	6. Competent authorities shall specify a period of time for the investigation of a suspected non-compliance and for the importing SoHO entity to rectify a confirmed non-compliance, during which the suspension shall remain in place. In cases where competent authorities have confirmed non-compliances referred to in paragraph 5 and the importing SoHO entity is not able to rectify them in the specified time period, competent authorities shall withdraw the authorisation of the importing SoHO entity.		6. ~~Competent authorities shall specify a period of time for the investigation of a suspected non-compliance and for the importing SoHO entity to rectify a confirmed non-compliance, during which the suspension shall remain in place. In cases where competent authorities have confirmed non-compliances referred to in paragraph 5 and the importing SoHO entity is not able to rectify them in the specified time period, competent authorities shall withdraw the authorisation of the importing SoHO entity.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 28(7)				
410	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 ~~*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 repeatedly failed to comply with the conditions of its authorisation.~~	
Article 28(8)				
411				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	8. In cases of authorisation suspension or withdrawal, as referred to in paragraphs 5, 6 and 7, competent authorities shall amend accordingly the authorisation status of the SoHO entity concerned in the EU SoHO Platform as referred to in Chapter XI without undue delay.		8. ~~In cases of authorisation suspension or withdrawal, as referred to in paragraphs 5, 6 and 7, competent authorities shall amend accordingly the authorisation status of the SoHO entity concerned in the EU SoHO Platform as referred to in Chapter XI without undue delay.~~	
Article 28(9)				
412	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	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	9. By derogation from paragraph 1, ~~in case of emergency~~**SoHO** competent authorities may authorise imports of ~~SoHOs~~**a SoHO** for immediate **human** application to a specific **SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	circumstances on a case-by-case basis.	immediate application to a specific recipient when ***duly*** justified by the clinical circumstances on a case-by-case basis.	recipient**, when requested by the SoHO entity responsible for that application and** when justified by the clinical circumstances on a case-by-case basis. **SoHO competent authorities may also authorise imports of SoHO in emergency situations for immediate human application to SoHO recipients whose health would be seriously endangered without such an import.**	
Article 28(10)				
413	10. The Commission is empowered to adopt delegated acts		10. The Commission ~~is~~**shall be** empowered to adopt delegated acts	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	in accordance with Article 77 in order to be able to supplement this Regulation by laying down specific criteria for the assessments, examinations and inspections in the course of the authorisation.		in accordance with Article 77 in order to be able to supplement this Regulation by laying down specific criteria for the assessments~~,~~ ~~examinations and inspections~~ in the course of the authorisation **of importing SoHO establishments**.	
Article 28(11)				
414	11. Where, in the case of risk to quality and safety of imported SoHOs, imperative grounds of urgency so require, the procedure provided for in Article 78 shall apply to delegated acts adopted pursuant to this Article.		11. Where, in the case of risk to quality and safety of imported SoHOs, imperative grounds of urgency so require, the procedure provided for in Article 78 shall apply to delegated acts adopted pursuant to this Article.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 29				
415	Article 29 Inspections of SoHO establishments		Article 29 Inspections of SoHO establishments	
Article 29(1)				
416	1. Competent authorities shall carry out the following inspections on SoHO establishments, as appropriate:		1. **SoHO** competent authorities **of the Member States where SoHO establishments are located** shall carry out ~~the following~~ inspections ~~on~~**of those** SoHO establishments,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~as appropriate:~~**and where applicable, of SoHO entities or third parties contracted by SoHO establishments.**	
Article 29(1a)				
416a			**1a. SoHO competent authorities shall carry out the following inspections on SoHO establishments, as appropriate:**	
Article 29(1), point (a)				
417	(a) announced routine system		(a) announced routine system	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	inspections;		inspections;	
Article 29(1), point (b)				
418	(b) announced or unannounced inspections, in particular in the case of investigations of fraudulent or other illegal activities, or on the basis of information that might indicate non-compliance with the rules of this Regulation;		(b) announced or unannounced inspections, in particular ~~in the case of investigations~~**for the investigation** of fraudulent or other illegal activities, or on the basis of information that might indicate non-compliance with ~~the rules of~~ this Regulation;	
Article 29(1), point (c)				
419				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(c) inspections as provided for in Article 22(6), Article 27(2), point (d), Article 28(4), Article 31 and Article 35(5).		(c) **announced or unannounced** inspections ~~as provided for in Article 22(6), Article 27(2), point (d)~~**targeted at a specific activity or topicas provided for in Articles 22(6)**, ~~Article 28(4), Article~~ **28(4),** 31 and ~~Article~~ 35(5).	
Article 29(2)				
420	2. Competent authorities that during inspections identify non-compliances with the rules of this Regulation may include follow-up inspections, where necessary and proportionate, to verify that SoHO establishments have undertaken		2. **SoHO** competent authorities that during inspections identify non-compliances with the rules of this Regulation may include follow-up inspections, where necessary and proportionate, to verify that SoHO establishments	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	effective corrective and preventive actions.		have undertaken ~~effective~~**appropriate** corrective and preventive actions.	
Article 29(3)				
421	3. Competent authorities of the Member State in which the SoHO establishment is located shall carry out the inspections.		3. ~~Competent authorities of the Member State in which the SoHO establishment is located shall carry out the inspections.~~	
Article 29(4)				
422	4. Competent authorities shall carry out on-site inspections of		4. ~~Competent authorities shall carry out on-site inspections of~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHO establishments and, where applicable, of any third parties contracted by the SoHO establishment to perform SoHO activities.		~~SoHO establishments and, where applicable, of any third parties contracted by the SoHO establishment to perform SoHO activities.~~	
Article 29(5)				
423	5. By derogation from paragraph 4, competent authorities may conduct inspections, in full or in part, by means of a remote document review, provided that:		5. ~~By derogation from paragraph 4,~~ **SoHO competent authorities shall carry out on-site inspections referred to in this Article. Exceptionally, SoHO** competent authorities may conduct inspections, in full or in part, by **virtual** means**, or by** ~~of a~~ remote document review, provided that:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 29(5), point (a)				
424	(a) such inspection mode does not pose a risk to the safety and quality of SoHOs;		(a) such inspection mode does not pose a risk to the safety and quality of ~~SoHOs~~**SoHO**;	
Article 29(5), point (b)				
425	(b) such inspection does not prejudice the effectiveness of inspections; and		(b) such inspection **mode** does not prejudice the effectiveness of inspections;~~ and~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 29(5), point (ba)				
425a			**(ba) protection of SoHO donors, SoHO recipients or offspring of medically assisted reproduction is respected; and**	
Article 29(5), point (c)				
426	(c) the maximum interval between two on-site inspections pursuant to paragraph 11 is not exceeded.		(c) the maximum interval between two on-site inspections pursuant to paragraph ~~11~~**10** is not exceeded.	
Article 29(6)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
427	6. Competent authorities shall ensure that inspections are carried out by inspectors meeting the requirements set out in Article 32.		6. **SoHO** competent authorities shall ensure that inspections are carried out by inspectors meeting the requirements set out in Article 32.	
Article 29(7), first subparagraph				
428	Inspectors shall verify that SoHO establishments meet the general standards concerning SoHO donor protection laid down in Article 53, the standards concerning the voluntary and unpaid nature of SoHO donations laid down in Article 54, the standards		~~Inspectors shall verify that SoHO establishments meet the general standards concerning SoHO donor protection laid down in Article 53, the standards concerning the voluntary and unpaid nature of SoHO donations laid down in Article 54, the standards~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	concerning information to be provided prior to consent or authorisation laid down in Article 55 and the general standards concerning recipient and offspring protection laid down in Article 58, as applicable.		~~concerning information to be provided prior to consent or authorisation laid down in Article 55 and the general standards concerning recipient and offspring protection laid down in Article 58, as applicable.~~	
Article 29(7a), first subparagraph				
428a			**7a. The inspections shall include the verification that SoHO establishments comply with the standards or elements thereof set by the Regulation.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 29(7), second subparagraph				
429	In cases where the SoHO establishments follow:		In cases where the SoHO establishments follow:	
Article 29(7), second subparagraph, point (a)				
430	(a) the technical guidelines published by the ECDC and by the EDQM referred to in Articles 56(4), point (a), and 59(4), point (a), as applicable, the inspectors shall consider the standards or elements thereof, to be met, insofar as they are addressed by the guidelines;		(a) the technical guidelines published by the ECDC and by the EDQM referred to in Articles 56(4), point (a), and 59(4), point (a), as applicable, the inspectors shall consider the standards ~~or elements thereof~~**set out in this Regulation**, to be met, insofar as they are addressed by the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			guidelines **referred to in this subparagraph**;	
Article 29(7), second subparagraph, point (b)				
431	(b) other guidelines as referred to in Articles 56(4), point (b), and 59(4), point (b), the inspectors shall assess on a case-by-case basis such guidelines in terms of level of safety, quality and efficacy achieved, as applicable, and accept or decline whether that level is equivalent to the level set by the technical guidelines referred to in Articles 56(4), point (a), and 59(4), point (a);		(b) other guidelines as referred to in Articles 56(4), point (b), and 59(4), point (b), ~~the inspectors shall assess on a case-by-case basis such guidelines in terms of level of safety, quality and efficacy achieved, as applicable, and accept or decline whether that level is equivalent to the level set~~**adopted by the Member State, according to paragraph 8, the inspectors shall consider the standards set out in this Regulation, to be met,**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			insofar as they are addressed by the ~~technical~~ guidelines referred to in ~~Articles 56(4), point (a), and 59(4), point (a)~~**this subparagraph**;	
Article 29(7), second subparagraph, point (c)				
432	(c) other technical methods as referred to in Articles 56(4), point (c), and 59(4), point (c), the inspectors shall evaluate the risk assessment and record provided, assess the adequacy of the technical methods applied.		(c) other technical methods **applied in specific circumstances,** as referred to in Articles 56(4), point (c), and 59(4), point (c), the inspectors shall evaluate the ~~risk assessment and record provided, assess the adequacy of the technical methods applied~~**steps taken by the SoHO establishment to ensurethe adequacy and compliance with the standards**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			set out in this Regulation. For this assessment, the SoHO establishments shall provide the inspectors with all the necessary information, pursuant to Articles 56(7) and 59(7).	
Article 29(8)				
433	8. In cases of paragraph 7, second subparagraph, point (b) where competent authorities, prior to the inspection, have accepted the level safety, quality and efficacy achieved by those other guidelines, as equivalent to the level set by the technical guidelines referred to in paragraph 7, second subparagraph,		8. In cases ~~of~~**referred to in** paragraph ~~7~~**7a**, second subparagraph, point (b)**, the Member State** ~~where competent authorities~~, prior to the inspection, **shall have adopted** ~~have accepted~~ the level ~~safety, quality and efficacy~~**of safety and quality** achieved by those ~~other~~ guidelines,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	point (a), the inspectors shall consider the standards or elements thereof, to be met, insofar as they are addressed by the guidelines.		as ~~equivalent to the level set by the technical guidelines referred to in paragraph 7, second subparagraph, point (a), the inspectors~~**compliant with the standards set out in Chapters VI and VII of this Regulation, and** shall ~~consider the standards or elements thereof, to be met, insofar as they are addressed by the guidelines~~**have made these guidelines available at the EU SoHO Platform**.	
Article 29(9)				
434	9. Inspectors may carry out one or more of the following activities:		9. Inspectors ~~may~~**shall** carry out one or more of the following activities:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 29(9), point (a)				
435	(a) inspect SoHO establishment facilities and, where applicable, the facilities of any third parties contracted by the SoHO establishment concerning SoHO activities;		(a) inspect ~~SoHO establishment facilities and, where applicable, the facilities of any third parties contracted by the SoHO establishment concerning SoHO activities~~**premises** ;	
Article 29(9), point (b)				
436	(b) evaluate and verify the procedures and the SoHO activities performed in SoHO establishments		(b) evaluate and verify **compliance of** the procedures and the SoHO activities performed ~~in~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	and, where applicable, in facilities of third parties that are relevant to the requirements of this Regulation;		~~SoHO establishments and, where applicable, in facilities of third parties that are relevant to~~**with** the requirements of this Regulation;	
Article 29(9), point (c)				
437	(c) examine any documents or other records kept by SoHO establishments and, where applicable, third parties relating to the requirements of this Regulation and in particular Chapter V thereof;		(c) examine any documents or other records ~~kept by SoHO establishments and, where applicable, third parties~~ relating to the requirements of this Regulation ~~and in particular Chapter V thereof~~;	
Article 29(9), point (d)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
438	(d) evaluate the design and implementation of the quality management system in place pursuant to Article 50;		(d) **if applicable,** evaluate the design and implementation of the quality management system in place pursuant to Article 50**;** ~~;~~	
Article 29(9), point (da)				
438a			**(da) evaluate the compliance with the vigilance system and the traceability system;**	
Article 29(9), point (e)				
439				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(e) take samples for analysis and copies of documents if required;		(e) take samples for analysis ~~and~~**,** copies of documents**, and photographs or videos,** if required;	
Article 29(9), point (f)				
440	(f) evaluate the emergency plan in place in accordance with Article 66, where applicable;		(f) evaluate the emergency plan in place in accordance with Article 66, where applicable;	
Article 29(9), point (g)				
441	(g) order the suspension or		(g) order **or propose to the SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	cessation of any procedure or activity where necessary and proportionate to the risk detected.		**competent authority,** the suspension or cessation of any procedure or activity **or impose other measures,** where necessary and proportionate to the risk detected. **In such case, the inspector shall take all the necessary steps without undue delay.**	
Article 29(10)				
442	10. Competent authorities shall carry out inspections pursuant to paragraph 1, point (a), regularly, on a risk basis and with appropriate frequency, taking account of:		10. **Subsequent to the inspection referred to in Article 27(2) point (e), SoHO** competent authorities shall carry out **periodic** inspections pursuant to paragraph ~~1~~**1a**, point (a), ~~regularly, on a risk basis and~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~with appropriate frequency, taking~~**so that the interval between two on-site inspections shall not exceed, in any event, four years. The frequency of inspections shall take** account of:	
Article 29(10), point (a)				
443	(a) identified risks associated with:		(a) identified risks associated with~~:~~ **the type of SoHO that are subject to the authorisation and the SoHO activities carried out;**	
Article 29(10), point (a)(i)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
444	(i) the SoHOs processed and stored;		(i) ~~the SoHOs processed and stored;~~	
Article 29(10), point (a)(ii)				
445	(ii) the activities of the SoHO establishments, in particular the processes carried out;		(ii) ~~the activities of the SoHO establishments, in particular the processes carried out;~~	
Article 29(10), point (b)				
446	(b) the establishments' past record as regards the outcome of previous		(b) the **SoHO** establishments' past record as regards the outcome of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	inspections carried out on them and their compliance with the rules of this Regulation;		previous inspections ~~carried out on them~~ and their compliance with the rules of this Regulation;	
Article 29(10), point (c)				
447	(c) results from certification or accreditation by international bodies, where those bodies verify provisions that are equivalent to those in this Regulation; and		(c) ~~results from~~**the** certification or accreditation by international bodies, where ~~those bodies verify provisions that are equivalent to those in this Regulation~~**relevant**; ~~and~~	
Article 29(10), point (d)				
448				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(d) the reliability and effectiveness of the quality management systems referred to in Article 50.		(d) the reliability and effectiveness of the quality management systems referred to in Article 50.	
Article 29(11)				
449	11. The interval between two on-site inspections shall not exceed 4 years.	11. The interval between ~~*two on-site inspections*~~***inspections shall be decided on based on the frequency necessary to mitigate any identified risks and*** shall not exceed 4 years.	11. ~~The interval between two on-site inspections shall not exceed 4 years~~.	
Article 29(12)				
450				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	12. Competent authorities shall consider on-site inspections carried out in the course of the authorisation of an establishment in accordance with Article 27(2), point (d), as the first on-site inspection in the sense of this Article.		12. ~~Competent authorities shall consider on-site inspections carried out in the course of the authorisation of an establishment in accordance with Article 27(2), point (d), as the first on-site inspection in the sense of this Article.~~**.**	
Article 29(13)				
451	13. Competent authorities shall provide immediate preliminary feedback on their findings at the request of the SoHO establishment concerned.		13. ~~Competent authorities shall provide immediate preliminary feedback on their findings at the request of the SoHO establishment concerned.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 29(14)				
452	14. Following each inspection, the competent authorities shall draw up a report on the findings of the inspection that concern compliance with the legal and technical requirements applicable under this Regulation and provide it to the SoHO establishment concerned. In the report, the competent authorities may set out any corrective or preventive action needed or may request the SoHO establishment to respond with a proposal for such actions, with associated dates for completion.		14. Following each inspection, the **SoHO** competent authorities shall draw up a report on the findings of the inspection ~~that concern compliance with the legal and technical requirements applicable under this Regulation~~ and provide it to the SoHO establishment concerned. ~~In the report, the~~ **When the result of the inspection so requires, the SoHO** competent authorities ~~may~~**shall, as appropriate,** set out any corrective or preventive action needed or ~~may~~**shall** request the SoHO establishment to respond with a proposal for such actions, with	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			associated dates for completion.	
Article 29(15)				
453	15. Where more than one authority is competent to perform SoHO supervisory activities in a Member State pursuant to Article 5(2), on a reasoned request from another competent authority in their Member State, the competent authority shall forthwith communicate the report referred to in paragraph 14 of this Article to the requesting competent authority.		15. ~~Where more than one authority is competent to perform SoHO supervisory activities in a Member State pursuant to Article 5(2), on a reasoned request from another competent authority in their Member State, the competent authority shall forthwith communicate the report referred to in paragraph 14 of this Article to the requesting competent authority.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 29(16)				
454	16. For the purpose of standardised inspections referred to in paragraph 1 of this Article, competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).		16. For the purpose of ~~standardised~~ inspections referred to in paragraph 1 of this Article, **SoHO** competent authorities shall ~~consult~~**take into account** the relevant best practices **on inspections** agreed and documented by the SCB as referred to in Article 68(1), point (c).	
Article 29(17), first subparagraph				
455	The Commission may adopt implementing acts concerning the		The Commission may adopt implementing acts concerning	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	procedures to be followed for inspections of SoHO establishments.		~~the~~**common elements of** procedures to be followed for inspections of SoHO establishments.	
Article 29(17), second subparagraph				
456	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	
Article 30				
457				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 30 Inspections of other SoHO entities		Article 30 Inspections of **SoHO entities** other **than SoHO establishments and of third parties**~~SoHO entities~~	
Article 30(1)				
458	1. Competent authorities may carry out inspections pursuant to Article 29(1) on SoHO entities other than SoHO establishments as necessary and proportionate to the risks associated with the SoHOs and the SoHO activities registered for that SoHO entity, and the SoHO entity's past record, in particular as regards the outcome		1. **SoHO** competent authorities may carry out inspections pursuant to Article 29(1) ~~on~~**of** SoHO entities other than SoHO establishments**, and of the third parties contracted,** as necessary and proportionate to the risks associated with the ~~SoHOs~~**SoHO** and the SoHO activities registered for that SoHO entity, and the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	of previous inspections carried out on it and its compliance with the rules of this Regulation.		SoHO entity's past ~~record, in particular as regards the outcome of previous inspections carried out on it and its~~ compliance ~~with the rules of this Regulation~~**records**.	
Article 30(2)				
459	2. In the cases referred to in paragraph 1, Article 29 shall apply, mutatis mutandis, to the inspection of SoHO entities other than SoHO establishments.		2. In the cases referred to in paragraph 1, Article 29 shall apply, ***mutatis mutandis***~~mutatis mutandis~~, to the inspection of SoHO entities other than SoHO establishments **and of the third parties contracted**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 30(3)				
460	3. For the purpose of a standardised approach to the inspection of SoHO entities other than SoHO establishments, competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).		3. ~~For the purpose of a standardised approach to the inspection of SoHO entities other than SoHO establishments, competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).~~	
Article 31				
461	Article 31		Article 31	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Joint inspections		Joint inspections	
Article 31(1)				
462	1. At a request of one or more competent authorities, inspections pursuant to Articles 29(1) and 30(1) may be carried out by inspectors from more than one Member State as a joint inspection.		1. At a request of one or more **SoHO** competent authorities **via their SoHO National Authority to another SoHO National Authority**, inspections pursuant to Articles 29(1) and 30(1) may be carried out ~~by~~**with the participation of** inspectors ~~from more than one~~**sent for that purpose by other** Member State as a joint inspection.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 31(2)				
463	2. The competent authority receiving a request for a joint inspection, shall make all reasonable efforts to accept such request, and coordinate and support that inspection, in cases where:		2. **With the previous consent of the SoHO National Authority, the SoHO** ~~The~~ competent authority receiving a request for a joint inspection~~,~~ shall make all reasonable efforts to accept such request, ~~and coordinate and support that inspection~~**taking into account their available resources**, in cases where:	
Article 31(2), point (a)				
464	(a) it is demonstrated, or there is		(a) ~~it is demonstrated, or there is~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	reasonable ground for suspecting, that the activities carried out on the territory of another Member State pose a risk to the safety and quality of SoHOs distributed in the requesting Member State;		~~reasonable ground for suspecting, that the~~**the SoHO entity to be inspected performs SoHO** activities ~~carried out on the territory of another~~**in more than one** Member State ~~pose a risk to the safety and quality of SoHOs distributed~~**, that have impact** in the requesting Member State;	
Article 31(2), point (b)				
465	(b) competent authorities of the requesting Member State require specialist technical expertise of another Member State for that inspection;		(b) **SoHO** competent authorities of the requesting Member State require specialist technical expertise of another Member State for that inspection;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 31(2), point (c)				
466	(c) the competent authority of the Member State receiving the request agrees that there are other reasonable grounds for conducting a joint inspection.		(c) the **SoHO** competent ~~authority~~**authorities** of the Member ~~State~~**States** receiving the request ~~agrees~~**agree** that there are other reasonable grounds for conducting a joint inspection.	
Article 31(2a), premier paragraphe				
466a			**2a. The SoHO competent authority receiving the request may decline and instead, without**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			undue delay, provide relevant information to the requesting SoHO competent authority about the SoHO entity that is the subject of concern, in particular if:	
Article 31(2a), point (i)				
466b			**(i) there has been of joint inspection in the Member State within the previous year;**	
Article 31(2a), point (ii)				
466c				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			(ii) a joint inspection is already being planned.	
Article 31(3), first subparagraph				
467	The authorities participating in a joint inspection shall conclude an agreement prior to the inspection that defines at least the following:		**3.** The **SoHO competent** authorities participating in a joint inspection shall conclude ~~an~~**a written** agreement prior to **carrying out** the inspection**. Such written agreement shall specify** ~~that defines~~ at least the following:	
Article 31(3), first subparagraph, point (a)				
468				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(a) the scope and objective of the joint inspection;		(a) the scope and objective of the joint inspection;	
Article 31(3), first subparagraph, point (b)				
469	(b) the roles of the participating inspectors during and following the inspection, including the designation of an authority leading the inspection;		(b) the roles of the participating inspectors during and following the inspection, including the designation of ~~an~~**the SoHO competent** authority leading the inspection;	
Article 31(3), first subparagraph, point (c)				
470				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(c) the powers and responsibilities of each of the authorities.		(c) the powers and responsibilities of each of the **SoHO competent** authorities **involved**.	
Article 31(3), second subparagraph				
471	The authorities participating shall commit themselves in that agreement to jointly accept the results of the inspection.		The **SoHO competent** authorities participating **in the joint inspection** shall commit themselves in that agreement to jointly accept the results of the inspection. **The agreement shall be signed by all the participating SoHO competent authorities, including the respective SoHO National Authorities.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 31(4), first subparagraph				
472	The authority leading the joint inspection shall ensure that joint inspections are carried out in accordance with the national legislation of the Member State in which the joint inspection takes place.		**4.** The authority leading the joint inspection shall ~~ensure that joint inspections are carried out in accordance with the national legislation of the Member State in which~~**be a SoHO competent authority of the Member State in which the joint inspection takes place and shall ensure that** the joint inspection ~~takes place~~**is carried out in accordance with their national legislation**.	
Article 31(4), second subparagraph				
473				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	The competent authority for the SoHO entity or SoHO establishment concerned shall, prior to the inspection, inform that SoHO entity or SoHO establishment about the joint inspection, unless the competent authorities concerned have reasonable grounds to suspect illegal or fraudulent activity.		The **SoHO** competent authority ~~for~~**supervising** the SoHO entity ~~or SoHO establishment concerned shall, prior to the~~**to be inspected through a joint** inspection~~,~~ **shall** inform ~~that SoHO entity or SoHO establishment~~**the SoHO entitiy in advance** about the ~~joint~~ inspection~~, unless the competent authorities concerned have~~ **and its nature unless there are** reasonable grounds**, duly justified,** to suspect ~~illegal or fraudulent activity~~**that such prior communication would compromise its effectiveness**.	
Article 31(5)				
474				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	5. Articles 7, 8 and 76 shall apply to all competent authorities involved in joint inspections.		5. ~~Articles 7, 8 and 76 shall apply to all competent authorities involved in joint inspections.~~	
Article 31(6)				
475	6. Member States may set up joint inspection programmes to facilitate routine joint inspections. Member States may operate such programmes under a single agreement as referred to in paragraph 3.		6. Member States may set up joint inspection programmes to facilitate routine joint inspections. Member States may operate such programmes under a single **written** agreement as referred to in paragraph 3.	
Article 31(6a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
475a			**6a. SoHO competent authorities shall take into account the relevant best practices agreed and documented by the SCB, as referred to in article 68(1), point (c).**	
Article 32				
476	Article 32 Specific obligations concerning inspectors		Article 32 Specific obligations concerning inspectors	
Article 32(1), first subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
477	Inspectors shall possess a diploma, certificate or other evidence of formal qualifications in a relevant field, awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned.		**1.** Inspectors shall possess a diploma, certificate or other evidence of formal qualifications in a relevant field, awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned.	
Article 32(1), second subparagraph				
478	In exceptional cases, competent authorities may consider that a person's considerable and relevant experience may exempt this person from the requirement set out in the		In exceptional cases, **SoHO** competent authorities may consider that a person's considerable and relevant experience may exempt this person from the requirement	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	first subparagraph.		set out in the first subparagraph.	
Article 32(1), second subparagraph a				
478a		***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.***		
Article 32(1a)				
478b		***1a. All inspectors shall act in an***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.		
Article 32(2)				
479	2. Competent authorities shall provide inspectors with a specific induction training before inspectors take up their duties. For the specific induction training, competent authorities shall consult the relevant best practices agreed		2. **SoHO** competent authorities shall provide inspectors with a specific induction training before inspectors take up their duties. For the specific induction training, **SoHO** competent authorities shall ~~consult~~**take into account** the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	and documented by the SCB as referred to in Article 68(1), point (c).		relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).	
Article 32(3)				
480	3. Competent authorities shall ensure that the specific induction training includes at least the following:		3. **SoHO** competent authorities shall ensure that the specific induction training includes at least the following:	
Article 32(3), point (a)				
481	(a) the inspection techniques and procedures to be followed,	(a) the inspection techniques and procedures to be followed,	(a) the inspection techniques and procedures to be followed,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	including practical exercises;	including practical exercises ***and conflict of interest rules***;	including practical exercises;	
Article 32(3), point (b)				
482	(b) an overview of relevant Union and national inspection guidance, and the best practices agreed and documented by the SCB as referred to in Article 68(1), point (c);		(b) an overview of relevant Union and national inspection guidance, **where applicable,** and the best practices agreed and documented by the SCB as referred to in Article 68(1), point (c);	
Article 32(3), point (c)				
483	(c) on overview of the		(c) ~~on~~**an** overview of the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorisation systems in the Member State concerned;		authorisation systems in the Member State concerned;	
Article 32(3), point (d)				
484	(d) the applicable legal framework for the performance of SoHO supervisory activities;		(d) the applicable legal framework for the performance of SoHO supervisory activities;	
Article 32(3), point (e)				
485	(e) technical aspects concerning SoHO activities;		(e) **an overview of the** technical aspects concerning SoHO activities;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 32(3), point (f)				
486	(f) SoHO technical guidelines as referred to in Articles 56 and 59;		(f) SoHO technical guidelines as referred to in Articles 56 and 59;	
Article 32(3), point (g)				
487	(g) an overview of the organisation and functioning of national regulatory authorities in the field of SoHOs and related fields;		(g) an overview of the organisation and functioning of national regulatory authorities in the field of ~~SoHOs~~**SoHO** and related fields;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 32(3), point (h)				
488	(h) an overview of the national health system and SoHO organisational structures in the Member State concerned.		(h) an overview of the national health system and SoHO organisational structures in the Member State concerned.	
Article 32(4)				
489	4. Competent authorities shall ensure that the specific induction training is complemented by specialised training for inspection of specific types of establishments and by continuous training, as appropriate, throughout the career		4. **SoHO** competent authorities shall ensure that the specific induction training is complemented by specialised training for inspection of specific types of establishments and by continuous training, as appropriate~~, throughout~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	of the inspectors. Competent authorities shall make all reasonable efforts to ensure that inspectors that participate in joint inspections have completed the relevant Union training referred to in Article 69(1) and are included in the list referred to in Article 69(5).		~~the career of the inspectors.~~**. SoHO** competent authorities shall ~~make all reasonable efforts~~**endeavour** to ensure that inspectors that participate in joint inspections have completed the relevant Union training referred to in Article 69(1) and are included in the list referred to in Article 69(5).	
Article 32(5)				
490	5. Inspectors may be assisted by technical experts provided that the competent authorities ensure that those experts comply with the requirements of this Regulation, in particular with the obligations set		5. Inspectors may be assisted by technical experts provided that the **SoHO** competent authorities ensure that those experts comply with the requirements of this Regulation~~, in particular with the~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	out in Articles 7 and 76.		~~obligations set out in Articles 7 and 76~~.	
Article 32(6)				
491	6. Paragraphs 1 to 5 shall also apply to delegated bodies.		6. ~~Paragraphs 1 to 5 shall also apply to delegated bodies.~~	
Article 33				
492	Article 33 Activity data extraction and publication		Article 33 Activity data extraction**,** **submission** and publication	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 33(1)				
493	1. Competent authorities shall verify that SoHO entities that have activity data collection and reporting obligations pursuant to Article 44 submit complete and accurate annual reports of those activities to the EU SoHO Platform referred to in Chapter XI.		1. **SoHO** competent authorities shall verify that SoHO entities that have activity data collection and reporting obligations pursuant to Article 44 submit ~~complete and accurate~~**to their SoHO competent authorities, via the EU SoHO Platform, an** annual ~~reports~~**report** of those activities ~~to~~**.** The EU SoHO Platform ~~referred to in Chapter XI~~**shall allow the compilation of the annual reports submitted by the SoHO entities and provide the SoHO competent authorities with an aggregated**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			annual report with the activity data from their SoHO entities.	
Article 33(1a)				
493a			**1a. By derogation from paragraph 1, Member States may decide that SoHO entities submit the activity data referred to in Article 44(1) to SoHO competent authorities through national or international registries, in cases where such registries collect activity data matching the data sets defined in the EU SoHO Platform. In this case, the SoHO competent authorities shall submit an**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			annual aggregated report to the EU SoHO platform.	
Article 33(2)				
494	2. Competent authorities shall extract an aggregated annual report of SoHO activity data for their SoHO entities from the EU SoHO Platform. They shall make that report available to the public, including on the internet.		2. **SoHO** competent authorities shall ~~extract an aggregated~~**ensure that the** annual **aggregated** report of SoHO activity data for their SoHO entities ~~from the EU SoHO Platform. They shall make that~~**is made available to the public in their Member States, including on the internet. The annual aggregated** report ~~available to the public, including~~**of SoHO activity data may also be published** on the ~~internet~~**EU SoHO Platform after**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			review and approval by SoHO National Authorities.	
Article 33(3)				
494a			**3. The Commission shall compile the annual aggregated reports from the SoHO competent authorities, prepare and, after having shared the report with the SoHO National Authorities for review and approval, publish and make available on the EU SoHO platform an annual SoHO Activity Report.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 34				
495	Article 34 Traceability		Article 34 Traceability **and coding**	
Article 34a				
495a		***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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		available to other Member States through the EU SoHO Platform referred to in Chapter XI.		
Article 34(1)				
496	1. Competent authorities shall verify that SoHO entities have appropriate procedures in place to ensure traceability and coding of SoHOs as referred to in Article 45.		1. **SoHO** competent authorities shall verify that SoHO entities have appropriate procedures in place to ensure traceability and coding of SoHOs as referred to in Article 45.	
Article 34(2)				
497				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	2. Competent authorities shall establish procedures for the unique identification of SoHO establishments that are subject to the provisions on the Single European Code in Article 46. Competent authorities shall ensure that such identification complies with the technical standards defined for that coding system. For this purpose, competent authorities may use a SoHO establishment identification code generated by the EU SoHO Platform.		2. **SoHO** competent authorities shall establish procedures for the unique identification of SoHO ~~establishments~~**entities** that are subject to the provisions on the Single European Code in Article 46. **SoHO** competent authorities shall ensure that such identification complies with the technical standards defined for that coding system. For this purpose, **SoHO** competent authorities may use a SoHO establishment identification code generated by the EU SoHO Platform.	
Article 35				
498				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 35 Vigilance		Article 35 Vigilance	
Article 35(1)				
499	1. Competent authorities shall be responsible for the management of vigilance associated with SoHO activities. They shall provide guidance and templates for the submission of SAO notifications and of SAO investigation reports as referred to in Article 47.		1. **SoHO** competent authorities shall be responsible for the ~~management~~**supervision** of vigilance associated with SoHO activities. ~~They shall provide guidance and templates for the submission of SAO notifications and of SAO investigation reports as referred to in Article 47.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 35(1a)				
499a			**1a. SoHO competent authorities shall provide guidance and templates for the submission of SAR or SAE notifications and investigation reports as referred to in Article 47. The guidance and templates provided shall take into account the best practices established by the SCB, as referred to in Article 68(1) point (c). SoHO competent authorities shall also establish procedures for the receipt of SAR or SAE notifications, pursuant to Article 47.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 35(2)				
500	2. Upon receipt of a SAO notification, competent authorities shall:		2. Upon receipt of a ~~SAO~~**SAR or SAE** notification **pursuant to Article 47(3), SoHO** ~~,~~competent authorities shall:	
Article 35(2), point (a)				
501	(a) acknowledge receipt of the SAO notification;		(a) ~~acknowledge receipt of the SAO notification;~~	
Article 35(2), point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
502	(b) verify that the SAO notification includes the information referred to in Article 47(3);		(b) verify that the ~~SAO~~ notification includes the information referred to in Article ~~47(3)~~**47(3a)**;	
Article 35(2), point (c)				
503	(c) assess the adequacy of the investigation planned to establish imputability and root cause;		(c) ~~assess the adequacy of the investigation planned to establish imputability and root cause;~~	
Article 35(2), point (d)				
504				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(d) respond to the submitting SoHO entity without undue delay.		(d) respond to the submitting SoHO entity ~~without undue delay~~**if additional documentation or corrections are required**.	
Article 35(3)				
505	3. Competent authorities may provide advice on the investigation planned by the SoHO entity. In preparing such advice, competent authorities may request contributing advice from the SCB pursuant to Article 68(1). In case the SAO concerns a suspected transmission of a communicable disease, competent authorities shall inform the ECDC and take into		3. ~~Competent authorities may provide advice on the investigation planned by the SoHO entity. In preparing such advice, competent authorities may request contributing advice from the SCB~~**Upon receipt of a SAR or SAE notification** pursuant to Article ~~68(1). In case the SAO concerns a suspected transmission of a communicable disease,~~**47(3),**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	account any advice or information provided by the ECDC or its SoHO expert network.		**SoHO** competent authorities ~~shall inform the ECDC and take into account any advice or information provided by the ECDC or its SoHO expert network.~~**may:**	
Article 35(3a)				
505a			**3a. provide advice on the investigation planned by the SoHO entity;**	
Article 35(3b)				
505b			**3b. request contributing advice**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			from the SCB pursuant to Article 68(1).	
Article 35(3), second paragraph				
505c			**3. In case the SAR or SAE notification concerns an outbreak of a communicable disease, Member States shall inform the ECDC and take into account any advice or information provided by the ECDC or its SoHO expert network.**	
Article 35(4)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
506	4. Upon receipt of a SAO investigation report, competent authorities shall:		4. Upon receipt of a ~~SAO~~**SAR or SAE** investigation report, **SoHO** competent authorities shall:	
Article 35(4), point (a)				
507	(a) acknowledge receipt of the SAO investigation report;		(a) ~~acknowledge receipt of the SAO investigation report~~;	
Article 35(4), point (b)				
508	(b) verify that the SAO investigation report includes the		(b) verify that the ~~SAO~~ investigation report includes the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	information pursuant to Article 47(5);		information pursuant to Article 47(5);	
Article 35(4), point (c)				
509	(c) assess the results of the investigation and of the corrective and preventive actions described;		(c) assess the results of the investigation and of the corrective and preventive actions described;	
Article 35(4), point (ca)				
509a			**(ca) request to the submitting SoHO entity additional documentation, if required;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 35(4), point (d)				
510	(d) inform the submitting SoHO entity of the conclusion of the SAO assessment.		(d) inform the submitting SoHO entity of the conclusion of the **assessment, if corrections are required** ~~SAO assessment~~.	
Article 35(5)				
511	5. Competent authorities may carry out inspections, pursuant to Articles 29 or 30, as appropriate, when the SAO notification or SAO investigation report received		5. **SoHO** competent authorities may carry out inspections, pursuant to Articles 29 or 30, as appropriate, when the ~~SAO~~ **SAR or SAE** notification or ~~SAO~~**the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	indicates, or gives reasonable grounds for suspecting, that requirements of this Regulation have not been complied with, or to verify an accurate implementation of corrective and preventive actions planned.		investigation report received indicates, or gives reasonable grounds for suspecting, that requirements of this Regulation have not been complied with, or to verify an accurate implementation of corrective and preventive actions planned **or when they consider that a particular SAR or SAE might constitute a public health threat**.	
Article 35(6)				
512	6. Upon receipt of a SAO notification with implications for safety, quality or supply of a product manufactured under other		6. Upon receipt of a ~~SAO~~ **SAR or SAE** notification with implications for ~~safety, quality~~**quality, safety,** or supply of a product	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Union legislation from that SoHO or SoHO preparation, competent authorities shall inform, without undue delay, the relevant authorities competent for that product, pursuant to Article 14(5).		manufactured **from a SoHO** under other Union legislation ~~from that SoHO or SoHO preparation,~~ **SoHO, SoHO** competent authorities shall inform, without undue delay **and via their SoHO National Authority**, the relevant authorities competent for that product, pursuant to Article 14(5).	
Article 35(6a)				
512a			**6a. Upon receipt of information regarding a serious incident within the meaning of Regulation (EU) 2017/745, or information regarding a serious adverse reaction within the meaning of**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Directive 2001/83/EC, associated with a product manufactured from or with a SoHO and indicating a possible association with the quality or safety of the SoHO used to manufacture that product, the SoHO competent authorities shall communicate without undue delay the information to the SoHO establishment that released the SoHO, to facilitate possible actions to prevent further distribution of the SoHO implicated in the serious incident or serious adverse reaction.	
Article 35(7)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
513	7. Upon receipt of information regarding a serious incident and field safety corrective action according to Regulation (EU) 2017/745, the competent authorities receiving such information shall inform the SoHO entities concerned. The competent authorities shall submit that information to their National SoHO Authority, provided that the incident meets the definition of a SAO.		7. Upon receipt of information regarding a serious incident and field safety corrective action ~~according to~~**within the meaning of** Regulation (EU) 2017/745 **and Regulation (EU) 2017/746 , the SoHO**~~, the~~ competent authorities receiving such information shall ~~inform~~**communicate it to** the SoHO entities **that may be using the device** concerned **when carrying out their SoHO activities . The SoHO**~~. The~~ competent authorities shall **also** submit that information to their ~~National~~ SoHO **National** Authority, provided that the incident meets the definition of a ~~SAO~~**SAE or SAR**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 35(8)				
514	8. Competent authorities shall provide a channel for self-reporting of SAOs by SoHO recipients and donors. Upon receipt of such notifications, competent authorities shall inform, as appropriate, the relevant SoHO entities or SoHO establishments thereof, and ensure that an adequate investigation of the occurrence is initiated by the SoHO entities or establishments concerned and that adequate corrective and preventive action have been taken by the SoHO entities or establishments		8. ~~Competent authorities shall provide a channel for self-reporting of SAOs by SoHO recipients and donors. Upon receipt of such notifications, competent authorities shall inform, as appropriate, the relevant SoHO entities or SoHO establishments thereof, and ensure that an adequate investigation of the occurrence is initiated by the SoHO entities or establishments concerned and that adequate corrective and preventive action have been taken by the SoHO entities or establishments~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	concerned when necessary, and respond to the recipient or donor concerned.		~~concerned when necessary, and respond to the recipient or donor concerned.~~	
Article 35(9)				
515	9. Competent authorities shall ensure that the procedures referred to in paragraphs 1 to 5 provide for an adequate interconnection between the SAO notifications pursuant to this Article and the reporting system established in accordance with Article 11 of Directive 2010/53/EU, for instances where SAO notifications relate to SoHO donations after death, by donors that also donated		9. **SoHO** competent authorities **or Member States** shall ensure that the procedures referred to in paragraphs 1 to 5 provide for an adequate interconnection between the ~~SAO~~ notifications pursuant to this Article and the reporting system established in accordance with Article 11 of Directive 2010/53/EU, for instances where ~~SAO~~**SAR or SAE** notifications relate to SoHO donations ~~after~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	organs.		~~death,~~ by donors that also donated organs.	
Article 35(10)				
516	10. Competent authorities shall submit to their SoHO National Authorities an annual summary of the SAO notifications and SAO investigation reports received. The SoHO National Authorities shall submit an annual summary of those SAO notifications and investigation reports to the EU SoHO Platform referred to in Chapter XI before 31 May of the subsequent year and shall make an aggregated version of that		10. **SoHO** competent authorities shall submit to their SoHO National Authorities an annual summary of the ~~SAO notifications and SAO investigation reports received. The SoHO National Authorities shall submit an annual summary of those SAO~~ **SAR and SAE** notifications and **the** investigation ~~reports to the EU SoHO Platform referred to in Chapter XI before 31 May of the subsequent year and shall make an~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	summary available to the public in their Member State, including on the internet. They shall include in the annual summary the numbers and types of those SAO reported to them that meet thresholds of seriousness and imputability that are agreed at Union level within the SCB.		~~aggregated version of that summary available to the public in their Member State, including on the internet. They shall include in the annual summary the numbers and types of those SAO~~**reportsof confirmed SAR or SAE . This report shall include recommendations, arising from an analysis of the SAR and SAE** reported**, where necessary** ~~to them that meet thresholds of seriousness and imputability that are agreed at Union level within the SCB~~.	
Article 35(10a)				
516a			**10a. SoHO National Authorities**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			shall submit an annual summary of confirmed SAR or SAE notifications and investigation reports to the EU SoHO Platform before 30 June of the subsequent year and shall make an aggregated version of that summary available to the public in their Member State, including on the internet. They shall include the numbers and types of SAR or SAE notifications reported to them that meet thresholds of seriousness and imputability that are agreed and documented as best practices by the SCB, as referred to in Article 68(1), point (c).	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 35(11)				
517	11. The Commission shall aggregate the annual summaries of the SoHO National Authorities, prepare and publish an annual SoHO vigilance report after having shared the report with the SoHO National Authorities for review and approval.		11. The Commission shall aggregate the annual summaries of the SoHO National Authorities, prepare and publish an annual **Union** SoHO vigilance report**,** after having shared ~~the report~~**it** with the SoHO National Authorities for review and approval. **The report should include overall pattern analysis and recommendations.**	
Article 35(12)				
518	12. For the development of the		12. ~~For the development of the~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	guidance and templates referred to in paragraph 1 of this Article, and for the submission of the annual summaries referred to in paragraph 10 of this Article, competent authorities shall consult the best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).		~~guidance and templates referred to in paragraph 1 of this Article, and for the submission of the annual summaries referred to in paragraph 10 of this Article, competent authorities shall consult the best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).~~	
Article 35(13), first subparagraph				
519	The Commission may adopt implementing acts concerning the procedures to be followed for consultation and coordination between competent authorities and the ECDC concerning relevant		**13.** The Commission may adopt implementing acts concerning the procedures to be followed for consultation and coordination between competent authorities and the ECDC concerning relevant	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SAO notifications and investigations.		~~SAO~~**SAR or SAE** notifications and investigations.	
Article 35(13), second subparagraph				
520	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	
Article 36				
521	Article 36 SoHO rapid alerts		Article 36 SoHO rapid alerts	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 36a				
521a		***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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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).***		
Article 36(1)				
522	1. Competent authorities shall, upon receipt of a notification of a SAO or other information with		1. **SoHO** competent authorities shall, upon receipt of a notification of a ~~SAO~~**SAR or a SAE** or other	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	implications for safety or quality or supply of SoHOs in one or more Member States, launch a SoHO rapid alert on the EU SoHO Platform referred to in Chapter XI.		information with implications for ~~safety or~~ quality**, safety** or supply of ~~SoHOs in one or more~~**SoHO in more than one** Member ~~States,~~ **State, inform their SoHO National Authorities, which shall, in turn** launch a SoHO rapid alert on the EU SoHO Platform ~~referred to in Chapter XI~~.	
Article 36(2)				
523	2. Competent authorities shall launch a SoHO rapid alert in particular in the following circumstances:		2. ~~Competent~~ **SoHO National** Authorities shall launch a SoHO rapid alert in particular in the following circumstances:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 36(2), point (a)				
524	(a) a risk to the quality or safety of SoHOs has been identified concerning SoHOs that have been distributed from their Member State to at least one other Member State;		(a) a risk to the quality or safety of ~~SoHOs~~**SoHO** has been identified concerning ~~SoHOs~~**SoHO** that have been distributed from their Member State to at least one other Member State;	
Article 36(2), point (b)				
525	(b) an outbreak of a communicable disease has occurred in their Member State and they have put in place donor deferral or testing measures to mitigate the risks of		(b) an outbreak of a communicable disease has occurred in their Member State and they have put in place donor deferral or testing measures to mitigate the risks of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	transmission by SoHOs;		transmission by ~~SoHOs~~**SoHO**;	
Article 36(2), point (c)				
526	(c) a defect or serious supply interruption has occurred concerning equipment, devices, materials or reagents that are critical for the collection, processing, storage or distribution of SoHOs and that might be used in other Member States;		(c) a defect or serious supply interruption has occurred concerning equipment, devices, materials or reagents that are critical for the collection, processing, storage or distribution of ~~SoHOs~~**SoHO** and that might be used in other Member States;	
Article 36(2), point (d)				
527				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(d) other information is available to the competent authorities that could reasonably be considered useful in other Member States to reduce risks to the safety or quality of SoHOs and where the launch of a SoHO rapid alert would be proportionate and necessary.		(d) other information is available to the ~~competent~~**SoHO National** Authorities that could reasonably be considered useful in other Member States to reduce risks to the ~~safety or quality of SoHOs~~**quality or safety of SoHO** and where the launch of a SoHO rapid alert ~~would be~~**is** proportionate and necessary.	
Article 36(3)				
528	3. The ECDC, with the support of its SoHO expert network, may also launch an alert in the EU SoHO		3. The ECDC, with the support of its SoHO expert network, may also launch an alert in the EU SoHO	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Platform when surveillance of communicable diseases indicates a new risk to the safety of SoHOs. The ECDC may indicate in such an alert that it has provided guidelines on the mitigation of risks associated with communicable disease outbreaks, in particular concerning the eligibility and testing of SoHO donors.		Platform when surveillance of communicable diseases indicates a new risk to the safety of SoHOs. The ECDC may indicate in such an alert that it has provided guidelines on the mitigation of risks associated with communicable disease outbreaks, in particular concerning the eligibility and testing of SoHO donors.	
Article 36(4)				
529	4. Competent authorities that receive a SoHO rapid alert shall communicate information to the relevant organisations representing groups of SoHO entities or		4. ~~Competent~~**SoHO National** Authorities that receive a SoHO rapid alert shall communicate **relevant** information to ~~the relevant organisations representing~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	professionals without undue delay with a view to ensuring that risk mitigating actions can be taken promptly and that relevant information available at the SoHO professional level can be shared with the competent authorities. Competent authorities may also supplement the information provided in the alert with further information such as details of relevant mitigating actions taken in their Member State.		~~groups of~~**SoHO competent authorities in their Member State and to the relevant** SoHO entities ~~or professionals~~ without undue delay with a view to ensuring that risk mitigating actions can be taken promptly and that relevant information available ~~at~~**among professionals in** the SoHO ~~professional level~~**sector** can be shared with the **SoHO** competent authorities. ~~Competent~~**SoHO National** Authorities may also supplement the information provided in the alert with further information such as details of relevant mitigating actions taken in their Member State.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 36(5)				
530	5. Competent authorities and the ECDC shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c), when launching and handling a SoHO rapid alert.		5. ~~Competent authorities~~**SoHO National Authoritie** and the ECDC shall ~~consult~~**take into account** the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c), when launching and handling a SoHO rapid alert.	
CHAPTER IV				
531	CHAPTER IV GENERAL OBLIGATIONS ON		CHAPTER IV GENERAL OBLIGATIONS ON	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SOHO ENTITIES		SOHO ENTITIES	
Article 37				
532	Article 37 SoHO entity registration		Article 37 SoHO entity registration	
Article 37(1)				
533	1. Entities shall register as a SoHO entity before commencing any SoHO activity. To register, they shall provide the information as referred to in Article 18. SoHO		1. Entities shall register as a SoHO entity before commencing any ~~SoHO activity. To register, they shall provide the information as~~**of the SoHO activities** referred to in	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	entities may request from their competent authorities an opinion on the applicability of the registration requirements in this Chapter to the SoHO activities concerned prior to the registration.		Article ~~18. SoHO entities may request from their competent authorities an opinion on the applicability of the registration requirements in this Chapter to the SoHO activities concerned prior to the registration.~~**2(1a).**	
Article 37(1a)				
533a			**1a. SoHO activities shall not be carried out by individuals that are not operating within a registered SoHO entity.**	
Article 37(1b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
533b			**1b. To register, the SoHO entity shall provide the following information:**	
Article 37(1b), point a				
533c			**(a) name of the SoHO entity and all addresses where the SoHO activities are performed by the SoHO entity;**	
Article 37(1b), point b				
533d				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			(b) name and contact details of the responsible person as referred in Article 37a;	
Article 37(1b), point c				
533e			**(c) acknowledgment from the SoHO entity that it may be inspected pursuant to Article 30 and that it will cooperate with the relevant SoHO competent authority in any matter relating to the conduct of supervisory activities included in this Regulation;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 37(1b), point d				
533f			**(d) a list of the SoHO and SoHO activities, as listed in Article 2(1c), that the SoHO entity carries out; when the SoHO entity carries out the activity referred to in Article 2(1c), point (iv), they shall also provide the name of the SoHO establishment responsible for the SoHO release prior to distribution;**	
Article 37(1b), point e				
533g			**(e) where applicable, a list of**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			SoHO establishment(s) for which the SoHO entity performs SoHO activities covered by an agreement;	
Article 37(1b), point f				
533h			**(f) where applicable, details of any accreditation or certification received from an external body;**	
Article 37(1b), point g				
533i			**(g) where applicable, information regarding activities**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			carried out and regulated under other Union legislation, as referred to in Article 14;	
Article 37(1c)				
533j			**1c. SoHO entities shall declare, when registering, that they need an authorisation pursuant to Articles 21, 27 or 28. They shall also conduct a self-assessment of whether they meet the criteria for being a critical SoHO entity and communicate the result.** **Organisations may request from their SoHO competent authorities, within their territory**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			an opinion on whether the activities they are carrying out are subject to the registration requirements in this Chapter.	
Article 37(2)				
534	2. In Member States where the EU SoHO Platform is used for registration of SoHO entities, as referred to in Article 18(2), organisations meeting the definition of a SoHO entity shall register directly in the EU SoHO Platform in accordance with their competent authorities' instructions.		2. In Member States where the EU SoHO Platform is used for registration of SoHO entities, as referred to in Article ~~18(2)~~**18(1)**, organisations meeting the definition of a SoHO entity shall register directly in the EU SoHO Platform in accordance with their **SoHO** competent authorities' instructions.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 37(3)				
535	3. SoHO entities that implement changes to their SoHO activities or contact details shall register those changes without undue delay. Where such changes imply SoHO activities including both processing and storage of SoHOs, those SoHO entities shall comply with the requirements of Articles 48 and 49.		3. SoHO entities ~~that implement~~**shall register without undue delay** changes to ~~their SoHO activities or contact details shall register those changes without undue delay~~**information registered pursuant to paragraph 1a points (a), (b), (e), (f), (g) and (h)**. Where such changes imply SoHO activities including ~~both~~**either** processing and storage**, or release, or import or exportof SoHO** ~~of SoHOs~~, those SoHO entities shall ~~comply with the requirements of Articles~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~48 and 49~~**apply for an authorisation as SoHO establishment**.	
Article 37(3a)				
535a			**3a. In case a registered SoHO entity partially or totally ceases to carry out its SoHO activities, it shall communicate this change on the register for SoHO entities without undue delay, indicating to which SoHO entity it will transfer SoHO for storage, and the data referred to in Article 45, when applicable.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 37(3b)				
535b			**3b. In case of storage of SoHO intended for autologous or within couple use, or highly matched SoHO for a specific SoHO recipient, if the SoHO entity ceases activities affecting the storage or the possible use of such SoHO, it shall inform the persons from whom such SoHO were collected, and provide them with information about the new SoHO entity that will store them.**	
Article 37a				
535c				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Article 37a **Responsible Person**	
Article 37a (1)				
535d			**1. SoHO entities shall designate a person responsible, within their entity, for ensuring that SoHO activities carried out by the SoHO entity comply with the requirements of this Regulation, as relevant to the SoHO activities carried out, are fulfilled.**	
Article 37a(1a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
535e			**1a. The responsible person shall be in possession of a diploma, certificate or other evidence of formal qualifications in the field of medical, pharmaceutical or life sciences awarded on completion of a university course of study or a course qualification recognised as equivalent by the Member State concerned and shall have at least two years of experience in the relevant field.**	
Article 37a(2)				
535f			**2. SoHO entities shall inform**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			their SoHO competent authority of the name and contact details of the responsible person. Where the responsible person is permanently or temporarily replaced, the SoHO entity shall inform without undue delay their SoHO competent authorities of the name and contact details of the new responsible person and the date on which the duties of that person commence.	
Article 37a(2a)				
535g			**2a. The responsible person may fulfil the roles of releasing officer, as referred to in Article**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			49a, or the role of physician, as referred to in Article 49b, in cases where they are in possession of the required qualifications or experience as laid down in those articles.	
Article 37b				
535h			**Article 37b** **Quality management system**	
Article 37b(1)				
535i				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			1. SoHO entities shall establish, maintain and update a quality management system, appropriate to their activities, achieving a high level of quality of SoHOs.	
Article 37b(2)				
535j			**2. SoHO entities shall design the quality management system to ensure that SoHO activities are carried out in a consistent manner, by personnel that have documented and periodically assessed competenceto perform the tasks allocated to them and in facilities that are designed and maintained in a manner that**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			prevents SoHO contamination, or cross-contamination between SoHO, or loss of traceability. In so doing, SoHO entities shall take into account the technical guidelines for quality management published by the EDQM, together with the EDQM Good Practice Guidelines, as indicated in the EU SoHO Platform. Alternative approaches to the design of the quality management system may be applied where SoHO entities can demonstrate to their SoHO competent authorities, that they achieve an equivalent level of quality.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 37b(3)				
535k			**3. SoHO entities shall put in place procedures and specifications covering, when applicable to their activities, the following:**	
Article 37b(3), (a)				
535l			**(a) documentation of roles, responsibilities of personnel and organization;**	
Article 37b(3), (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
535m			**(b) selection, training and competence assessment of personnel;**	
Article 37b(3), (c)				
535n			**(c) the procurement qualification, validation and monitoring of premises, materials and equipment, ,including information technology systems;**	
Article 37b(3), (ca)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
535o			**(ca) other documentation relevant for the quality management sytem put in place;**	
Article 37b(3), (d)				
535p			**(d) quality control, and monitoring of key performance indicators of SoHO activities;**	
Article 37b(3), (da)				
535q			**(da) quarantine and release;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 37b(3), (e)				
535r			**(e) withdrawal of SoHOs from the inventory of released SoHOs and recalls;**	
Article 37b(3), (f)				
535s			**(f) internal audits;**	
Article 37b(3), (g)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
535t			**(g) management of contracted third parties;**	
Article 37b(3), (h)				
535u			**(h) management of cases where procedures have not been followed or specifications have not been met;**	
Article 37b(3), (ha)				
535v			**(ha) complaints;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 37b(3), (hb)				
535w			**(hb) management of traceability and vigilance, pursuant to Articles 45, 46 and 47;**	
Article 37b(3), (hc)				
535x			**(hc) continuity planning.**	
Article 37b(4)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
535y			**4. SoHO entities shall review the quality management system at regular intervals to verify its effectiveness and introduce corrective and preventive measures if deemed necessary.**	
Article 37b(5), first subparagraph				
535z			**5. The Commission may adopt implementing acts regarding selected elements of and specifications of the quality management system in order to ensure uniform quality management.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 37b(5), second subparagraph				
535aa			**5. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).**	
Article 38				
536	Article 38 Responsible person for release of SoHOs		Article 38 ~~Responsible person for release of SoHOs~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 38(1)				
537	1. In cases where a SoHO entity releases SoHOs or SoHO preparations for distribution for human application, or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, as referred to in Article 60, that entity shall designate a person responsible for release.		1. ~~In cases where a SoHO entity releases SoHOs or SoHO preparations for distribution for human application, or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, as referred to in Article 60, that entity shall designate a person responsible for release.~~	
Article 38(2)				
538	2. The responsible person for	2. The responsible person for	2. ~~The responsible person for~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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. ***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.***	~~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.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 38(3)				
539	3. The responsible person for release of SoHOs may delegate the tasks specified in paragraph 1 to other persons who shall be qualified by training and experience to perform such tasks. In such cases, that person shall perform those tasks under the responsibility of the responsible person for release of SoHOs.		3. ~~The responsible person for release of SoHOs may delegate the tasks specified in paragraph 1 to other persons who shall be qualified by training and experience to perform such tasks. In such cases, that person shall perform those tasks under the responsibility of the responsible person for release of SoHOs.~~	
Article 39				
540	Article 39		Article 39	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Export		~~Export~~	
Article 39, first paragraph				
541	SoHO entities shall ensure that SoHOs or SoHO preparations exported or re-exported from the Union comply with the relevant requirements of this Regulation unless the SoHO entity can demonstrate that the authorities of the importing country or the laws, regulations, standards, codes of practice or other legal and administrative procedures as may be in force in the importing country indicate that a deviation from the requirements of this Regulation is		~~SoHO entities shall ensure that SoHOs or SoHO preparations exported or re-exported from the Union comply with the relevant requirements of this Regulation unless the SoHO entity can demonstrate that the authorities of the importing country or the laws, regulations, standards, codes of practice or other legal and administrative procedures as may be in force in the importing country indicate that a deviation from the requirements of this Regulation is~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	acceptable. SoHO entities shall not deviate from the standards referred to in Chapter VI.		~~acceptable. SoHO entities shall not deviate from the standards referred to in Chapter VI.~~	
Article 40				
542	Article 40 SoHO preparation authorisation		Article 40 SoHO preparation authorisation	
Article 40(1)				
543	1. SoHO entities shall not release or, in an autologous context, prepare and apply immediately to a	1. SoHO entities shall not release or, in an autologous context, prepare and apply immediately to a	1. SoHO entities shall not release or, in an autologous context **as referred to in Article 2(2)(a)**,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.***	prepare and apply ~~immediately to a~~ **to a SoHO** 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~~**, other than in the context of implementing an approved clinical outcome monitoring plan as part of** SoHO preparation **authorisation**.	
Article 40(2)				
544	2. SoHO entities may request		2. SoHO entities may request	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	advice from their competent authorities on the applicability of the authorisation requirements in this Regulation to their SoHO activities prior to submitting an application for a preparation authorisation.		~~advice~~ **an opinion** from their **SoHO** competent authorities on the applicability of the authorisation requirements in this Regulation to their SoHO activities prior to submitting an application for a **SoHO** preparation authorisation.	
Article 40(3)				
545	3. SoHO entities may request to their competent authorities a derogation from the requirement for a SoHO preparation authorisation in the exceptional circumstances referred to in Article 64.	3. SoHO entities may request to their competent authorities a derogation from the requirement for a SoHO preparation authorisation in the exceptional circumstances referred to in ~~*Article 64*~~ ***Articles 61 and 61a***.	3. SoHO entities may request to their **SoHO** competent authorities a derogation from the requirement for a SoHO preparation authorisation in **emergency situations referred to in Article 64, or for a specific SoHO recipient when justified by the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			clinical ~~the exceptional~~ circumstances**, as** referred to in Article ~~64~~**21(9a)**.	
Article 41				
546	Article 41 Application for the authorisation of SoHO preparations		Article 41 Application for **SoHO preparation** ~~the~~ authorisation ~~of SoHO preparations~~	
Article 41(1)				
547	1. SoHO entities shall send		1. SoHO entities shall ~~send~~**submit**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	applications for the authorisation of a SoHO preparation to their competent authorities. The applicant shall provide the name and contact details of the prospective SoHO preparation authorisation holder responsible for the application. This paragraph shall be without prejudice to Article 38(1).		applications for ~~the authorisation of a~~ SoHO preparation **authorisation** to ~~their competent authorities. The applicant shall provide the name and contact details of the prospective SoHO preparation authorisation holder responsible for the application. This paragraph shall be without prejudice to Article 38(1).~~ **the SoHO competent authority of their territory.**	
Article 41(2)				
548	2. The applicant shall provide the following:		2. The ~~applicant~~ **applications for SoHO preparation authorisation** shall ~~provide~~**include** the following:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 41(2), point (-a)				
548a			**(-a) the name and contact details of the applicant SoHO entity responsible for the SoHO preparation authorisation;**	
Article 41(2), point (a)				
549	(a) a SoHO preparation dossier describing the details of the SoHO activities performed for that SoHO preparation and including at least:		(a) ~~a SoHO preparation dossier describing the~~ details of the SoHO activities performed for that SoHO preparation and including at least:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 41(2), point (a)(-i)				
549a			**(-i) a description of the SoHO used for the SoHO preparation;**	
Article 41(2), point (a)(i)				
550	(i) any specific SoHO donor eligibility or SoHO donor testing procedures;		(i) ~~any~~**a list of the** specific SoHO donor eligibility ~~or~~**criteria including** SoHO donor ~~testing procedures~~**tests specific for the SoHO preparation**;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 41(2), point (a)(ii)				
551	(ii) any specific SoHO collection procedures;		(ii) ~~any specific~~**a summary of** SoHO collection procedures **and any specific quality controls carried out on the collected SoHO prior to processing**;	
Article 41(2), point (a)(iii)				
552	(iii) a description of the processing applied including details of the air quality standards maintained in the processing facilities and the rationale for the air quality standard applied;		(iii) a description of the **steps of the** processing applied including details of ~~the air quality standards maintained in the processing facilities~~**relevant materials and equipment used, environmental**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			conditions and the ~~rationale for the air quality standard applied~~**process parameters and controls at each step**;	
Article 41(2), point (a)(iv)				
553	(iv) a description of equipment, reagents and materials used and their certification status in accordance with Regulation (EU) 2017/745;		(iv) a description of equipment, reagents and materials ~~used~~**coming into direct contact with the SoHO during processing** and their certification status in accordance with Regulation (EU) 2017/745**, when applicable, and, in the case of the use of in-house developed equipment, reagents or materials, a evidence of the validation of their quality**;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 41(2), point (a)(v)				
554	(v) any specific storage conditions and storage time limits;		(v) any specific storage **and transport** conditions and storage time **limits including validation of those conditions and** limits;	
Article 41(2), point (a)(vi)				
555	(vi) any quality control and release parameters;		(vi) ~~any~~**a specification of the SoHO preparation including** quality control and- release parameters;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 41(2), point (a)(vii)				
556	(vii) data concerning procedures performed for process validation and equipment qualification;		(vii) data ~~concerning procedures performed for~~**resulting from** process validation and equipment qualification;	
Article 41(2), point (a)(viii)				
557	(viii) details of any third parties contracted by the SoHO entity to perform activities for the SoHO preparation;		(viii) details of any **SoHO entities or** third parties contracted ~~by the SoHO entity to perform activities~~**to perform activities or relevant steps of the processing applied**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			for the SoHO preparation;	
Article 41(2), point (a)(ix)				
558	(ix) the clinical indications for which the SoHO preparation is to be applied;		(ix) the clinical indications for which the SoHO preparation is to be applied **and the clinical data justifying this indication**;	
Article 41(2), point (a)(x)				
558a			**(x) where relevant, non-clinical data on efficacy and toxicity of the preparation.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 41(2), point (b)				
559	(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 ~~*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:*~~ ***in accordance with Article 41a(4);***	(b) the results of a ~~risk~~**benefit-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~~**the application for authorisation is submited**, taking into account:	
Article 41(2), point (b)(i)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
560	(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);	*deleted*	(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)~~ **or a specification included in technical guidelines referred to in Article 59(4)**;	
Article 41(2), point (b)(ii)				
561	(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	*deleted*	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	indication and with the mode of application to which that monograph refers, where such details are provided in that monograph;		indication and with the mode of application to which that monograph refers, where such details are provided in that monograph **or meets requirements as referred to in Article 59(4) point (b)**;	
Article 41(2), point (b)(iii)				
562	(iii) information regarding previous use and authorisation of the SoHO preparation in other SoHO entities, as available in the EU SoHO Platform;	*deleted*	(iii) information regarding previous use and authorisation of the SoHO preparation **or a comparable SoHO preparation** in other SoHO entities, as available in the EU SoHO Platform;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 41(2), point (b)(iv)				
563	(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;	*deleted*	(iv) **where applicable, clinical functionality** evidence generated as part of ~~the process of certification~~**conformity assessment procedures**, in accordance with Regulation (EU) 2017/745, of ~~any~~**a** certified medical device ~~used~~ **that is critical to the specific processing** for the SoHO preparation, **in cases** where ~~available~~**the applicant has access to such data**;	
Article 41(2), point (b)(v)				
564				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(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;	*deleted*	(v) documentation of a ~~systematic~~**standardised** process of identification, quantification and evaluation of any risks to ~~the donor~~**SoHO donors, SoHO recipients** or the ~~recipient~~**offspring from medically assisted reproduction** arising from the chain of activities performed for the SoHO preparation **and taking into account the technical guidelines published by EDQM for the performance of such risk assessments, as referred to in Articles 56(4)(a) and 59(4)(a)**;	
Article 41(2), point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
565	(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)***;	(c) in cases where the indicated risk is ~~other~~**greater** than negligible, **or the expected clinical effectiveness is unknown, a proposed plan**~~a proposal~~ for clinical outcome monitoring ~~to demonstrate safety, quality and efficacy~~**for providing evidence, where necessary,** of the SoHO preparation, in line with the results of the ~~risk~~**benefit-risk** assessment **and pursuant to Article 22a**;	
Article 41(2), point (d)				
566	(d) an indication of the data which		(d) an indication of the data which	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	should be regarded as proprietary accompanied by verifiable justification, where appropriate.		should be regarded as proprietary accompanied by verifiable justification, where appropriate.	
Article 41(3)				
567	3. In the proposal referred to in paragraph 2, point (c), the applicant shall propose a clinical outcome monitoring plan as follows:	*deleted*	3. ~~In the proposal referred to in paragraph 2, point (c)~~**If the application for SoHO preparation authorisation includes recording the results of the clinical outcome monitoring in an existing clinical registry, in accordance with Article 22(5)**, the applicant shall ~~propose a clinical outcome monitoring plan as follows:~~**request approval for the use of such registry to their**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			SoHO competent authorities.	
Article 41(3), point (a)				
568	(a) in cases of low risk, clinical follow-up of a defined number of patients;	*deleted*	(a) ~~in cases of low risk, clinical follow-up of a defined number of patients;~~	
Article 41(3), point (b)				
569	(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	*deleted*	(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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	endpoints;		~~endpoints;~~	
Article 41(3), point (c)				
570	(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.	*deleted*	(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.~~	
Article 41(4)				
571	4. SoHO entities shall perform the	4. SoHO entities shall perform the	4. SoHO entities shall ~~perform the~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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 ~~*paragraph 3*~~***Article 41a(5)***, points ~~*(b) and (c)*~~***(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***	~~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~~**prepare and distribute the SoHO preparation in question solely for the performance, and within the limitations of** the clinical ~~investigation study as referred to in paragraph 3, points (b) and (c), for~~**outcome monitoring after approval of the clinical outcome monitoring plan by** the SoHO ~~preparation concerned~~**competent authority**, **pursuant to Article 21(2), point (c), and submit the results and their analysis to their SoHO** ~~the applicant may use an existing clinical registry to record~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		applicant shall register that study and the results obtained on the EU SoHO Platform in accordance with Article 36a.	~~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~~**according to the timeline set in the approval**.	
Article 41(5)				
572	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	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***	5. SoHO entities shall not make any **significant** change ~~to the chain of~~**within steps of the processing applied or in the** activities performed for an ~~authorised~~**authorized** SoHO preparation, without the prior written ~~approval~~ **authorisation** of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	changes in the SoHO preparation authorisation holder's details.	***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.	their **SoHO** competent authorities. SoHO entities shall also **inform, without undue delay,** ~~inform~~ their **SoHO** competent authorities of **any** changes ~~in the SoHO preparation authorisation holder's~~**that might affect the authorisation, including the changes related to name and contact** details **of the SoHO entity previously authorised for the SoHO preparation**.	
Article 41a				
572a		***Article 41a***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.***		
Article 41b				
572b				
Article 41(6)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
573	6. The SoHO preparation authorisation holder shall be based in the Union. In cases where other SoHO entities carry out one or more of the processing steps for the SoHO preparation, the SoHO entity that holds the SoHO preparation authorisation shall be responsible for the release and shall supervise it, even if the release physically takes place at the site of the other SoHO entities.		6. ~~The SoHO preparation authorisation holder shall be based in the Union. In cases where other SoHO entities carry out one or more of the processing steps for the SoHO preparation,~~ The SoHO entity ~~that holds~~**authorised for** the SoHO preparation~~ authorisation~~ shall be ~~responsible for the release and shall supervise it, even if the release physically takes place at the site of the other SoHO entities~~**based in the Member State where the application is submitted**.	
Article 42				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
574	Article 42 Importing SoHO entity authorisation		Article 42 Importing SoHO ~~entity~~ **establishment** authorisation	
Article 42(1)				
575	1. SoHO entities shall not import SoHOs without a prior importing SoHO entity authorisation.		1. SoHO ~~entities~~**establishments** shall not import ~~SoHOs~~**SoHO** without a prior importing SoHO ~~entity~~ **establishment** authorisation.	
Article 42(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
576	2. In the case of importing SoHO entities that only import human plasma that is intended to be used for the manufacture of medicinal products regulated by other Union legislation and is included in a plasma master file (PMF) as referred to in Directive 2003/63/EC, paragraph 1 of this Article shall not apply.		2. In the case of importing ~~SoHO entities that only import~~ human plasma that is intended to be used for the manufacture of medicinal products regulated by other Union legislation and is included in a plasma master file (PMF) as referred to in Directive 2003/63/EC, paragraph 1 of this Article shall not apply **as these importers are already authorised by other Union legislation. In these cases, the importers shall be registered as SoHO entities**.	
Article 42(2a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
576a			**2a. SoHO entities responsible for human application to a specific SoHO recipient may request to their SoHO competent authorities a derogation from the requirement for an importing SoHO establishment authorisation in the circumstances referred to in Article 28(9).**	
Article 42(3)				
577	3. The Commission shall adopt delegated acts in accordance with Article 77 supplementing this		3. The Commission shall adopt delegated acts in accordance with Article 77 supplementing this	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Regulation by laying down obligations and procedures for importing SoHO entities regarding the import of SoHOs in order to verify equivalent standards of quality and safety of such imports.		Regulation by laying down obligations and procedures for importing SoHO entities regarding the import of SoHOs in order to verify equivalent standards of quality**,** and safety of such imports.	
Article 43				
578	Article 43 Application for importing SoHO entity authorisations		Article 43 Application for importing SoHO ~~entity~~**establishment** authorisations	
Article 43(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
579	1. SoHO entities shall send applications for authorisation as importing SoHO entities to their competent authorities.		1. ~~SoHO entities~~**Article 49** shall ~~send applications for authorisation as~~**apply *mutatis mutandis* to the applications for** importing SoHO ~~entities to their competent authorities~~**establishments authorisation** .	
Article 43(1a)				
579a			**1a. Prior to applying for importing SoHO establishment authorisation, SoHO establishments shall put in place written agreements with one or more third country suppliers.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Such agreements shall include the elements described in paragraph 2 of this Article.	
Article 43(2)				
580	2. The applicant SOHO entity shall provide the name and contact details of the prospective importing SoHO entity authorisation holder. This paragraph shall be without prejudice to Article 38(1).		2. The applicant ~~SOHO entity shall provide the name and contact details of the prospective importing SoHO entity authorisation holder. This paragraph~~**SoHO establishment** shall ~~be without prejudice to Article 38(1).~~**also provide:**	
Article 43(2-a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
580a			**(-a) documentation of the accreditation, designation, authorisation or licence of the third country supplier by a competent authority or authorities for the purposes of these activities.**	
Article 43(2a)				
580b			**(a) a written agreement as referred to in paragraph 1 shall include, at least:**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 43(2), point (a)(i)				
580c			**(i) details of the third country supplier contracted;**	
Article 43(2), point (a)(ii)				
580d			**(ii) the requirements to be met to ensure the equivalency of the quality, safety and effectiveness standards of the SoHO to be imported;**	
Article 43(2), point (a)(iii)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
580e			**(iii) the right of the SoHO competent authorities to inspect the activities, including the facilities, of any third country supplier or organisation sub-contracted by that supplier, contracted by the importing SoHO establishment.**	
Article 43(2b)				
580f			**(b) documentation describing the SoHO imported and proving that the procedures the third country suppliers have in place will ensure that the imported**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			SoHO will be equivalent, in terms of quality, safety and effectiveness, to SoHO authorised according to the provisions of this Regulation.	
Article 43(3)				
581	3. The importing SoHO entity shall not make any substantial changes to the importing SoHO activities subject to the authorisation without the prior written approval of its competent authority. The same shall apply in case of changes in the importing SoHO entity authorisation holder's details.		3. ~~The importing SoHO entity shall not make any substantial changes to the importing SoHO activities subject to the authorisation without the prior written approval of its competent authority. The same shall apply in case of changes in the importing SoHO entity authorisation holder's details.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 43(4)				
582	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	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	4. The importing SoHO ~~entity authorisation holder~~ **establishment** shall be ~~based in the Union, and be~~ responsible for the physical reception and visual examination and verification of imported ~~SoHOs~~**SoHO** prior to their release. The importing SoHO ~~entity~~ **establishment** 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**,**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	guidelines as referred to in Articles 57, 58 and 59.	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.***	**taking into account** ~~with~~ the relevant standards and technical guidelines as referred to in Articles 57, 58 and 59.	
Article 43(5)				
583	5. An authorised importing entity may delegate the physical reception, visual examination and verification referred to in paragraph 4 to the entity that will apply the SoHO to the recipient in cases where imports are organised for individual named recipients.		5. An authorised importing ~~entity~~ **SoHO establishment** may delegate the physical reception, visual examination and verification referred to in paragraph 4 to the **SoHO** entity that will apply the SoHO to the **SoHO** recipient in cases where imports are organised for individual ~~named~~**specific**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			SoHO recipients.	
Article 43(5a)				
583a			**5a. The releasing officer of an importing SoHO establishment shall release imported SoHO for distribution only when they have verified compliance with the quality, safety and effectiveness requirements specified in the agreement referred to in paragraph 2 of this Article and when the physical and documentation controls referred to in paragraph 4 are satisfactory. In the case of national or international donor**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			registries that are authorised as importing SoHO establishments, the physical and documentation controls referred to in this paragraph may be delegated to the SoHO entity that receives the imported SoHO for human application and the release step may be completed remotely.	
Article 43(6), first subparagraph				
584	The Commission shall adopt implementing acts specifying the information to be provided in an application for an authorisation for importing SoHOs or SoHO preparations to ensure		**6.** The Commission shall adopt implementing acts specifying the information to be provided in an application for an authorisation for importing SoHOs or SoHO preparations to ensure	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	compatibility and comparability of such data.		compatibility and comparability of such data.	
Article 43(6), second subparagraph				
585	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	
Article 44				
586	Article 44 Activity data collection and		Article 44 Activity data collection and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	reporting		reporting	
Article 44(1)				
587	1. SoHO entities shall collect data relating to their activities in cases where those activities include:		1. SoHO entities shall collect **and report** data relating to ~~their activities in cases where those~~**any of the following SoHO** activities ~~include~~:	
Article 44(1), point (a)				
588	(a) SoHO donor recruitment;		(a) ~~SoHO~~ donor ~~recruitment~~ **registration**;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 44(1), point (b)				
589	(b) collection;		(b) collection;	
Article 44(1), point (c)				
590	(c) distribution;		(c) distribution;	
Article 44(1), point (d)				
591	(d) import;		(d) import;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 44(1), point (e)				
592	(e) export;		(e) export;	
Article 44(1), point (f)				
593	(f) human application.		(f) human application.	
Article 44(2)				
594	2. The data collected pursuant to		2. The data collected pursuant to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	paragraph 1 shall comprise the elements set out in the EU SoHO Platform as referred to in Chapter XI.		paragraph 1 shall comprise the ~~elements set out~~ **data set indicated** in the EU SoHO Platform ~~as referred to in Chapter XI~~.	
Article 44(3), first subparagraph				
595	The Commission shall adopt implementing acts laying down technical procedures to ensure uniformity and compatibility and comparability for the implementation of this Article.		**3.** The Commission shall adopt implementing acts laying down technical procedures **for setting and updating the list of data sets to be reported** to ensure uniformity and compatibility and comparability ~~for the implementation of this Article~~**on the activity data report, extraction, submission and**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			publication.	
Article 44(3), second subparagraph				
596	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	
Article 44(4)				
597	4. SoHO entities shall submit to the EU SoHO Platform an annual summary of the data collected pursuant to this Article. In cases		4. SoHO entities shall submit to the EU SoHO Platform an annual ~~summary~~**report** of the data collected pursuant to this Article~~.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	where national or international registries collect activity data meeting the criteria defined in the SoHO platform and such registries have been verified by competent authorities as having in place data quality management procedures that ensure accuracy and completeness of data, SoHO entities may delegate the submission of the activity data referred to in this Article to such registries. The Commission shall aggregate the annual summaries of the SoHO entities, prepare and publish an Annual SoHO Activity Report.		~~In cases where national or international registries collect activity data meeting the criteria defined in the SoHO platform and such registries have been verified by competent authorities as having in place data quality management procedures that ensure accuracy and completeness of data, SoHO entities may delegate the submission~~ **before 30 June** of the ~~activity data referred to in this Article to such registries. The Commission shall aggregate the annual summaries of the SoHO entities, prepare and publish an Annual SoHO Activity Report.~~**subsequent year.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 44(4a)				
597a			**4a. By derogation from paragraph 4, where SoHO competent authorities require SoHO entities to report activity data as referred to in Article 33(1a), SoHO entities shall submit their annual report of activity data to the indicated registries, before 30 June of the subsequent year.**	
Article 45				
598	Article 45		Article 45	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Traceability and coding		Traceability and coding	
Article 45(1)				
599	1. SoHO entities shall implement a traceability system in order to unmistakably link each SoHO donor to their SoHO donation and to all documents, samples, SoHO preparations and SoHO entities that are associated with that SoHO from the point of collection to human application and outcome monitoring. With regard to imported SoHOs, importing SoHO entities shall ensure an equivalent level of traceability.		1. SoHO entities shall implement a traceability system**,** in order to unmistakably link each SoHO donor **or the person from whom SoHO are collected for autologous use,** to their SoHO ~~donation~~ and to all **the** documents, samples, SoHO preparations and SoHO entities that are associated with that SoHO ~~from the~~**at any** point ~~of collection to human application and outcome monitoring. With regard to imported SoHOs,~~ **.** Importing	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			SoHO ~~entities~~**establishments** shall ensure an equivalent level of traceability **with regard to imported SoHO**.	
Article 45(1a)				
599a			**1a. The traceability system referred to in paragraph 1 should have the ability to:**	
Article 45(1a), point (a)				
599b			**(a) identify the SoHO donor or the person from whom SoHO are**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			collected for autologous use and the establishment releasing the SoHO;	
Article 45(1a), point (b)				
599c			**(b) identify the SoHO recipient at the SoHO entity applying the SoHO to the SoHO recipient, or the manufacturer of products regulated by other Union legislation, as provided for in Article 2(3);**	
Article 45(1a), point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
599d			**(c) locate and identify all relevant data relating to the safety and quality of the SoHO and any materials or equipment coming into contact with those SoHO that might pose a risk to their quality or safety.**	
Article 45(2)				
600	2. SoHO entities distributing SoHOs shall generate a code that contains the information included in the traceability system referred to in paragraph 1. They shall ensure that the code:		2. SoHO entities distributing ~~SoHOs~~**SoHO** shall ~~generate~~**apply** a code that contains the information included in the **requirements of the** traceability system referred to in paragraph 1.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			They shall ensure that the code **generated**:	
Article 45(2), point (a)				
601	(a) is unique within the Union;		(a) is unique within the Union;	
Article 45(2), point (b)				
602	(b) is machine-readable, unless the size or storage conditions mean that a machine-readable code cannot be applied;		(b) is machine-readable, unless the size or storage conditions mean that a machine-readable code cannot be applied;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 45(2), point (c)				
603	(c) does not reveal the identity of the donor;		(c) does not reveal the identity of the **SoHO** donor **or the person from whom SoHO are donated in the case of autologous use**;	
Article 45(2), point (d)				
604	(d) complies with technical rules for the Single European Code (SEC) for SoHOs, referred to in Article 46, where applicable as indicated in that Article.		(d) complies with technical rules for the Single European Code (SEC) for SoHOs, referred to in Article 46, where applicable as indicated in that Article.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 45(3)				
605	3. SoHO entities shall include the codes referred to in paragraph 2 on the labels to be applied to the SoHO or SoHO preparations prior to distribution, or on the documents accompanying the distributed SoHO or SoHO preparations where it can be guaranteed that such documents will not be separated from the SoHO or SoHO preparation concerned.		3. SoHO entities shall include the codes referred to in paragraph 2**, prior to distribution,** on the labels ~~to be~~ applied to the SoHO~~ or SoHO preparations prior to distribution~~, or on the documents accompanying the distributed SoHO~~ or SoHO preparations~~**,** where it can be guaranteed that such documents will not be separated from the SoHO or **will be kept digitally linked to the** SoHO~~ preparation~~ concerned.	
Article 45(4)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
606	4. SoHO entities shall use a labelling system that meets the labelling requirements set out in the relevant technical guidelines referred to in Articles 56(4) and 59(4). SoHO entities shall keep the data necessary to ensure traceability for a minimum of 30 years. They may store the data in electronic form.		4. SoHO entities shall use a labelling system that meets the labelling requirements set out in the relevant technical guidelines referred to in Articles 56(4) and 59(4). ~~SoHO entities shall keep the data necessary to ensure traceability for a minimum of 30 years. They may store the data in electronic form.~~	
Article 45(4a)				
606a			**4a. SoHO entities shall keep the data necessary to ensure traceability, appropriately**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			safeguarded and accessible to the SoHO competent authority, for a minimum of 30 years from the SoHO application date. They may store the data in electronic form. In case a SoHO entity ceases its activity, the traceability data shall be transferred to a contracted SoHO entity for the completion of the traceability period, with the prior information to the corresponding SoHO competent authorities.	
Article 45(4b)				
606b			**4b. The Commission shall adopt implementing acts concerning**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			the minimum SoHO donor and SoHO recipient data set to be kept to ensure traceability. **Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).**	
Article 46				
607	Article 46 European coding system		Article 46 European coding system	
Article 46(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
608	1. SoHO entities shall apply a Single European Code ('SEC') to SoHO preparations distributed for human application. In cases where SoHOs or SoHO preparations are transferred for further processing in another SoHO entity or released for manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, SoHO entities shall, at least, apply the part of the SEC that allows identification of the donation. The SEC shall appear on the packaging or on a label attached thereto, or on the documents referring to the SoHO where it can be guaranteed that such documents accompany the		1. SoHO entities shall apply a Single European Code ('SEC') to SoHO ~~preparations~~ distributed for human application. In cases where ~~SoHOs or SoHO preparations~~ **SoHO** are transferred for further processing in another SoHO entity or released for manufacture of products regulated by other Union legislation~~, or as the starting and raw material thereof~~ **as provided for in Article 2(3) or exported to third countries**, SoHO entities shall, at least, apply the ~~part~~**elements** of the SEC that ~~allows~~**allow the** identification of the donation[1]. The SEC shall **also** appear on the **primary** packaging or on a label attached thereto, or on	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHO concerned.		the documents referring to the SoHO where it can be ~~guaranteed~~**ensured** that such documents accompany the SoHO concerned. _____ **1. 'Donation identification sequence' in Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells Directive.**	
Article 46(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
609	2. Paragraph 1 shall not apply to:		2. Paragraph 1 shall not apply to:	
Article 46(2), point (a)				
610	(a) reproductive cells for within couple use;		(a) reproductive ~~cells~~**SoHO** for within couple use;	
Article 46(2), point (b)				
611	(b) blood or blood components for transfusion or for the manufacture of medicinal products;		(b) blood or blood components for transfusion or for the manufacture of medicinal products;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 46(2), point (c)				
612	(c) SoHOs applied to a recipient without being stored;		(c) ~~SoHOs~~**SoHO** applied to a **SoHO** recipient without being stored;	
Article 46(2), point (d)				
613	(d) SoHOs imported into the Union in case of emergency authorised directly by competent authorities pursuant to Article 28(9);		(d) ~~SoHOs~~**SoHO** imported into the Union ~~in case of emergency~~**by derogation and** authorised directly by **SoHO** competent authorities pursuant to Article 28(9);	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 46(2), point (e)				
614	(e) SoHOs that are imported to or donated in the same SoHO entity where they are applied.		(e) ~~SoHOs~~**SoHO** that are imported to or donated in the same SoHO entity where they are applied.	
Article 46(3), first subparagraph				
615	The Commission shall adopt implementing acts concerning the format of the Single European Code and the requirements related to its application to SoHO establishments and to SoHOs at the		**3.** The Commission shall adopt implementing acts concerning the format of the Single European Code and the requirements related to its application to SoHO establishments and to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	point of distribution or point of transport and delivery for further processing.		~~SoHOs~~**SoHO** at the point of distribution ~~or point of transport and delivery for further processing~~.	
Article 46(3), second subparagraph				
616	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	
Article 47				
617	Article 47		Article 47	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Vigilance and reporting		Vigilance and reporting	
Article 47(1)				
618	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***.	1. SoHO entities shall maintain a system for detecting, investigating and recording information concerning adverse ~~occurrences~~**reactions and adverse events**, including ~~adverse occurrences~~**those** detected during clinical outcome monitoring as part of a SoHO preparation authorisation application as referred to in Article 41.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 47(2)				
619	2. Where applicable, SoHO entities shall make all reasonable efforts to encourage prospective parents of children born from third party donation to commit to communicate information concerning any genetic conditions that emerge, as those children grow up, to the SoHO entity where they were treated. That entity shall communicate, without undue delay, the information to the SoHO entity that distributed or applied the reproductive cells with a view to preventing further distribution of SoHO from the implicated SoHO donor.		2. ~~Where applicable,~~ SoHO entities shall make all reasonable efforts to encourage prospective parents of children born from third party donation to ~~commit to communicate~~**communicat** information concerning ~~any~~ genetic conditions ~~that emerge, as those children grow up~~**as soon as they emerge in the children** , to the SoHO entity where they were treated. ~~That~~**The SoHO** entity shall communicate, without undue delay, ~~the~~**that** information to the SoHO ~~entity that distributed or applied the reproductive cells~~**establishment that released**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			the reproductive SoHO for application or distribution with a view to **investigating the suspected SAR and** preventing further distribution of SoHO from the implicated SoHO donor**, in accordance with national legislation on the storage and use of reproductive SoHO**.	
Article 47(3)				
620	3. In cases where SoHO entities detect or suspect that an adverse occurrence meets the definition of a serious adverse occurrence (SAO), they shall submit a SAO notification to their competent		3. In cases where SoHO entities detect or suspect that an adverse ~~occurrence~~**reaction or adverse event** meets the definition of a ~~serious adverse occurrence (SAO)~~**SAR or a SAE** , they shall	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorities within five working days. SoHO entities shall include the following in the notification:		submit a ~~SAO~~ notification to their **SoHO** competent authorities ~~within five working days. SoHO entities~~**without undue delay and** shall include the following ~~in the notification~~**information**:	
Article 47(3a)				
620a		***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.***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 47(3), point (a)				
621	(a) a full description of the suspected SAO;		(a) a ~~full~~ description of the suspected ~~SAO~~**SAR or SAE**;	
Article 47(3), point (b)				
622	(b) a preliminary assessment of the level of imputability of the suspected SAO;		(b) a preliminary assessment of the level of imputability**, if applicable** ~~of the suspected SAO~~;	
Article 47(3), point (c)				
623				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(c) a plan for an investigation to establish the level of imputability and the root cause;		(c) ~~a plan for an investigation to establish the level of imputability and the root cause;~~	
Article 47(3), point (d)				
624	(d) proposed mitigation strategies;		(d) ~~proposed mitigation strategies~~**details of any immediate steps taken to limit harm, where applicable**;	
Article 47(3), point (e)				
625	(e) a preliminary assessment of the		(e) a preliminary assessment of the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	seriousness of the consequences of the SAO for a donor, a recipient or the offspring from medically assisted reproduction or for public health in general.		seriousness of the consequences of the ~~SAO for a donor, a recipient or the offspring from medically assisted reproduction or for public health in general.~~**suspected SAR or SAE.**	
Article 47(3a)				
625a			**3a. SoHO entities other than SoHO establishments shall communicate adverse reactions or adverse events to the SoHO establishment for which they carry out SoHO activities in the context of an agreement or to the SoHO establishment that distributed the SoHO to them, as**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			appropriate. In such cases, the SoHO establishments receiving the communication shall be responsible for the investigation and shall report to their SoHO competent authorities when the adverse reaction or adverse event concerned is deemed a SAR or a SAE. All other SoHO entities shall investigate and report SAR or SAE directly to their SoHO competent authorities.	
Article 47(3b)				
625b			**3b. Upon receipt of information regarding a serious incident and field safety corrective action**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			within the meaning of Regulation (EU) 2017/745 or Regulation (EU) 2017/746, concerning a medical device or in-vitro diagnostic device that is used by a SoHO entity, the SoHO entity receiving such information shall communicate it to its SoHO competent authority.	
Article 47(4)				
626	4. SoHO entities shall have in place a procedure to accurately, efficiently and verifiably withdraw from distribution or use those SoHOs affected by adverse occurrence referred to in paragraph		4. SoHO entities shall have in place a procedure to accurately, efficiently and verifiably withdraw from distribution or use those ~~SoHOs~~**SoHO** affected by adverse ~~occurrence~~**reactions or adverse**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	1, as appropriate.		**events** referred to in paragraph ~~1~~**3**, as appropriate. **In the case of reproductive SoHO, those procedures shall be in accordance with national legislation.**	
Article 47(5)				
627	5. SoHO entities shall conduct an investigation of each SAO detected. On completion of an investigation of a SAO, SoHO entities shall provide a SAO investigation report to their competent authorities pursuant to Article 35(4). The SoHO entities shall include in the report:		5. SoHO entities shall conduct an investigation of each ~~SAO~~**SAR or SAE** detected. On completion of ~~an~~**that** investigation ~~of a SAO~~, SoHO entities shall provide ~~a SAO~~**an** investigation report to their **SoHO** competent authorities pursuant to Article 35(4). The SoHO entities shall include in the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			report:	
Article 47(5), point (a)				
628	(a) a full description of the investigation and the final assessment of the imputability of the SAO to the donation or application of the SoHO;		(a) a full description of the investigation and the final assessment of the imputability ~~of the SAO~~ to the donation or application of the SoHO**, if applicable**;	
Article 47(5), point (b)				
629	(b) the final assessment of the seriousness of the consequences of		(b) the final assessment of the seriousness of the consequences ~~of~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the SAO for a donor, a recipient or the offspring of medically assisted reproduction or for public health in general;		~~the SAO~~ for a **SoHO** donor, a **SoHO** recipient or the offspring of medically assisted reproduction or for public health in general**, including a risk assessment of the likelihood of the recurrence risk, where relevant**;	
Article 47(5), point (c)				
630	(c) a description of the corrective or preventive actions that have been taken to limit any harm or to prevent recurrence.		(c) a description of the corrective or preventive actions that have been taken to limit any harm or to prevent recurrence.	
Article 47(6)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
631	6. SoHO entities shall report information concerning a SAO to other SoHO entities engaged in the collection, processing, testing, storage and distribution of SoHO collected from the same donor, or otherwise possibly affected by the SAO concerned. They shall only report information necessary and appropriate in order to facilitate traceability and ensure quality and safety in such cases, and shall, in particular, limit the information to details necessary to take mitigating actions. SoHO entities shall also report such information to organ procurement organisations in cases where a donor who is implicated in the SAO has also donated organs.		6. SoHO entities shall ~~report~~**communicate** information concerning a ~~SAO~~**SAR or a SAE** to other SoHO entities engaged in the collection, processing, testing, storage and distribution of SoHO collected from the same **SoHO** donor, or otherwise possibly affected ~~by the SAO concerned.~~ **.** They shall only ~~report~~**communicate** information necessary and appropriate in order to facilitate traceability and ensure quality and safety in such cases, and shall, in particular, limit the information to details necessary to take mitigating actions. **A risk assessment of the seriousness and likelihood of recurrence shall be**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			included in the communication. SoHO entities**, where relevant,** shall also ~~report~~**communicate** such information to organ procurement organisations in cases where ~~a~~**the SoHO** donor who is implicated in the ~~SAO~~**SAR or SAE** has also donated organs **or to manufacturers in cases where SoHO collected from that SoHO donor have been distributed to manufacture products regulated by other Union legislation, as referred to in Article 2(3)**.	
CHAPTER V				
632	CHAPTER V		CHAPTER V	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	GENERAL OBLIGATIONS ON SoHO ESTABLISHMENTS		GENERAL OBLIGATIONS ON SoHO ESTABLISHMENTS	
Article 48				
633	Article 48 SoHO establishment authorisation		Article 48 SoHO establishment authorisation	
Article 48(1)				
634	1. SoHO establishments shall not carry out any activities without prior SoHO establishment authorisation. This shall apply	1. SoHO establishments shall not carry out any ***SoHO*** activities without prior SoHO establishment authorisation. This shall apply	1. SoHO establishments shall not carry out any **of the SoHO** activities **that qualify them as an establishment according to art 3**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	whether all activities are carried out by the establishment itself or one or more are contracted to another SoHO entity.	whether all activities are carried out by the establishment itself or one or more are contracted to another SoHO entity.	**(40), without prior SoHO establishment authorisation. In case of a need for an authorisation under Article 25(3), the establishment shall not carry out the activity motivating such a need for authorisation as communicated by the SoHO competent authority,** without prior SoHO establishment authorisation. This shall apply whether all activities are carried out by the **SoHO** establishment itself or one or more are contracted to another SoHO entity.	
Article 48(2)				
635				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	2. In cases where SoHO establishments contract other SoHO entities to perform part or all of certain SoHO activities, the SoHO establishments shall ensure that those contracted SoHO entities carry out those contracted activities in compliance with the provisions of this Regulation. Such contracted entities shall agree to be audited by the SoHO establishments to verify that the contracted activities are carried out in compliance with this Regulation. In addition, the contracted entities shall agree to be inspected by competent authorities if the authorities require such inspection. The SoHO establishments shall document these agreements.		2. In cases where SoHO establishments contract other SoHO entities to perform part or all of certain SoHO activities, the SoHO establishments shall ensure that those contracted SoHO entities carry out those contracted activities in compliance with the provisions of this Regulation. Such contracted ~~entities shall agree to~~**SoHO entities may** be audited by the **contracting SoHO establishment or inspected by the SoHO competent authority, in particular in cases where**~~SoHO establishments to verify that the contracted activities are carried out in compliance with this Regulation. In addition,~~ the contracted ~~entities shall agree to be inspected by competent authorities if the~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~authorities require such inspection. The SoHO establishments shall document these agreements~~**entity has not been accredited, certified or authorised, as part of a national programme, for the specific activities carried out under the contract**.	
Article 48(3)				
636	3. The requirement to obtain a SoHO establishment authorisation shall be without prejudice to more stringent measures put in place by a Member State pursuant to Article 4 and directly affecting the activities carried out in the SoHO		3. The requirement to obtain a SoHO establishment authorisation shall be without prejudice to more stringent measures put in place by a Member State pursuant to Article 4 and directly affecting the activities carried out in the SoHO	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	establishment or contracted SoHO entities concerned pursuant to paragraph 2 of this Article.		establishment or contracted SoHO entities concerned pursuant to paragraph 2 of this Article.	
Article 49				
637	Article 49 Application for SoHO establishment authorisations		Article 49 Application for SoHO establishment authorisations	
Article 49(1)				
638	1. SoHO entities shall send the application for authorisations as		1. SoHO entities shall ~~send~~**submit** the application for authorisations as	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHO establishments to their competent authorities.		SoHO establishments to ~~their~~**the SoHO** competent authorities **of their territories**.	
Article 49(2)				
639	2. The applicant SoHO establishment shall provide the name and contact details of the prospective SoHO establishment authorisation holder responsible for the application and carrying out the SoHO activities subject to the authorisation. This paragraph shall be without prejudice to Article 38(1). The applicant SoHO establishment shall not make any substantial changes to the SoHO		2. The applicant SoHO establishment shall provide the name and contact details of the ~~prospective SoHO establishment authorisation holder responsible for the application and~~ **responsible person for** carrying out the SoHO activities subject to the authorisation~~. This paragraph shall be without prejudice~~**, pursuant** to Article ~~38(1). The applicant~~**37a. The** SoHO establishment shall not	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	activities subject to the authorisation without the prior written approval of the competent authority. The same shall apply in case of changes in the SoHO establishment authorisation holder's details.		make any ~~substantial~~**significant** changes **with regards to SoHO or**~~**to the**~~ SoHO activities subject to the authorisation without the prior written ~~approval~~**authorisation** of the **SoHO** competent authority. ~~The same shall apply in case of changes in the SoHO establishment authorisation holder's details.~~	
Article 49(2a)				
639a			**2a. Significant changes for which an application for an updated authorisation shall be required pursuant to paragraph 2 are those relating to the types of SoHO concerned, to the types**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			of SoHO activities carried out, to the use of new premises or to the modification of premises having an impact on the conditions under which SoHO activities are carried out.	
Article 49(2b)				
639b			**2b. SoHO establishments shall also, without undue delay, inform their SoHO competent authorities of any changes of an administrative nature, related to the SoHO establishment authorisation, including a change of responsible person.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 49(3)				
640	3. SoHO establishment authorisation holders shall be based in the Union.		3. ~~SoHO establishment~~**The legal entity that holds the** authorisation ~~holders~~**for the SoHO establishment** shall be based in the ~~Union~~**Member State where the SoHO establishment is authorised**.	
Article 49a				
640a			**Article 49a**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Releasing officer	
Article 49a(1)				
640b			**1. In cases where a SoHO establishment releases SoHO, it shall designate one or more releasing officers.**	
Article 49a(2)				
640c			**2. The releasing officer shall be in possession of a diploma, certificate or other evidence of**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			formal qualifications in the field of medical, pharmaceutical or life sciences awarded on completion of a university course of study or a course qualification recognised as equivalent by the Member State concerned and shall have at least two years of experience in the relevant field.	
Article 49a(3)				
640d			**3. The releasing officer may delegate the tasks to carry out the activity specified in paragraph 1 to other persons who shall be qualified by training and experience to**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			perform such tasks. In such cases, that person shall perform those tasks under the responsibility of the releasing officer who will always be responsible for the release. The responsibility of releasing SoHOmay be delegated to an alternate in case of short term absence of a releasing officer, on condition that the alternate meets the requirements specified in paragraph 2.	
Article 49b				
640e			**Article 49b**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Physician	
Article 49b(1)				
640f			**1. SoHO establishments shall designate a physician who carries out its tasks in the same Member State and who shall at least fulfil the following conditions and have the following qualifications:**	
Article 49b(1a.)				
640g			**(a) possession of formal**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			qualification as a physician; and	
Article 49b(1.b)				
640h			**(b) at least two years' practical experience in the relevant field.**	
Article 49b(2)				
640i			**2.** **The physician referred to in paragraph 1 shall be responsible for at least the following tasks:**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 49b(2), point (a)				
640j			**(a) development, review and approval of procedures for establishing and applying SoHO donor eligibility criteria, procedures for SoHO collection and criteria for the allocation of SoHO;**	
Article 49b(2), point (aa)				
640k			**(aa) supervision of the implementation of procedures**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			referred to in point (a) when they are carried out by SoHO entities contracted by the SoHO establishment;	
Article 49b(2), point (b)				
640l			**(b) the clinical aspects of investigation of suspected adverse reactions in SoHO donors, SoHO recipients and offspring from medically assisted reproduction from the perspective of the SoHO establishment;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 49b(2), point (c)				
640m			**(c) design and supervision, in collaboration with treating physicians, of clinical data collection activities to acquire evidence gathering to support applications for SoHO preparation authorisations pursuant to Article 41;**	
Article 49b(2), point (d)				
640n			**(d) other tasks of relevance to the health of SoHO donors, SoHO recipients and offspring**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			from medically assisted reproduction of SoHOs collected or supplied by the SoHO establishment.	
Article 49b(2a.)				
640o			**2a.** **The physician may delegate the tasks specified in paragraph 2 to other persons who shall be qualified by training and experience to perform such tasks. In such cases, that person shall perform those tasks under the responsibility of the physician.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 49c				
640p			**Article 49c** **Export**	
Article 49c(new 1.)				
640q			**new 1. SoHO establishments shall ensure that SoHO released for export comply with the requirements of this Regulation.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 49c(new 2.)				
640r			**new 2. By derogation from paragraph new 1, SoHO not complying with all the relevant standards and guidelines referred to in Articles 58 and 59 may be released for export in the circumstances of exceptional release pursuant to Article 61(new 3).** **SoHO establishments shall, also in these circumstances, not deviate from the standards referred to in Chapter VI, as well as those related to vigilance and traceability.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 50				
641	Article 50 Quality management system		Article 50 ~~Quality management system~~	
Article 50(1)				
642	1. SoHO establishments shall establish, maintain and update, as necessary, a quality management system achieving a high level of quality of SoHOs by following, in particular, the Good Practice Guidelines published by the EDQM and which are included in the technical guidelines referred to		1. ~~SoHO establishments shall establish, maintain and update, as necessary, a quality management system achieving a high level of quality of SoHOs by following, in particular, the Good Practice Guidelines published by the EDQM and which are included in the technical guidelines referred to~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	in Article 56(4), point (a), and Article 59(4), point (a).		~~in Article 56(4), point (a), and Article 59(4), point (a).~~	
Article 50(2)				
643	2. SoHO establishments shall design the quality management system to ensure that SoHO activities are carried out in a consistent manner, by personnel that are competent to perform the tasks allocated to them and in facilities that are designed and maintained in a manner that prevents SoHO contamination, or cross-contamination, with infectious agents or loss of traceability.		2. ~~SoHO establishments shall design the quality management system to ensure that SoHO activities are carried out in a consistent manner, by personnel that are competent to perform the tasks allocated to them and in facilities that are designed and maintained in a manner that prevents SoHO contamination, or cross-contamination, with infectious agents or loss of traceability.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 50(3)				
644	3. SoHO establishments shall put in place procedures and specifications covering the following:		3. ~~SoHO establishments shall put in place procedures and specifications covering the following:~~	
Article 50(3), point (a)				
645	(a) documentation of roles and responsibilities of personnel;		(a) ~~documentation of roles and responsibilities of personnel;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 50(3), point (b)				
646	(b) selection, training and competence assessment of personnel;		(b) ~~selection, training and competence assessment of personnel;~~	
Article 50(3), point (c)				
647	(c) premises and equipment procurement, qualification and monitoring;		(c) ~~premises and equipment procurement, qualification and monitoring;~~	
Article 50(3), point (d)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
648	(d) quality control, as applicable, of SoHO activities;		(d) ~~quality control, as applicable, of SoHO activities;~~	
Article 50(3), point (e)				
649	(e) withdrawal of SoHOs from the inventory of released SoHOs and recall of unused SoHOs following distribution;		(e) ~~withdrawal of SoHOs from the inventory of released SoHOs and recall of unused SoHOs following distribution;~~	
Article 50(3), point (f)				
650	(f) internal audits;		(f) ~~internal audits;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 50(3), point (g)				
651	(g) management of contracted third parties;		(g) ~~management of contracted third parties;~~	
Article 50(3), point (h)				
652	(h) management of identified cases where personnel have not followed procedures or specifications have not been complied with.		(h) ~~management of identified cases where personnel have not followed procedures or specifications have not been complied with.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 50(4)				
653	4. SoHO establishments shall review the quality management system at regular intervals to verify its effectiveness and introduce corrective measures if deemed necessary.		4. ~~SoHO establishments shall review the quality management system at regular intervals to verify its effectiveness and introduce corrective measures if deemed necessary.~~	
Article 50(5), first subparagraph				
654	The Commission may adopt implementing acts regarding further details on the procedures and specifications of the quality management system in order to		~~The Commission may adopt implementing acts regarding further details on the procedures and specifications of the quality management system in order to~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	ensure uniform quality management.		~~ensure uniform quality management.~~	
Article 50(5), second subparagraph				
655	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).		~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).~~	
Article 51				
656	Article 51 Physician	Article 51 ~~*Physician*~~***Physicians***	Article 51 ~~Physician~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 51(1)				
657	1. Each SoHO establishment shall designate a physician who resides and carries out its tasks in the same Member State and who shall at least fulfil the following conditions and have the following qualifications:		1. ~~Each SoHO establishment shall designate a physician who resides and carries out its tasks in the same Member State and who shall at least fulfil the following conditions and have the following qualifications:~~	
Article 51(1), point (a)				
658	(a) possession of formal qualification as a physician;		(a) ~~possession of formal qualification as a physician;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 51(1), point (b)				
659	(b) at least two years' practical experience in relevant fields.		(b) ~~at least two years' practical experience in relevant fields.~~	
Article 51(2)				
660	2. The physician referred to in paragraph 1 shall be responsible for at least the following tasks:		2. ~~The physician referred to in paragraph 1 shall be responsible for at least the following tasks:~~	
Article 51(2), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
661	(a) development, review and approval of policies and procedures for establishing and applying SoHO donor eligibility criteria and criteria for the allocation of SoHOs and SoHOs preparations;		(a) ~~development, review and approval of policies and procedures for establishing and applying SoHO donor eligibility criteria and criteria for the allocation of SoHOs and SoHOs preparations;~~	
Article 51(2), point (b)				
662	(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*** ~~*and recipients*~~;	(b) ~~investigation of suspected adverse occurrences in SoHO donors and recipients;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 51(2), point (c)				
663	(c) design and supervision of clinical data collection activities to support evidence gathering to support applications for SoHO preparation authorisations pursuant to Article 41;		(c) ~~design and supervision of clinical data collection activities to support evidence gathering to support applications for SoHO preparation authorisations pursuant to Article 41;~~	
Article 51(2), point (d)				
664	(d) other tasks of relevance to the health of donors and recipients of SoHOs collected or supplied by the		(d) ~~other tasks of relevance to the health of donors and recipients of SoHOs collected or supplied by the~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHO establishment.		~~SoHO establishment.~~	
Article 51(3)				
665	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*** ~~*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 and recipients.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
CHAPTER VI				
666	CHAPTER VI SoHO DONOR PROTECTION		CHAPTER VI SoHO DONOR PROTECTION	
Article 52				
667	Article 52 Objectives regarding SoHO donor protection		Article 52 Objectives regarding SoHO donor protection	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 52(1)				
668	1. SoHO entities shall ensure high levels of safety of SoHO donors.		1. SoHO entities shall ensure ~~high levels of safety~~**respect for the dignity and integrity** of SoHO donors.	
Article 52(2)				
669	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.	2. SoHO entities shall **ensure high levels of safety and** protect the health of living **SoHO** donors **from risks related to the donation, by identifying and minimising such risks** before, during and after the ~~donation~~**SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			collection.	
Article 52(2a)				
669a		***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.***	**2a. SoHO competent authorities shall verify the compliance of the provisions laid down in this chapter as well as the national provisions on consent and voluntary and unpaid donation.**	
Article 53				
670				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 53 Standards concerning SoHO donor protection		Article 53 Standards concerning SoHO donor protection	
Article 53(1)				
671	1. In case of collection of SoHOs from allogeneic donors, regardless of whether or not the donor is genetically related to the intended recipient, SoHO entities shall:		1. In case of collection of ~~SoHOs from allogeneic~~**SoHO from living** donors, regardless of whether or not the **SoHO** donor is ~~genetically~~ related to the intended recipient, SoHO entities shall:	
Article 53(1), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
672	(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;	(a) meet all applicable consent or authorisation requirements in force in the Member State concerned;	
Article 53(1), point (b)				
673	(b) provide donors or their relatives or any persons granting authorisation on their behalf, in accordance with national legislation, with the information referred to in Article 55 and in a way that is adequate in view of their capacity to understand it;	(b) provide donors or their relatives or any persons granting authorisation on their behalf, in accordance with national legislation, with the information referred to in Article 55 and in a way that ~~*is adequate in view of their capacity to understand it*~~***enables them to give informed***	(b) provide **SoHO** donors or**, where applicable,** ~~their relatives or~~ any persons granting ~~authorisation~~**consent** 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;~~**:**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		consent and request further information if needed;		
Article 53(1), point (i)				
673a			**(i) the information referred to in Article 55 and in a way that is adequate in view of their capacity to understand it;**	
Article 53(1), point (ii)				
673b			**(ii) the contact details of the SoHO entity responsible for the collection from which they can**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			request further information, if needed;	
Article 53(1), point (c)				
674	(c) provide donors or their relatives or any persons granting authorisation on their behalf, in accordance with national legislation, with the contact details of the responsible SoHO entity from which they can request further information, if needed;		(c) ~~provide donors or their relatives or any persons granting authorisation on their behalf, in accordance with national legislation, with the contact details of the responsible SoHO entity from which they can request further information, if needed;~~	
Article 53(1), point (d)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
675	(d) safeguard the rights of the donor to physical and mental integrity, to privacy and to the protection of the personal data concerning them in accordance with Regulation (EU) 2016/679;		(d) safeguard the rights of the **SoHO** donor to physical and mental integrity, to privacy and to the protection of the personal data**, including health data,** concerning them in accordance with Regulation (EU) 2016/679;	
Article 53(1), point (e)				
676	(e) ensure that donation is voluntary and unpaid, pursuant to Article 54;		(e) ensure that donation is voluntary and unpaid, pursuant to Article 54;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 53(1), point (f)				
677	(f) verify the eligibility of the donor on the basis of a donor health evaluation that aims to minimise any risk that the donation might pose to the donor's health;		(f) verify the eligibility of the **SoHO** donor on the basis of a donor health evaluation that aims to **identify and** minimise any risk that the ~~donation~~**SoHO collection** might pose to the **SoHO** donor's health;	
Article 53(1), point (g)				
678	(g) document the results of the donor health evaluation referred to in point (f);		(g) document the results of the **SoHO** donor health evaluation ~~referred to in point (f);~~**;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 53(1), point (h)				
679	(h) communicate and clearly explain the results of the donor health evaluation to the donor or his/her relatives or any persons granting authorisation on his/her behalf, in accordance with national legislation;		(h) communicate and clearly explain the results of the **SoHO** donor health evaluation to the **SoHO** donor or**, where applicable,** ~~his/her relatives or~~ any persons granting ~~authorisation on his/her~~**consent on their** behalf, in accordance with national legislation;	
Article 53(1), point (i)				
680				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(i) identify and minimise any risks to the health of the donor during the donation procedure, including exposure to reagents or solutions that might be toxic;		(i) identify and minimise any risks to the health of the **SoHO** donor during the ~~donation~~**collection** procedure, including exposure to reagents or solutions that might be ~~toxic~~**harmful to health**;	
Article 53(1), point (j)				
681	(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 ~~a registry~~***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;	(j) verify, by means of a registry, **as referred to in paragraph 3, that SoHO**~~that~~ donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article ~~56 and demonstrate~~**56(4) and monitor relevant health indicators to evaluate** that their	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			health is not compromised;	
Article 53(1), point (ja)				
681a		***(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;***		
Article 53(1), point (k)				
682	(k) develop and implement a plan		(k) develop and implement a plan	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	for monitoring the donor's health after the donation in cases where the SoHO donations imply a significant risk to a donor as referred to in paragraph 3;		for monitoring the **SoHO** donor's health after the donation in cases where the SoHO donations imply a significant risk to a **SoHO** donor as referred to in paragraph ~~3~~**4**;	
Article 53(1), point (l)				
683	(l) in the case of an allogeneic and unrelated donation, refrain from revealing the donor's identity to the recipient, apart from exceptional circumstances where such information exchange is permitted in the Member State and follows the expressed wishes of both parties.		(l) in the case of an ~~allogeneic and~~ unrelated donation, refrain from revealing the **SoHO** donor's identity to the **SoHO** recipient **or to the offspring**, apart from ~~exceptional~~ circumstances where such information exchange is permitted in the Member State ~~and follows the expressed wishes of both parties~~**concerned**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 53(1), point (la)				
683a		***(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.***		
Article 53(1a)				
683b		***1a. SoHO entities shall not***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.		
Article 53(2)				
684	2. In the course of the donor health evaluations referred to in paragraph 1, point (f), SoHO entities shall	2. In the course of the donor health evaluations referred to in paragraph 1, point (f), SoHO entities shall	2. In the course of the **living SoHO** donor health evaluations referred to in paragraph 1, point (f),	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	conduct interviews with the donors and gather information concerning the donors' present and recent state of health and their health histories to assure the safety of the donation process for those donors. SoHO entities may perform laboratory tests as part of the donor health evaluations. They shall perform such tests in cases where evaluations indicate that laboratory tests are necessary to establish the eligibility of those donors from the perspective of their own protection. The physician, as referred to in Article 51, shall approve the procedure and criteria for donor health evaluations.	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 procedure and criteria for donor health evaluations.	SoHO entities shall conduct interviews with the **SoHO** donors and gather information concerning the **SoHO** 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~~**additional** tests as part of the **SoHO** donor health evaluations. They shall perform such tests in cases where evaluations indicate that ~~laboratory~~**such** tests are necessary to establish the eligibility of those **SoHO** donors from the perspective of their own protection. The physician, ~~as~~ referred to in Article ~~51~~**49b**, shall approve the procedure and criteria for **SoHO** donor health evaluations.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 53(3)				
685	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	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	3. SoHO entities that collect ~~SoHOs~~**SoHO** from donors that are subjected to a surgical procedure in order to donate, that are treated with ~~hormones~~**prescribed medication** to facilitate donation, or that donate ~~on a frequent and repeated basis~~**with a frequency that might negatively influence their health**, shall register such **SoHO** donors and the results of their donor health evaluations **and relevant health indicators** in a cross-entity registry that allows interconnection with other such	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	between them.	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.***	registries, as referred to in paragraph 1, point (j).-SoHO entities that manage such registries shall ensure interconnectivity between them**, in accordance with national legislation**.	
Article 53(4)				
686	4. The SoHO entities referred to in paragraph 3 shall ensure that the plan for monitoring donor health after donation, as referred to in paragraph 1, point (k), is proportionate to the risks associated with the donation. They		4. The SoHO entities referred to in paragraph 3 shall ensure that the plan for monitoring **the SoHO** donor health after **living** donation, as referred to in paragraph 1, point (k), is proportionate to the risks associated with the donation. They	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	shall include in the plan the time period during which the monitoring shall continue.		shall include in the plan the time period during which the monitoring shall continue.	
Article 53(5)				
687	5. In case of collection of SoHOs for autologous use or in the context of individuals or couples from whom SoHOs are collected as part of their own current or future medically assisted reproduction treatment, the treating physician shall ensure that any risks associated with the collection are explained to the individuals and are outweighed by the potential benefit for those individuals.		5. ~~In case of collection of SoHOs for autologous use or in the context of individuals or couples from whom SoHOs are collected as part of their own current or future medically assisted reproduction treatment, the treating physician shall ensure that any risks associated with the collection are explained to the individuals and are outweighed by the potential benefit for those individuals.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 53(5a)				
687a			**5a. In case of collection of SoHO from deceased SoHO donors, in accordance with national legislation, the paragraphs 1(a), (b), (e) and (l) shall apply.**	
Article 53(6)				
688	6. The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this	6. The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this	6. The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Regulation in cases where additional standards are needed in order to ensure the protection of donors.	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***.	Regulation in cases where additional standards are needed in order to ensure the protection of donors.	
Article 53(7)				
689	7. Where, in the case of risk to the safety of donors, imperative grounds of urgency so require, the procedure provided for in Article 78 shall apply to delegated acts adopted pursuant to this Article.		7. Where, in the case of risk to the safety of **SoHO** donors, imperative grounds of urgency so require, the procedure provided for in Article 78 shall apply to delegated acts adopted pursuant to this Article.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 54				
690	Article 54 Standards concerning voluntary and unpaid nature of SoHO donations		Article 54 Standards concerning voluntary and unpaid nature of SoHO donations	
Article 54(1)				
691	1. SoHO entities shall not provide financial incentives or inducements to donors or their relatives or any persons granting authorisation on		1. SoHO entities shall not provide financial incentives or inducements to **SoHO** donors or ~~their relatives or~~ any persons granting	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	their behalf, in accordance with national legislation.		~~authorisation~~**consent** on their behalf~~, in accordance with national legislation~~.	
Article 54(2)				
692	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	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*** ~~*through fixed*~~ rate allowances ***set at national***	2. **Where** Member States ~~may~~ allow for the ~~compensation or reimbursement from the SoHO entities to~~**reimbursement of SoHO donors for actual expenses incurred in connection with SoHO donation or for the compensation of SoHO** donors for losses related to their participation in **SoHO** donations**, including** through fixed rate allowances~~. In such case, Member States shall~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	***level. Based on transparent criteria*** ~~*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*~~***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 ~~*allowances*~~***forms of compensation or reimbursement*** to independent bodies that are established in accordance with national	~~establish~~ the conditions for such ~~allowances~~**reimbursement or compensation shall be established** in national legislation, including the setting of an upper limit that ensures ~~that allowances are financially neutral and~~**financial neutrality,** consistent with the standards laid down in this Article. ~~They~~**Member States** may delegate the setting of conditions for such ~~allowances~~**reimbursement or compensation** to independent bodies that are established in accordance with national legislation.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.***		
Article 54(2a)				
692a			**2a. When Member States allow for the reimbursement or compensation of SoHO donors as referred to in paragraph 2, the conditions for such reimbursement or compensation applied by each Member State**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			shall be made available on the EU SoHO Platform and be updated without undue delay if modified.	
Article 54(2b)				
692b			**2b. Member States shall take all necessary measures to ensure that any promotion and publicity activities in support of the donation of SoHO does not include the compensation or reimbursement as a promotional element of such activities.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 54(3)				
693	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.***	3. SoHO entities may ~~compensate or reimburse~~**reimburse or compensate SoHO** donors as provided for by their ~~competent authorities~~**Member States,** pursuant to paragraph 2.	
Article 54(3a)				
693a				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.	**3a. Member States may take appropriate measures to aim for transparency in the fees for technical services required for making SoHO available.**	
Article 54(3b)				
693b		***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.***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Recruitment campaigns and advertisements shall not refer to any compensation.		
Article 54(3c)				
693c		***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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		made available to the public.		
Article 55				
694	Article 55 Standards concerning information to be provided prior to consent or authorisation	Article 55 Standards concerning information to be provided prior to ***informed*** consent or authorisation ***to donate SoHOs***	Article 55 Standards concerning information to be provided prior to consent ~~or authorisation~~	
Article 55(1)				
695	1. SoHO entities shall provide prospective SoHO donors, their		1. SoHO entities shall provide ~~prospective~~**living** SoHO donors **or,**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	relatives or any persons granting authorisation on their behalf, in accordance with national legislation, with all appropriate information relating to the donation and collection process in accordance with national legislation, including a general description of the potential uses and benefits of the donation.		**if applicable,**~~, their relatives or~~ any persons granting ~~authorisation~~**consent** on their behalf, ~~in accordance with national legislation,~~ with all appropriate information relating to the donation ~~and collection~~ process**,** in accordance with national legislation~~, including a general description of the potential uses and benefits of the donation.~~**.**	
Article 55(2)				
696	2. SoHO entities shall provide the information referred to in paragraph 1 before the consent is given or authorisation is granted	2. SoHO entities shall provide the information referred to in paragraph 1 before the consent is given or authorisation is granted	2. SoHO entities shall provide the information referred to in paragraph 1 before the consent ~~is given or authorisation~~**to donate** is	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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~~**SoHO** donors or**, if applicable, any** ~~the~~ persons ~~to~~**granting** consent ~~or authorise the donation. It~~**on their behalf. The information** shall not ~~mislead the prospective donors or persons granting authorisation on their behalf~~**be misleading**, in particular, as to the benefits of the donation to future recipients of the SoHO concerned.	
Article 55(3)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
697	3. In case of living donors, SoHO entities shall provide information regarding:		3. In case of living **SoHO** donors **or, if applicable, persons granting consent on their behalf**, SoHO entities shall provide information regarding:	
Article 55(3), point (a)				
698	(a) the purpose and nature of the donation;		(a) the purpose and nature of the donation;	
Article 55(3), point (aa)				
698a				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			(aa) the intended use of the donated SoHO, specifically covering proven benefits for the future SoHO recipients and any possible research or commercial uses of SoHO, including the use to manufacture products regulated by other Union legislation, as provided for in Article 2(3), to which specific consent shall be granted;	
Article 55(3), point (b)				
699	(b) the consequences and risks of the donation;		(b) the consequences and risks of the donation;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 55(3), point (ba)				
699a			**(ba) the obligation for consent, in accordance with national legislation, in order for SoHO collection to be carried out;**	
Article 55(3), point (c)				
700	(c) the right to withdraw consent and any restrictions on the right to withdraw consent following donation;		(c) the right to ~~withdraw~~**revoke** consent and any restrictions on ~~the~~**that** right ~~to withdraw consent following donation~~**after the collection**;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 55(3), point (d)				
701	(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;	(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;~~	
Article 55(3), point (e)				
702	(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***;	(e) the ~~analytical~~**purpose of the** tests that will be performed in course of the donor health evaluation**, in accordance with**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Article 53(2);	
Article 55(3), point (f)				
703	(f) the right of the donor to receive the confirmed results of the analytical tests when relevant for their health;		(f) the right of the **SoHO** donor **or, if applicable, the person granting consent on their behalf** to receive the confirmed results of the ~~analytical~~ tests when relevant for their health **in accordance with national legislation**;	
Article 55(3), point (g)				
704	(g) the recording and protection of		(g) the recording and protection of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	donor personal and health data and medical confidentiality, including any potential sharing of data in the interest of donor health monitoring and of public health, as necessary and proportionate;		**SoHO** donor**'s** personal ~~and~~**data, including** health data**,** and medical confidentiality, including any potential sharing of data in the interest of **the SoHO** donor health monitoring and of public health, as necessary and proportionate**, in accordance with Article 76**;	
Article 55(3), point (ga)				
704a			**(ga) the possibility that the SoHO donor identity may be revealed to offspring born from their SoHO donation in cases where national legislation grants this right to such offspring;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 55(3), point (h)				
705	(h) the applicable safeguards intended to protect the donor and their personal data;		(h) ~~the~~**other** applicable safeguards ~~intended~~ to protect the **SoHO** donor**.** ~~and their personal data;~~	
Article 55(3), point (i)				
706	(i) the obligation for consent and authorisation, as applicable in the Member State, in order for SoHOs collection to be carried out.		(i) ~~the obligation for consent and authorisation, as applicable in the Member State, in order for SoHOs collection to be carried out.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 55(3a)				
706a			**(3a) In case of deceased SoHO donors, SoHO entities shall provide any persons granting consent to donation, and in accordance with national legislation, with the information referred to in paragraphs 3(a), (aa), and (c).**	
Article 56				
707	Article 56 Implementation of the standards		Article 56 Implementation of the standards	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	concerning SoHO donor protection		concerning SoHO donor protection	
Article 56(1), first subparagraph				
708	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 ~~*may*~~***is empowered to*** adopt ~~*implementing acts*~~***delegated acts in accordance with Article 77 to supplement this Regulation by*** describing particular procedures to be followed and applied to meet	**1.** 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~~**53or** 55, in order to ensure convergent and high levels of **SoHO** donor ~~safety~~**protection**, the Commission may adopt implementing acts describing particular procedures to be followed and applied to meet such standard, or element thereof.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		such standard, or element thereof.		
Article 56(1), second subparagraph				
709	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	*deleted*	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	
Article 56(2)				
710	2. On duly justified imperative grounds of urgency relating to a risk to donor health, the Commission shall adopt	2. ~~*On duly justified imperative grounds of urgency relating to*~~ ***Where, in the case of*** a risk to donor health, ~~*the Commission shall*~~	2. On duly justified imperative grounds of urgency relating to a risk to **SoHO** donor health, the Commission shall adopt	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	immediately applicable implementing acts in accordance with the procedure referred to in Article 79(3).	~~*adopt immediately applicable implementing acts in accordance with the procedure referred to in*~~***imperative grounds of urgency so require, the procedure provided for in Article 78 shall apply to delegated acts adopted pursuant to this*** Article ~~*79(3)*~~.	immediately applicable implementing acts in accordance with the procedure referred to in Article 79(3).	
Article 56(3)				
711	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	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*~~***delegated*** act adopted	3. ~~In order to apply the standards concerning donor protection or elements thereof, referred to in Articles 53, 54 and 55,~~**The implementing acts adopted in accordance with paragraphs 1 and 2 of this Article shall also**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	paragraphs 1 and 2 of this Article.	in accordance with paragraphs 1 and 2 of this Article.	**apply to** SoHO entities ~~shall follow the procedures laid down in any implementing act adopted in accordance with paragraphs 1 and 2 of this Article~~**when they apply the standards or elements concerning SoHO donors protection as referred to in Articles 53 and 55**.	
Article 56(4)				
712	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 ~~*implementing*~~***delegated*** act has been adopted, in order to apply such standards or elements thereof,	4. For those standards concerning **SoHO** donor protection or elements thereof for which no implementing act has been adopted, ~~in order to apply such standards or elements thereof,~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		SoHO entities shall follow ***in order of priority***:	SoHO entities shall ~~follow~~**take into account**:	
Article 56(4), point (a)				
713	(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:	(a) the most recent technical guidelines, as indicated on the EU SoHO Platform ~~referred to in Chapter XI~~, as follows:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 56(4), point (a)(i)				
714	(i) published by the ECDC concerning the prevention of communicable disease transmission through SoHO donation;		(i) published by the ECDC concerning the prevention of communicable disease transmission ~~through SoHO donation~~;	
Article 56(4), point (a)(ii)				
715	(ii) published by the EDQM concerning donor protection other than from transmission of communicable disease through donation;		(ii) published by the EDQM concerning **SoHO** donor protection other than from transmission of communicable ~~disease through donation~~**diseases**;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 56(4), point (b)				
716	(b) other guidelines accepted by competent authorities, as achieving an equivalent level of donor safety as set by the technical guidelines referred to in point (a);		(b) other guidelines**, adopted by Member States, as** ~~accepted by competent authorities, as achieving an equivalent level of donor safety as set by the technical guidelines~~ referred to in **article 29(7a)** point ~~(a)~~**(b)**;	
Article 56(4), point (c)				
717	(c) where the guidelines referred to in points (a) or (b) do not		(c) ~~where the guidelines referred to in points (a) or (b) do not~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	address a particular technical method, other technical methods in line with relevant international guidelines and scientific evidence in peer-reviewed scientific publications, where available.		~~address a particular technical method,~~ other technical methods**, applied in specific circumstances, as referred to in article 29 (7a) point (c)** ~~in line with relevant international guidelines and scientific evidence in peer-reviewed scientific publications, where available~~.	
Article 56(5)				
718	5. In those cases referred to in paragraph 4, point (a), for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall be able to demonstrate to their competent		5. In those cases referred to in paragraph 4, point (a), for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall ~~be able to~~ demonstrate to their **SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorities, for each of the standards or elements thereof, which and to what extent they follow the guidelines referred to in paragraph 4, point (a).		competent authorities, for each of the standards or elements thereof, which and to what extent they follow the **technical** guidelines referred to in paragraph 4, point (a).	
Article 56(6)				
719	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	*deleted*	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 **SoHO** competent authorities, for each of the standards or elements thereof, ~~the equivalence of the other guidelines applied in terms of~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	level of safety, quality and efficacy to the level set by the technical guidelines referred to in paragraph 4, point (a).		~~the level of safety, quality and efficacy to the level set by~~**which and to what extent they follow** the technical guidelines referred to in paragraph 4, point ~~(a)~~**(b)**.	
Article 56(7)				
720	7. In those cases referred to in paragraph 4, point (c), for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall perform a risk assessment to demonstrate that the technical methods applied achieve a high level of donor safety, and record the practice followed to establish the technical methods.		7. In those cases referred to in paragraph 4, point (c), for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall perform a risk assessment to demonstrate that the technical methods applied achieve a high level of ~~donor safety~~**protection of SoHO donors**, and record the practice followed to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	They shall make the assessment and record available for review by their competent authorities during inspection or on specific request of the competent authorities.		establish the technical methods. They shall make the assessment and record available for review by their **SoHO** competent authorities during inspection or on specific request of the **SoHO** competent authorities.	
CHAPTER VII				
721	CHAPTER VII SOHO RECIPIENT AND OFFSPRING PROTECTION		CHAPTER VII SOHO RECIPIENT AND OFFSPRING PROTECTION	
Article 57				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
722	Article 57 Objectives regarding SoHO recipient and offspring protection		Article 57 Objectives regarding SoHO recipient and offspring protection	
Article 57, first paragraph				
723	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.	SoHO entities shall protect the health of SoHO recipients and offspring from medically assisted reproduction from risks posed by SoHO ~~preparations~~**, within the scope of their respective competences**. They shall do so by identifying, minimising or eliminating those risks.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 57, first paragraph a				
723a		***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.***		
Article 58				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
724	Article 58 Standards concerning SoHO recipient and offspring protection		Article 58 Standards concerning SoHO recipient and offspring protection	
Article 58(1)				
725	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,	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	1. SoHO entities shall establish procedures ~~with measures, and, where necessary, combinations of measures,~~ that ensure high levels of safety and quality **of SoHO and that the**~~and demonstrate~~ benefits for SoHO recipients and offspring from medically assisted reproduction ~~that~~ outweigh	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	achieve a high level of assurance that pathogens, toxins or genetic conditions are not transmitted to recipients or offspring from medically assisted reproduction.	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.	~~any~~**residual** risks. They shall, in particular, achieve a high level of assurance that pathogens, toxins or **serious** genetic conditions **that are potentially life-threatening, disabling or incapacitating, attributable to the donated SoHO that was applied,** are not transmitted to **SoHO** recipients or offspring from medically assisted reproduction**, to the extent that national legislation allows for genetic testing**.	
Article 58(1a)				
725a		***1a. Where possible, SoHO entities shall use technologies to reduce***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		clinical risks for SoHO recipients and offspring from medically assisted reproduction, and to improve the quality of SoHOs.		
Article 58(2)				
726	2. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks of communicable disease transmission from SoHO donors to recipients by combining, at least, the following measures:		2. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks of communicable disease transmission from SoHO donors to **SoHO** recipients by combining, at least, the following measures:	
Article 58(2), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
727	(a) reviewing and evaluating the donors' current and past health, travel and relevant behavioural histories to allow the application of temporary or permanent deferrals when risks cannot be fully eliminated by donor testing;		(a) reviewing and evaluating ~~the~~**SoHO** donors' current and past health, travel and relevant behavioural histories **and, where relevant, their family history,** to allow the application of temporary or permanent deferrals when risks cannot be ~~fully eliminated by~~ **minimised by SoHO** donor testing;	
Article 58(2), point (b)				
728	(b) testing of donors for communicable diseases using certified and validated testing	(b) testing of donors for communicable diseases using certified and validated testing	(b) testing of **SoHO** donors for communicable diseases **in laboratories duly accredited,**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	methods;	methods ***or other methods deemed appropriate in EDQM and ECDC guidelines***;	**certified or authorised, by** using certified and validated testing methods **or, when not feasible, by using other methods validated by those laboratories**;	
Article 58(2), point (c)				
729	(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*** ~~*or eliminate*~~ any potential communicable pathogens.	(c) when feasible, ~~using processing technologies~~**taking other measures** that reduce or eliminate any potential communicable pathogens.	
Article 58(3)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
730	3. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks of non-communicable disease transmission, including genetic conditions and cancer, from donors to the recipients or to offspring from medically assisted reproduction by combining, at least, the following measures:		3. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks of non-communicable disease transmission, **when they apply to the SoHO concerned,** including **serious** genetic conditions and cancer, from **SoHO** donors to the **SoHO** recipients or to offspring from medically assisted reproduction by combining, at least, the following measures:	
Article 58(3), point (a)				
731	(a) reviewing the donors' current		(a) reviewing the **SoHO** donors'	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	and past health to allow temporary or permanent deferral of donors that carry a risk of transmitting cancerous cells or other non-communicable diseases that might be passed to a recipient by SoHO application;		current and past health **and, where relevant, their family history,** to allow temporary or permanent deferral of **SoHO** donors that carry a risk of transmitting cancerous cells**, serious genetic conditions** or other non-communicable diseases that might be passed to a **SoHO** recipient by SoHO application;	
Article 58(3), point (b)				
732	(b) where the transmission of genetic conditions is an identified risk, and in particular in the case of medically assisted reproduction with third party donation:		(b) where the transmission of **serious** genetic conditions is an identified risk, and in particular in the case of medically assisted reproduction with third party	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			donation**, and insofar as national legislation allows for those testing**:	
Article 58(3), point (b)(i)				
733	(i) testing donors for those conditions, as indicated by prevalence or severity as presenting the highest risk; or		(i) **routinely** testing **SoHO** donors for ~~those conditions, as indicated by prevalence or severity as presenting the highest risk;~~ ~~or~~**potentially life-threatening, disabling or incapacitating genetic conditions with a significant prevalence in the SoHO donor population; or**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 58(3), point (b)(ii)				
734	(ii) testing prospective recipients to identify any relevant genetic risk, combined with testing donors for such identified genetic conditions to ensure matching that will prevent the concerned condition in the offspring.		(ii) testing ~~prospective~~**SoHO** recipients to identify ~~any relevant genetic risk~~**genetic risk for potentially life-threatening, disabling or incapacitating conditions, according to family history**, combined with testing **third party SoHO** donors for such identified **serious** genetic conditions to ensure matching that will prevent the concerned condition in the offspring.	
Article 58(4)				
735				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	4. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks of communicable or non-communicable disease transmission to the recipients through cross-contamination of donations during collection, processing, storage and distribution by measures that ensure that physical contact between SoHOs from different donors is avoided or, in cases where combining donations is necessary for efficacy of the SoHO preparation, is minimised.		4. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks of communicable or non-communicable disease transmission to the **SoHO** recipients ~~through~~**resulting from** cross-contamination ~~of donations~~**between SoHO** during collection, processing, storage and distribution**. Such** ~~by~~ measures ~~that~~**shall** ensure that physical contact between ~~SoHOs~~**SoHO** from different **SoHO** donors**, SoHO collected from different individuals for future autologous or within couple use,** is avoided or, in cases where ~~combining donations~~**pooling SoHO** is necessary for ~~efficacy~~**effectiveness or feasibility** of the SoHO preparation, is ~~minimised~~**limited to**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			the justifiable level.	
Article 58(5)				
736	5. In the procedures referred to in paragraph 1, SoHO entities shall mitigate risks arising from microbial contamination of SoHOs from the environment, the personnel, the equipment, materials or solutions coming into contact with SoHOs during collection, processing, storage or distribution. SoHO entities shall mitigate such risks by, at least, the following measures:		5. In the procedures referred to in paragraph 1, SoHO entities shall mitigate risks arising from microbial contamination of ~~SoHOs~~**SoHO** from the environment, the personnel, the equipment~~, materials or solutions~~ **and the materials** coming into contact with ~~SoHOs~~**SoHO** during collection, processing, storage or distribution. SoHO entities shall mitigate such risks by, at least, the following measures:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 58(5), point (-a)				
736a			**(-a) Specifying and verifying the hygiene procedures of the personnel of the SoHO entity in contact with the SoHO throughout the SoHO preparation chain;**	
Article 58(5), point (a)				
737	(a) specifying and verifying the cleanliness of collection areas;		(a) specifying and verifying the cleanliness of collection areas**, taking into account the degree of**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			exposure of SoHO to the environment during collection, and of storage areas;	
Article 58(5), point (b)				
738	(b) specifying, based on a structured and documented risk assessment for each SoHO preparation, validating and maintaining a defined air quality in processing areas;		(b) **in cases where SoHO are exposed to the environment during processing,** specifying, based on a structured and documented risk assessment for each SoHO preparation, validating and maintaining a defined air quality in processing areas;	
Article 58(5), point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
739	(c) specifying, procuring and decontaminating equipment, materials and solutions such that their sterility is ensured.		(c) specifying, procuring and decontaminating equipment~~,~~ **and** materials ~~and solutions~~**that come into contact with SoHO during collection, processing, storage or distribution,** such that their sterility**, where necessary,** is ensured~~.~~**;**	
Article 58(5), point (ca)				
739a		***(ca) where possible and appropriate, using methods of detection, inactivation or elimination of microorganisms.***	**(ca) quality control of SoHO for microbial contamination, when appropriate and feasible.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 58(6)				
740	6. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks that any reagents and solutions added to SoHOs or coming in contact with SoHOs during collection, processing, storage and distribution might be transmitted to recipients and have a toxic, or other, detrimental effect on their health by combining, at least, the following measures:		6. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks that any reagents and solutions added to ~~SoHOs~~**SoHO** or coming ~~in~~**into** contact with ~~SoHOs~~**SoHO** during collection, processing, storage and distribution might be ~~transmitted to~~**transferred to SoHO** recipients and have a ~~toxic, or other, detrimental~~**harmful** effect on their health by combining, at least, the following measures:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 58(6), point (a)				
741	(a) specifying such reagents and solutions prior to their purchase;		(a) specifying such reagents and solutions prior to their purchase **and use**;	
Article 58(6), point (b)				
742	(b) verifying any required certifications of such reagents and solutions;		(b) verifying any required certifications of such reagents and solutions;	
Article 58(6), point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
743	(c) demonstrating the removal of such reagents and solutions, when necessary, prior to distribution.		(c) demonstrating the removal of such reagents and solutions, when necessary, prior to distribution.	
Article 58(7)				
744	7. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks that inherent properties of SoHOs, necessary for clinical efficacy, have been changed by any SoHO activity performed, in a manner that renders SoHO preparations ineffective or less effective when applied to recipients by combining,		7. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks that inherent properties of ~~SoHOs~~**SoHO**, necessary for clinical ~~efficacy~~**effectiveness**, have been changed by any SoHO activity performed, in a manner that renders ~~SoHO preparations ineffective~~**the SoHOineffective** or	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	at least, the following measures:		less effective when applied to **SoHO** recipients by combining, at least, the following measures:	
Article 58(7), point (a)				
745	(a) conducting comprehensive process validation and equipment qualification as referred to in Article 41(2), point (a)(vii);		(a) conducting comprehensive process validation and equipment qualification as referred to in Article 41(2), point (a)(vii);	
Article 58(7), point (b)				
746	(b) gathering evidence of efficacy as referred to in Article 41(4),		(b) gathering evidence of ~~efficacy~~**effectiveness** as referred to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	when needed.		in Article 41(4), when needed.	
Article 58(8)				
747	8. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks that SoHOs cause an immune reaction in recipients by combining, at least, the following measures:		8. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks that ~~SoHOs~~**SoHO** cause an **unexpected** immune reaction in **SoHO** recipients by combining, at least, the following measures:	
Article 58(8), point (a)				
748	(a) accurately typing and matching		(a) ~~accurately~~**adequately** typing	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	of patients to donors, when such matching is necessary;		and matching of ~~patients to~~ **SoHO recipients to SoHO** donors, when such matching is necessary;	
Article 58(8), point (aa)				
748a			**(aa) including procedures to reduce, when feasible, those elements of SoHO that stimulate an unintended immune response, as applicable;**	
Article 58(8), point (b)				
749	(b) correctly distributing SoHOs to		(b) correctly distributing	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the correct recipients pursuant to Article 45.		~~SoHOs~~**and applying SoHO** to the correct **SoHO** recipients pursuant to Article 45.	
Article 58(9)				
750	9. In the procedures referred to in paragraph 1, SoHO entities shall mitigate any other risk to the health of SoHO recipients or of offspring from medically assisted reproduction arising from the application of SoHOs or SoHO preparations and not addressed in paragraphs 2 to 8 by applying procedures that they have validated as safely and effectively mitigating the risk concerned or that are		9. In the procedures referred to in paragraph 1, SoHO entities shall mitigate any other **avoidable** risk to the health of SoHO recipients or of offspring from medically assisted reproduction arising from ~~the application of SoHOs or SoHO preparations~~**SoHO applied** and not addressed in paragraphs 2 to 8**,** by applying procedures that they have validated as safely and effectively mitigating the risk concerned or	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	demonstrated as mitigating the risk by published scientific evidence.		that are demonstrated as mitigating the risk by published scientific evidence.	
Article 58(9a)				
750a			**9a. SoHO entities distributing reproductive SoHO from third party donation shall comply with rules established in national legislation regarding the limits of offspring from medically assisted reproduction or applications with reproductive SoHO from a single SoHO donor, if applicable. SoHO entities shall monitor compliance with such limits via registries for gamete donors, in**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			accordance with the national legislation. Without prejudice of the former, when reproductive SoHO are distributed to another Member State, the distributing SoHO entity shall respect the limits imposed by the receiving Member State. **This article does not affect Member States's rules concerning limits on the cross-border distribution of reproductive SoHO.**	
Article 58(9b)				
750b			**9b. When carrying out SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			activities, SoHO entities shall, to the extent possible, make use of technologies that reduce the risk of human error.	
Article 58(10)				
751	10. SoHO entities shall not:		10. SoHO entities shall not:	
Article 58(10), point (a)				
752	(a) apply SoHO preparations to recipients without proven benefit, except in the context of a clinical investigation approved in the	(a) apply SoHO preparations to recipients without proven benefit, except in the context of a clinical investigation approved in the	(a) apply SoHO preparations to **SoHO** recipients without proven benefit, except in the context of **an approved clinical outcome**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	context of a conditional authorisation of the SoHO preparation by their competent authority pursuant to Article 41(4);	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***;	**monitoring plan of a SoHO preparation by their SoHO competent authority pursuant to Article 41(4) or,**~~a clinical investigation approved~~ in the context of ~~a conditional authorisation of the SoHO preparation by their competent authority~~**use pursuant to Article 21(9a), an individual treatment attempt with respect to the clinician's decisions on therapy and in health emergency situations** pursuant to Article ~~41(4)~~**64**;	
Article 58(10), point (b)				
753				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(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;***	(b) apply SoHO preparations to **SoHO** recipients unnecessarily;	
Article 58(10), point (c)				
754	(c) advertise or promote particular SoHO preparations to potential recipients or to healthcare professionals using information that is misleading, in particular, as to the potential use and benefits to		(c) advertise or promote particular SoHO ~~preparations~~ to potential **SoHO** recipients**, or to any persons granting consent on their behalf,** or to healthcare professionals using information that is misleading, in particular, as	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	recipients of the SoHO concerned.		to the potential use and benefits to **SoHO** recipients**, or minimising the associated risks** of the SoHO concerned~~.~~**;**	
Article 58(10), point (ca)				
754a		***(ca) prioritise aesthetic uses over therapeutic uses, especially in the event of a possible shortage of SoHOs.***	**(ca) distribute or apply allogenic SoHO for purposes other than the prevention or treatment of a medical condition, or for medically assisted reproduction.**	
Article 58(11), first subparagraph				
755				

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	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(1), point (f)*~~ ***53***.	**11.** For the measures referred to in paragraphs 2 and 3, SoHO entities shall verify the eligibility of a **SoHO** 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).~~**:**	
Article 58(11), point a				
755a			**(a) an interview with them, in**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			case of donation from a living SoHO donor or, if applicable, with any persons granting consent on their behalf; or	
Article 58(11), point b				
755b			**(b) in case of collection of SoHO from deceased SoHO donors, an interview with a relevant individual that is informed regarding the SoHO donor's health and lifestyle history.**	
Article 58(11), second subparagraph				

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756	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***.	**In case of donation from a living SoHO donor, the interview may also include any part of the interview conducted as part of the evaluation referred to in Article 53(1), point (f).** **For living SoHO** ~~For~~ donors that donate repeatedly, the interviews referred to in the ~~first subparagraph~~**paragraph 11(a)** may be limited to aspects that might have changed and may be replaced with questionnaires. **Interviews shall be added in cases where responses provided in questionnaires indicate changes in relevant information. This shall be without prejudice to 53(1), points (e) and (f) and**	

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			Article 53(2).	
Article 58(12)				
757	12. In cases where SoHO entities or operators regulated by other Union legislation intend to subsequently subject the SoHO to a sterilisation process or another process that reduces the level of the risks described in paragraphs 2 to 5 of this Article, the measures required pursuant to paragraphs 2 and 3 of this Article concerning donor eligibility verification may be adjusted in line with the provisions, guidelines or methods referred to in Article 59.		12. ~~In cases where SoHO entities or operators regulated by other Union legislation intend to subsequently subject the SoHO to a sterilisation process or another process that reduces the level of the risks described in paragraphs 2 to 5 of this Article, the measures required pursuant to paragraphs 2 and 3 of this Article concerning donor eligibility verification may be adjusted in line with the provisions, guidelines or methods referred to in Article 59.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 58(13), first subparagraph				
758	SoHO entities shall document the results of donor eligibility verification referred to in paragraphs 2 and 3, and shall communicate and clearly explain the results of donor eligibility verification to donors or, where relevant, their relatives or any persons granting authorisation on their behalf, in accordance with national legislation.		**13.** SoHO entities shall document the results of **SoHO** donor eligibility verification referred to in paragraphs 2 and 3, and shall communicate and clearly explain the results of **SoHO** donor eligibility verification to **SoHO** donors or, where relevant, ~~their relatives or~~ any persons granting ~~authorisation~~**consent** on their behalf, in accordance with national legislation.	
Article 58(13), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
759	In case of donations after death, SoHO entities shall communicate and explain the results to the relevant persons in accordance with national legislation.		In case of ~~donations after death~~**collection of SoHO from deceased SoHO donors**, SoHO entities shall communicate and explain the results **of the SoHO donor eligibility verification, notably any condition identified in the donor that might imply a risk for the health of SoHO donors relatives or close contacts,** to the relevant persons**,** in accordance with national legislation.	
Article 58(14), first subparagraph				
760				

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	SoHO entities applying SoHOs to recipients shall obtain their consent for the application of SoHOs.		**14.** SoHO entities applying ~~SoHOs to~~ **SoHO to SoHO** recipients shall obtain their consent **or, where relevant, that of any person granting consent on their behalf, in accordance with national legislation,** for the application of ~~SoHOs~~**SoHO**.	
Article 58(14), second subparagraph				
761	SoHO entities shall inform the recipients of, at least, the following:		SoHO entities shall inform the **SoHO** recipients **or any person granting consent on their behalf,** of, at least, the following:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 58(14), second subparagraph, point (a)				
762	(a) the safeguards intended to protect their data and the data of the offspring in the case of medically assisted reproduction;		(a) the safeguards intended to protect ~~their data and the data~~**the personal data, including health data,** of the ~~offspring in the case of~~**SoHO recipients, and where relevant of the offspring from** medically assisted reproduction;	
Article 58(14), second subparagraph, point (b)				
763	(b) the need to report back any unintended reactions following the application of SoHOs or any genetic conditions in offspring in		(b) the need **for SoHO recipients** to report back any unintended reactions following the application of ~~SoHOs~~**SoHO** or any genetic	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the case of medically assisted reproduction with third party donation, in line with Article 47(2).		conditions in offspring ~~in the case of~~**from** medically assisted reproduction with third party donation, ~~in line with~~**as referred to in** Article 47(2).	
Article 58(15)				
764	15. The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this Regulation in cases where additional standards are deemed necessary to ensure the protection of SoHO recipients or offspring from risks posed by the application of SoHO preparations.		15. The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this Regulation in cases where additional standards are deemed necessary to ensure the protection of SoHO recipients or offspring from ~~risks posed by the application of SoHO preparations~~**medically**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			assisted reproduction from risks associated with SoHO.	
Article 58(16)				
765	16. Where, in the case of risk to SoHO recipients and offspring from medically assisted reproduction arising from inadequate levels of safety and quality of SoHOs, imperative grounds of urgency so require, the procedure provided for in Article 78 shall apply to delegated acts adopted pursuant to this Article.		16. Where, in the case of risk to SoHO recipients and offspring from medically assisted reproduction arising from inadequate levels of safety and quality of ~~SoHOs~~**SoHO**, imperative grounds of urgency so require, the procedure provided for in Article 78 shall apply to delegated acts adopted pursuant to this Article.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 59				
766	Article 59 Implementation of the standards concerning recipient and offspring protection		Article 59 Implementation of the standards concerning **SoHO** recipient and offspring protection	
Article 59(1), first subparagraph				
767	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 Article 58, in order to ensure convergent and high levels of the protection of		**1.** 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 Article 58, in order to ensure convergent and high levels of ~~the~~ protection of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHO recipients and offspring from medically assisted reproduction, the Commission may adopt implementing acts describing particular procedures to be applied and followed to meet such standard or element thereof.		SoHO recipients and offspring from medically assisted reproduction, the Commission may adopt implementing acts describing particular procedures to be applied and followed to meet such standard or element thereof.	
Article 59(1), second subparagraph				
768	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	
Article 59(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
769	2. On duly justified imperative grounds of urgency relating to a risk to recipient or offspring health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 79(3).		2. On duly justified imperative grounds of urgency relating to a risk to **SoHO** recipient or offspring health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 79(3).	
Article 59(3)				
770	3. In order to apply the standards or elements thereof, concerning recipient and offspring protection as referred to in Article 58, SoHO entities shall follow the procedures		3. ~~In order to apply the standards or elements thereof, concerning recipient and offspring protection as referred to in Article 58,~~**The implementing acts adopted in**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	laid down in any implementing act adopted in accordance with paragraphs 1 and 2 of this Article.		**accordance with paragraphs 1 and 2 of this Article shall also apply to** SoHO entities ~~shall follow the procedures laid down in any implementing act adopted in accordance with paragraphs 1 and 2 of this~~**when they apply the standards or elements concerning SoHO recipient and offspring protection as referred to in** Article **58**.	
Article 59(4)				
771	4. For those standards or elements of standards concerning recipient and offspring protection for which no implementing act has been	4. For those standards or elements of standards concerning recipient and offspring protection for which no implementing act has been	4. For those standards or elements of standards concerning **SoHO** recipient and offspring protection for which no implementing act has	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	adopted, in order to apply such standards or elements thereof, SoHO entities shall follow:	adopted, in order to apply such standards or elements thereof, SoHO entities shall follow ***in order of priority***:	been adopted, ~~in order to apply such standards or elements thereof,~~ SoHO entities shall ~~follow~~**take into account**:	
Article 59(4), point (a)				
772	(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, as indicated on the EU SoHO Platform ~~referred to in Chapter XI~~, as follows:	
Article 59(4), point (a)(i)				
773	(i) published by the ECDC		(i) published by the ECDC	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	concerning the prevention of communicable disease transmission through human application of SoHOs;		concerning the prevention of communicable disease transmission ~~through human application of SoHOs~~;	
Article 59(4), point (a)(ii)				
774	(ii) published by the EDQM concerning recipient and offspring protection other than from transmission of communicable disease through human application of SoHOs.		(ii) published by the EDQM concerning **SoHO** recipient and offspring protection other than from transmission of communicable disease ~~through human application of SoHOs~~.	
Article 59(4), point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
775	(b) other guidelines accepted by competent authorities as achieving an equivalent level of safety and quality of SoHOs as set by the technical guidelines referred to in point (a);		(b) other guidelines**, adopted by Member States, as** ~~accepted by competent authorities as achieving an equivalent level of safety and quality of SoHOs as set by the technical guidelines~~ referred to in **Article 29(7a)** point ~~(a)~~**(b)**;	
Article 59(4), point (c)				
776	(c) where the guidelines referred to in points (a) or (b) do not address a particular technical method, other technical methods in line with relevant international standards and scientific evidence in		(c) ~~where the guidelines referred to in points (a) or (b) do not address a particular~~**other** technical ~~method, other technical methods in line with relevant international standards and scientific evidence in~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	peer-reviewed scientific publications, where available.		~~peer-reviewed scientific publications, where available.~~**methods, applied in specific circumstances, as referred to in Article 29(7a) point (c)**	
Article 59(5)				
777	5. In those cases referred to in paragraph 4, point (a), for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall be able to demonstrate to their competent authorities, for each of the standards or elements thereof, which and to what extent they		5. In those cases referred to in paragraph 4, point (a), for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall ~~be able to~~ demonstrate to their **SoHO** competent authorities, for each of the standards or elements thereof, which and to what extent they	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	follow the guidelines referred to in paragraph 4, point (a).		follow the **technical** guidelines referred to in paragraph 4, point (a).	
Article 59(6)				
778	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	*deleted*	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 **SoHO** 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~~**which and to what extent they follow**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	4, point (a).		the technical guidelines referred to in paragraph 4, point ~~(a)~~**(b)**.	
Article 59(7)				
779	7. In those cases referred to in paragraph 4, point (c), for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall perform a risk assessment to demonstrate that the technical methods applied achieve a high level of protection of recipients and offspring from medically assisted reproduction and record the practice followed to establish the technical methods. They shall make the assessment		7. In those cases referred to in paragraph 4, point (c), for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall perform a risk assessment to demonstrate that the technical methods applied achieve a high level of protection of **SoHO** recipients and offspring from medically assisted reproduction and record the practice followed to establish the technical methods. They shall make the assessment	

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	and record available for review by their competent authorities during inspection or on specific request of competent authorities.		and record available for review by their **SoHO** competent authorities during inspection or on specific request of **the SoHO** competent authorities.	
Article 60				
780	Article 60 SoHO release		Article 60 SoHO release	
Article 60, first paragraph				
781	A SoHO entity that releases		A SoHO ~~entity~~**establishment** that	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SoHOs for human application or for manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, shall have a procedure in place, under the control of the responsible person for SoHO release as referred to in Article 38, to ensure that the standards or elements of a standard referred to in Article 58 and their implementation, as referred to in Article 59, have been verified and documented prior to release and that all conditions included in any applicable authorisations in accordance with this Regulation have been complied with.		releases ~~SoHOs for human application or for manufacture of products regulated by other Union legislation, or as the starting and raw material thereof~~**SoHO for distribution or export**, shall have a procedure in place, under the control of the ~~responsible person for SoHO release~~**releasing officer,** as referred to in Article ~~38~~**49a, for SoHO release**, to ensure that the standards or elements of a standard referred to in ~~Article~~**Articles** 58 and ~~their implementation, as referred to in Article 59~~**59 and their implementation**, have been verified and documented prior to release and that all conditions included in any applicable authorisations in accordance with this Regulation have been	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			complied with.	
Article 60, second paragraph				
781a			**SoHO processed for autologous or within couple use, without SoHO storage, shall not require release before application if this is envisaged in the SoHO preparation authorisation.**	
Article 61				
782	Article 61		Article 61	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Exceptional release		Exceptional release	
Article 61a				
782a		***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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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,***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.***		
Article 61, new 1.				
783	The physician referred to in Article 51 may authorise the responsible		**new 1.** The physician referred to in Article ~~51~~**49b** may authorise ~~the~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	person for release of SoHOs pursuant to Article 38, to release a certain SoHO preparation for application to a certain recipient in cases where that SoHO preparation does not meet all of the relevant standards and guidelines referred to in Article 59, when the significant potential benefit for the recipient outweighs the risks and no alternative is available. The physician shall authorise such an exceptional release only when the physician treating the intended recipient is in agreement. The physician referred to in Article 51 shall document the decision process in a risk-benefit assessment. In such circumstances, the intended recipient shall be informed of the exceptional release		~~responsible person for release of SoHOs~~**a releasing officer in a SoHO establishment** pursuant to Article ~~38~~**49a**, to release **for distribution** a certain SoHO preparation for **its** application to a certain **SoHO** recipient in cases where that SoHO preparation does not meet all of the relevant standards ~~and guidelines~~ referred to in ~~Article 59, when the significant potential benefit for the recipient outweighs the risks and no alternative is available. The physician shall authorise such an exceptional release only when the physician treating the intended recipient is in agreement. The physician~~**Articles 58 and 59, or their implementation, does not comply with the SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	and shall give consent in accordance with national legislation prior to the SoHO application.		**preparation authorisation provisions in Article 21, or has been imported under the derogation** referred to in Article ~~51 shall document the decision process in a risk-benefit assessment. In such circumstances, the intended recipient shall be informed of~~**28(9), when the potential benefit for the SoHO recipient outweighs the risks and no alternative is available.** The exceptional release ~~and~~**condition** shall ~~give consent in accordance with national legislation prior to the SoHO application~~**be explicitly indicated on the label or in the accompanying documentation associated with the released SoHO preparation**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 61, new 2.				
783a			**new 2. Exceptional release, as referred to in paragraph 1, shall only be authorised in the case of release for distribution, on the basis of a documented request from the physician treating the intended SoHO recipient, where such a request includes a confirmation of full knowledge and agreement of any deviation from the provisions of this Regulation . The physician referred to in Article 49b shall document the decision process in a risk-benefit assessment. In such**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			circumstances, the intended SoHO recipient, or person granting consent on their behalf, shall be informed of the exceptional release and shall give consent in accordance with national legislation prior to the SoHO application. **The SoHO establishment which releases for distribution, in coordination with the SoHO entity which applies the SoHO preparation, when applicable, shall establish a plan for monitoring SoHO recipient's health after application. The plan shall monitor the risks associated with the exceptional SoHO release. The SoHO establishment, in coordination which that SoHO entity, shall lay**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			down a time period during which the monitoring shall continue.	
Article 61, new 3.				
783b			**new 3. Exceptional release, as referred to in paragraph new 1, may also be authorised in the case of release for export, on the basis of a documented request from a treating physician, or from a regulatory authority, in a third country, where such a request includes a confirmation of full knowledge of any deviation from the provisions of this Regulation.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 61, new 4.				
783c			**new 4. Exceptional release, as referred to in paragraph new 1, may also be authorised in the case of certain SoHO to be used for the manufacture of a product regulated under other Union legislation and intended for a specific recipient, in cases where the SoHO do not meet all of the relevant standards and guidelines referred to in Articles 58 or 59 and on the basis of a documented request from the manufacturer, where such a request includes a confirmation**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			of full knowledge and agreement of any deviation from the provisions of this Regulation.	
CHAPTER VIII				
784	CHAPTER VIII SUPPLY CONTINUITY		CHAPTER VIII SUPPLY CONTINUITY	
Article 61a				
784a			**Article -62** **Critical SoHO supply sufficiency**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 61a(1)				
784b			**1. Member States, in collaboration with SoHO National Authorities, SoHO competent authorities and SoHO entities within their respective tasks and within their territories, shall consider all reasonable efforts for a sufficient, adequate and resilient supply of critical SoHO aimed to to appropriately meet recipients' needs.**	
Article 61a(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
784c			**2. Member States shall make all reasonable efforts to facilitate public participation in SoHO donation activities for critical SoHO, with a view to ensuring a broad SoHO donor base and a sufficient, adequate and resilient supply and responsive increases in donation rates when risks of shortage are detected, in accordance with Article 54. In so doing, they shall encourage the collection of SoHO with a strong public and non-profit sector involvement.**	
Article 61a(3)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
784d			**3. Critical SoHO entities shall establish appropriate mechanisms for the continuous monitoring of their stocks of critical SoHO and shall be in a position to communicate this information to SoHO competent authorities that shall establish appropriate mechanisms to receive this information.**	
Article 62				
785	Article 62 Establishment of national SoHO	Article 62 Establishment of national SoHO	Article 62 ~~Establishment of~~ National SoHO	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	emergency plans	emergency plans ***and of plans to ensure continuity of supply of SoHOs***	emergency plans	
Article 62(1)				
786	1. Member States, in collaboration with National SoHO Authorities, shall draw up national SoHO emergency plans setting out measures to be applied without undue delay when the supply situation for critical SoHOs presents or is likely to present a serious risk to human health.	1. Member States, in collaboration with National SoHO Authorities, shall draw up national ~~*SoHO emergency*~~***plans 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 ~~*setting out*~~***shall in particular include*** measures to ~~*be applied without*~~	1. Member States, in collaboration with ~~National~~ SoHO **National** Authorities, shall draw up national SoHO emergency plans setting out measures to be applied without undue delay when the **demand or the** supply situation for critical ~~SoHOs presents or is~~**SoHO present or are** likely to present a serious risk to human health.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		~~*undue delay when*~~***ensure that the donor base is resilient, actions to make a more efficient use of SoHOs, monitoring of trends in*** the supply ~~*situation for*~~***of*** critical SoHOs ~~*presents or is likely to present a serious risk to human health*~~***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***.		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 62(-1), second subparagraph				
786a			**In developing national SoHO emergency plans, Member States shall ensure cooperation and consultation, as appropriate, with their health surveillance bodies, military medical services, civil protection services and other services routinely involved in emergency responses. Member States shall implement national SoHO emergency plans in coordination with other response actions at national or Union level, if adopted, and, where relevant, in a manner consistent**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			with the national prevention, preparedness and response plans developed in accordance with Article 6 of Regulation (EU) 2022/2371 and Directive (EU) 2022/2557.	
Article 62(2)				
787	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	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	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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	encourage the collection of SoHO with a strong public and non-profit sector involvement.	risks of shortage are detected. In so doing, they shall***, among other measures:*** ***(a) include all relevant stakeholders in the drawing up of their national plans;*** ***(b) ensure that there is an adequate number*** ~~*encourage the collection*~~ 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***	~~encourage the collection of SoHO with a strong public and non-profit sector involvement.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		strategies are put in place, including communication campaigns and education programmes; ***(e) establish quantitative collection targets for critical SoHOs***.		
Article 62(2a)				
787a		***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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		monitoring the availability of SoHOs at national level.		
Article 62(3)				
788	3. Member States shall specify the following in the plans referred to in paragraph 1:	3. ***In cases where the availability of SoHOs or products derived from them depends on potential commercial interests, each*** Member ~~*States*~~***State*** shall ~~*specify the following in the plans referred to in paragraph 1:*~~***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***	3. Member States shall ~~specify the following in~~**draw up** the plans referred to in paragraph 1 **laying down the following elements**:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.		
Article 62(3), point (a)				
789	(a) potential risks to the supply of critical SoHOs;	*deleted*	(a) potential risks to the supply of critical ~~SoHOs~~**SoHO**;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 62(3), point (b)				
790	(b) the critical SoHO entities to be involved;	*deleted*	(b) the **designation of** critical SoHO entities **and any other relevant third party** to be involved **in the supply of critical SoHO**;	
Article 62(3), point (ba)				
790a			**(ba) critical SoHO entities emergency plans;**	
Article 62(3), point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
791	(c) the powers and responsibilities of competent authorities;	*deleted*	(c) the powers and responsibilities of **SoHO** competent authorities **in cases of emergency as referred to in paragraph 1**;	
Article 62(3), point (d)				
792	(d) channels and procedures for sharing information between competent authorities including competent authorities of other Member States and other parties concerned, as appropriate;	*deleted*	(d) ~~channels and procedures for sharing~~**the** information **exchanged** between ~~competent authorities including competent~~**SoHO National** Authorities of other Member States and other parties concerned, as appropriate**, via the EU SoHO Platform**;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 62(3), point (e)				
793	(e) a procedure for the development of preparedness plans for specific identified risks, in particular those concerning communicable disease outbreaks;	*deleted*	(e) ~~a procedure for the development of preparedness plans~~**preparedness and response measures** for specific identified risks, in particular those concerning communicable disease outbreaks**, war or terrorist attacks and enviromental disasters**;	
Article 62(3), point (f)				
794				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(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.	*deleted*	(f) a procedure for the assessment and authorisation~~, when justified~~ **in the context of an emergency situation and in accordance with paragraph 4**, of requests from SoHO entities for derogations to the standards defined in Chapters VI and VII~~.~~**;**	
Article 62(3), point (fa)				
794a			**(fa) a mechanism to ensure that in case of emergency, critical SoHO are prioritised according to the specific medical needs.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 62(3a)				
794b		***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.***		
Article 62(4)				
795	4. Member States shall ensure that any derogation granted in	4. ***In order to be able to deal with emergency situations that arise,***	4. Member States shall ensure that any derogation granted in	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	***when the supply situation for critical SoHOs presents or is likely to present a serious risk to human health,*** 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*~~***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;***	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~~ **critical** SoHO.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		(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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		and certain patients in the event of shortages ~~*that are lower than the risk of shortage of the specific SoHO*~~.		
Article 62(4a)				
795a				
Article 62(4b)				
795b				
Article 62(4c)				
795c				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 62(4d)				
795d				
Article 62(5)				
796	5. Member States shall take into account the guidance of the ECDC, for emergencies related to epidemiological outbreaks, and of the guidelines published by the EDQM, for emergency planning in general.	5. Member States shall ~~*take into account the guidance of the ECDC, for emergencies related to epidemiological outbreaks, and of the guidelines published by the EDQM, for emergency planning in general*~~***ensure that any derogation granted in accordance with paragraph 4, point (f), is time-limited and is justified insofar as it***	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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		implies risks that are lower than the risk of shortage of the specific SoHO.		
Article 62(6)				
797	6. Member States shall review regularly their national SoHO emergency plans to take into account changes in the organisation of competent authorities and experience gained from implementing the plans and simulation exercises.	6. Member States shall ~~*review 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*~~***take into account the guidance of the ECDC, for emergencies related to epidemiological outbreaks, in particular to ensure pandemic***	6. Member States shall ~~review regularly~~**cooperate with the critical SoHO entities in the elaboration of** their national SoHO emergency plans **and shall review at least every four years such plans in order** to take into account changes in the **designation of critical SoHO entities, the** organisation of **SoHO** competent authorities and **the** experience gained from implementing the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		prevention and preparedness, and the guidelines published by the EDQM, for emergency planning in general.	plans and simulation exercises.	
Article 62(6a)				
797a			**6a. The SCB, in cooperation with the Commission, shall support a coordinated approach to the implementation of emergency plans in cases where an emergency affects more than one Member States and, in the case of emergencies with an effect beyond the Union, to communicate and collaborate with relevant international**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			organisations and authorities.	
Article 62(7), first subparagraph				
798	The Commission may adopt implementing acts describing:	The Commission ~~*may*~~***is empowered to*** adopt ~~*implementing acts*~~***delegated acts in accordance with Article 77 to supplement this Regulation by*** describing:	~~The Commission may adopt implementing acts describing:~~	
Article 62(7), first subparagraph, point (a)				
799	(a) rules for the establishment of the national SoHO emergency plans provided for in paragraph 1	(a) rules for the establishment of the national ~~*SoHO emergency*~~ plans provided for in paragraph 1	(a) ~~rules for the establishment of the national SoHO emergency plans provided for in paragraph 1~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	to the extent necessary to ensure the consistent and effective management of supply interruptions;	to the extent necessary to ensure the consistent and effective management of supply interruptions;	~~to the extent necessary to ensure the consistent and effective management of supply interruptions;~~	
Article 62(7), first subparagraph, point (b)				
800	(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 EDOM*** in the establishment and operation of national ~~*SoHO emergency*~~ plans~~.~~**;**	(b) ~~the role of stakeholders and the supportive role of the ECDC in the establishment and operation of national SoHO emergency plans.~~	
Article 62(7), second subparagraph				
801				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	*deleted*	~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).~~	
Article 62a				
801a		***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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.***		
Article 63				
802				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 63 Supply alerts for critical SoHOs		Article 63 Supply alerts for critical SoHOs	
Article 63(1)				
803	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	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	1. Critical SoHO entities shall**,** without undue delay**, send** ~~launch~~ a SoHO supply alert to their **SoHO** competent authorities in case of ~~a~~ significant ~~interruptions~~**hortages of supply of critical SoHO**, indicating the underlying ~~reason~~**reasons**, the expected impact on ~~patients~~ **recipients** and any mitigating actions taken**,** including possible alternative supply channels if appropriate.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	critical SoHO is cancelled or postponed due to unavailability and this poses a serious risk to health.	critical SoHO is cancelled or postponed due to unavailability and this poses a serious risk to ***human*** health.	~~Interruptions~~**Shortages** 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.~~**:**	
Article 63(1), point (a)				
803a			**(a) the application of critical SoHO or the distribution of critical SoHO for the manufacture of products defined in other Union legislation, as referred to in Article 2(3), is cancelled or postponed, or is a significant risk of being cancelled or postponed, due to**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			unavailability; and	
Article 63(1), point (b)				
803b			**(b) the situation referred to in point (a) poses a serious risk to health.**	
Article 63(2)				
804	2. Competent authorities that receive an alert referred to in paragraph 1 shall:		2. **SoHO** competent authorities that receive an alert referred to in paragraph 1 shall:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 63(2), point (a)				
805	(a) communicate the SoHO supply alert to their SoHO National Authority;		(a) communicate the SoHO supply alert to their SoHO National Authority;	
Article 63(2), point (b)				
806	(b) implement measures to mitigate the risks, if and to the extent possible; and	(b) implement measures to mitigate the risks~~, *if and*~~ to the extent possible; and	(b) implement **appropriate** measures to mitigate the risks,~~ if and~~ to the extent possible; and	
Article 63(2), point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
807	(c) take into account the information received in accordance with paragraph 1 of this Article in the regular review of their national SoHO emergency plans referred to in Article 62.		(c) take into account the information received in accordance with paragraph 1 of this Article in the ~~regular~~ review of their national SoHO emergency plans referred to in Article 62.	
Article 63(3)				
808	3. The SoHO National Authorities may submit to the EU SoHO Platform the SoHO supply alert received in cases where the supply interruption might affect other Member States or where such interruption might be addressed	3. The SoHO National Authorities ~~*may*~~***shall, without undue delay,*** 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*~~	3. The SoHO National Authorities ~~may~~**shall** submit to the EU SoHO Platform the SoHO supply alert received- in cases where the supply interruption might affect other Member States ~~or~~**and may do so** where such interruption	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	through cooperation between Member States pursuant to Article 62(3), point (d).	~~*be addressed through cooperation between Member States pursuant to Article 62(3), point (d)*~~.	might be addressed through cooperation between Member States pursuant to Article 62(3), point (d).	
Article 64				
809	Article 64 Derogation from the obligations to authorise SoHO preparations in emergency situations	*deleted*	Article 64 Derogation from the obligations to authorise SoHO preparations in **health** emergency situations	
Article 64(1)				
810				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	*deleted*	1. By way of derogation from Article 21, **SoHO** 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.~~**:**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 64(-1), first subparagraph, point (a)				
810a			**(a) the use of those SoHO preparations is in the interest of public health;**	
Article 64(-1), first subparagraph, point (b)				
810b			**(b) the SoHO preparations have a level of quality and safety that is acceptable to what is required by this Regulation or the available data indicate a positive benefit-risk assessment; and**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 64(-1), first subparagraph, point (c)				
810c			**(c) the SoHO preparation is for immediate application to a defined group of recipients, who has no therapeutic alternative, the treatment cannot be postponed and where the prognosis is life-threatening and the expected benefit outweighs the risks.**	
Article 64(-1), second subparagraph				
810d			**The intended SoHO recipients or, where applicable, persons**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			granting consent on their behalf, shall be informed of the derogation and shall give their consent to the immediate application of that SoHO preparation, in accordance with national legislation, prior to the SoHO application itself.	
Article 64(1a)				
810e			**1a. SoHO competent authorities shall:**	
Article 64(-1a), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
810f			**(a) indicate the period of time for which the permit referred to in paragraph 1 is granted and if such SoHO preparations may be distributed to other Member States;**	
Article 64(-1a), point (b)				
810g			**(b) instruct the requesting SoHO entity to submit an application for a SoHO preparation authorisation pursuant to article 41 and collect retrospectively data on the use of the SoHO preparation during the health**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			emergency;	
Article 64(-1a), point (c)				
810h			**(c) inform the SoHO National Authority of the permit as referred to in paragraph 1 provided for the SoHO preparation concerned.**	
Article 64(2)				
811	2. Competent authorities shall inform the SoHO National Authority of the emergency	*deleted*	2. ~~Competent authorities shall inform the SoHO National Authority of the emergency~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.		~~authorisation.~~ The SoHO National Authority shall inform the Commission and the other Member States **via the EU SoHO Platform** 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~~.	
Article 64(2a)				
811a			**2a. In cases where such SoHO preparations might be distributed to other Member States, the SoHO National**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Authority of the receiving Member State shall confirm the validity of the permit within its territory before the distribution takes place.	
Article 65				
812	Article 65 Additional emergency measures by Member States	Article 65 Additional emergency ***and supply*** measures by Member States	Article 65 ~~Additional~~ Emergency ~~measures by Member States~~**derogations in man-made or natural disasters**	
Article 65, first paragraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
813	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.	Member States may ~~take additional measures to the ones~~**allow for derogations from the standards** 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~~**this Regulation when large scale life-threatening situations in the context of man-made or natural disasters, notably in the context of armed conflicts, cannot otherwise be avoided, while ensuring the protection of**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			SoHO donors and SoHO recipients insofar as possible.	
Article 66				
814	Article 66 SoHO entity emergency plans	Article 66 SoHO entity emergency ***and continuity of supply*** plans	Article 66 SoHO entity emergency plans	
Article 66, first paragraph				
815	Each SoHO entity carrying out SoHO activities that concern critical SoHOs shall have a SoHO	Each SoHO entity carrying out SoHO activities that concern critical SoHOs shall have a	Each ~~SoHO entity carrying out SoHO activities that concern critical SoHOs~~**critical SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	entity emergency plan that supports the implementation of the national SoHO emergency plan as referred to in Article 62.	***continuity of supply plan and a*** SoHO entity emergency plan**.** ***Those plans shall support*** ~~*that supports*~~ the implementation of the national ~~*SoHO*~~ ***continuity of supply and SoHO*** emergency ~~*plan*~~***plans*** as referred to in Article 62.	**entity** shall ~~have~~**draw up** a SoHO entity emergency plan that ~~supports the implementation of~~**implements** the national SoHO emergency plan as referred to in Article 62.	
Article 66, first paragraph a				
815a			**Member States may consider that the measures set out in Chapter VIII of this Regulation are at least equivalent to the obligations laid down in Directive (EU) 2022/2557.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
CHAPTER IX				
816	CHAPTER IX SOHO COORDINATION BOARD		CHAPTER IX SOHO COORDINATION BOARD	
Article 67				
817	Article 67 SoHO Coordination Board		Article 67 SoHO Coordination Board	Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 67(1)				
818	1. The SoHO Coordination Board is hereby established in order to promote coordination between Member States concerning the implementation of this Regulation and the delegated and implementing acts adopted pursuant to it, and to support them in that coordination, as well as to facilitate cooperation with stakeholders in that regard.		1. The SoHO Coordination Board **(SCB)** is hereby established in order to promote coordination between Member States concerning the implementation of this Regulation and the delegated and implementing acts adopted pursuant to it, and to support them in that coordination, as well as to facilitate cooperation with stakeholders in that regard.	
Article 67(2)				
819				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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	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 **or other relevant authorities**. The SoHO National Authority may nominate members from other **SoHO** 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~~**SCB may** invite experts and observers to attend its meetings, and may cooperate with other external experts**,** as appropriate. **The SCB may also invite, where relevant,** other Union institutions,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.***	bodies, offices and agencies**. In such cases, they** shall have an observer ~~role~~**status**.	
Article 67(3)				
820	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 ~~*publish*~~***make publicly available*** the membership list ~~*in*~~***on*** the EU SoHO Platform. ***The list setting out the authorities, organisations***	3. Member States shall submit the names and affiliation of their nominated members **and alternates, together with the corresponding declaration of interest for any member and alternate, stating the absence of any financial or other interest,** to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		or bodies to which the SCB participants belong shall be published on the Commission's website.	the Commission~~, who~~**. The Commission** shall publish **in the EU SoHO Platform** the membership list**, the name, the institution of origin and the declaration of interest of each nominated member and alternate** ~~in the EU SoHO Platform~~.	
Article 67(3a)				
820a		***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,***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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).***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 67(4)				
821	4. The Commission shall chair the meetings of the SCB. The chair shall not take part in votes of the SCB.	4. ***The SCB shall be co-chaired by a representative of*** the Commission ***and by one rotating representative of the Member States, who*** shall ~~*chair the meetings of*~~***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.	4. The Commission shall ~~chair~~**co-chair** the meetings of the SCB~~.~~ ~~The chair shall not take part in votes of the SCB~~ **together with the SoHO National Authority of a Member State**.	
Article 67(5)				
822	5. The Commission shall provide		5. The Commission shall provide	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the secretariat for the SCB in accordance with Article 72.		the secretariat for the SCB in accordance with Article 72.	
Article 67(5a)				
822a			**5a. The SCB shall deliberate by consensus as far as possible. If consensus cannot be achieved, the SCB shall deliberate and adopt an opinion or other positions by, at least, a majority of two thirds of the votes of all the Member States. The representative of the Commission co-chairing the SCB shall not take part in votes of the SCB. Each Member State shall have one vote.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 67(6)				
823	6. The rules of procedure of the SCB put forward by the Commission shall, in particular, lay down procedures for the following:		6. **When establishing the SCB,** the rules of procedure of the SCB **shall be** put forward by the Commission**, and shall be approved by the SCB within the first semester of functioning. They** shall, in particular, lay down procedures for the following:	
Article 67(6), point (a)				
824	(a) meeting scheduling;		(a) meeting scheduling;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 67(6), point (aa)				
824a			**(aa) the election of the SoHO National Authority co-chairing the meetings of the SCB and the duration of this mandate;**	
Article 67(6), point (b)				
825	(b) reaching consensus and voting;		(b) ~~reaching consensus~~**deliberation** and voting**, as well as timeframes for issuing opinions, taking into account the complexity of the file, the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			available evidence or other factors;	
Article 67(6), point (c)				
826	(c) the adoption of opinions or other positions, including in cases of urgency;		(c) the adoption of opinions or other positions, including in cases of urgency;	
Article 67(6), point (d)				
827	(d) requesting advice to the SCB, including eligibility criteria for requests for advice to the SCB, and for other communications with the		(d) ~~requesting advice to the SCB, including eligibility criteria for requests~~**the submission of request** for advice to the SCB, and for	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	SCB;		other communications ~~with~~**to** the SCB;	
Article 67(6), point (e)				
828	(e) consultation with advisory bodies established under other relevant Union legislation;		(e) consultation with advisory bodies established under other relevant Union legislation;	
Article 67(6), point (f)				
829	(f) the delegation of routine tasks to working groups, including on vigilance, inspection, traceability, and on the applicability of the		(f) the delegation of ~~routine~~ tasks to working groups, including on vigilance, inspection, traceability, and on the applicability of the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	provisions of this Regulation;		provisions of this Regulation;	
Article 67(6), point (g)				
830	(g) the delegation of ad-hoc tasks to SCB members or technical experts to explore and report to the SCB on specific technical topics, as required;		(g) the delegation of ad-hoc tasks to SCB members or technical experts to explore and report to the SCB on specific technical topics, as required;	
Article 67(6), point (h)				
831	(h) invitation of experts to take part in the work of the SCB working groups and or to		(h) **the** invitation of experts to take part in the work of the SCB working groups and or to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	contribute to ad-hoc tasks, on the basis of their personal experience and expertise or on behalf of recognised Union level or global professional associations;		contribute to ad-hoc tasks, on the basis of their personal experience and expertise or on behalf of recognised Union level or global professional associations;	
Article 67(6), point (i)				
832	(i) invitation of individuals, organisations, or public entities in the capacity of observers;		(i) **the** invitation of individuals, organisations, or public entities in the capacity of observers;	
Article 67(6), point (j)				
833	(j) the rules for declarations	(j) the rules for declarations	(j) the rules for declarations	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	regarding conflict of interests of invited experts;	regarding conflict of interests of ***SCB members, alternates, observers and*** invited experts;	regarding conflict of interests of invited experts;	
Article 67(6), point (k)				
834	(k) the composition and rules of procedure for the working groups and the delegation of ad-hoc tasks.		(k) the composition and rules of procedure for the working groups and the delegation of ad-hoc tasks.	
Article 67(6), point (ka)				
834a		***(ka) make available to the public a summary of the topics discussed***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		at the meetings.		
Article 67(7), first subparagraph				
835	The Commission shall, by means of implementing acts, adopt the necessary measures for the establishment, management and functioning of the SCB.	The Commission shall~~, *by means of implementing acts, adopt*~~ ***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.	**7.** The Commission shall, by means of implementing acts, adopt the necessary measures for the establishment~~, management and functioning~~ **and management** of the SCB.	
Article 67(7), second subparagraph				
836				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	*deleted*	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	
Article 67(7a)				
836a		***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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.***		
Article 67(7b)				
836b		***7b. Members of the SCB, experts and observers shall declare, at each meeting, any specific interests which could be considered to be prejudicial to***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		their independence with respect to the items on the agenda. Such declarations shall be made available to the public.		
Article 68				
837	Article 68 Tasks of the SoHO Coordination Board		Article 68 Tasks of the SoHO Coordination Board	
Article 68(1)				
838	1. The SCB shall assist the		1. The SCB shall assist ~~the~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Member States' competent authorities regarding any issue related to the coordination of implementation of this Regulation and the implementing and delegated acts adopted pursuant to it, by:		~~Member States'~~**SoHO** competent authorities regarding ~~any issue related to the coordination of~~**the coordinated** implementation of this Regulation and the implementing and delegated acts adopted pursuant to it, by:	
Article 68(1), point (a)				
839	(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(2) first sub-paragraph*~~***14(1) and (2)***, on the regulatory status under this	(a) preparing opinions**,** at the request of **SoHO** competent authorities**, via their SoHO National Authorities,** in accordance with Article 14(2) first sub-paragraph, on the regulatory status under this Regulation of a substance, product or activity and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Regulation of a substance, product or activity and transmitting its opinions to the compendium;	~~transmitting its~~**including such** opinions ~~to the~~**in the SoHO** compendium;	
Article 68(1), point (aa)				
839a			**(aa) By [one year after the date of entry into force publication of this Regulation], the SCB shall draw up a list of the existing products, substances, or activities for which an opinion on the regulatory status under this Regulation is not available and is needed to avoid risks to the safety of SoHO donors, SoHO recipients or offspring from medically assisted reproduction,**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			or of a compromised access of recipients to safe and effective treatments. This list shall be updated at the discretion of the SCB;	
Article 68(1), point (b)				
840	(b) when preparing the opinions referred to in point (a) of this paragraph, initiating, at Union level, a consultation with equivalent advisory bodies established in other relevant Union legislation in accordance with Article 14(2) second sub-paragraph, and including in the compendium the opinions		(b) when preparing the opinions referred to in point (a) of this paragraph, initiating, at Union level, a consultation with equivalent advisory bodies established in other relevant Union legislation in accordance with Article 14(2) second sub-paragraph, and including in the compendium the opinions	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	concerning the Union legislation to be applied in cases where there is agreement with the equivalent advisory bodies;		concerning the Union legislation to be applied in cases where there is agreement with the equivalent advisory bodies;	
Article 68(1), point (c)				
841	(c) exchanging and documenting best practices on the implementation of the SoHO supervisory activities, and publishing agreed and documented best practices on the EU SoHO Platform;		(c) ~~exchanging and documenting~~**documenting and publishing** best practices on the implementation of ~~the~~ SoHO supervisory activities~~, and publishing agreed and documented best practices~~ on the EU SoHO Platform;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 68(1), point (d)				
842	(d) recording information notified in accordance with Article 14(3), and including such information in the compendium;		(d) recording information notified in accordance with Article 14(3), and including such information in the **SoHO** compendium;	
Article 68(1), point (da)				
842a			**(da) defining criteria of 'critical SoHO' and the criteria to be qualified as a critical SoHO entity, providing and updating a list of 'critical SoHO', and making such information available on the EU SoHO**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Platform;	
Article 68(1), point (db)				
842b			**(db) documenting practices among Member States for establishing the conditions for reimbursement and compensation as referred to in article 54(2);**	
Article 68(1), point (dc)				
842c			**(dc) providing assistance and advice for the cooperation**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			between SoHO competent authorities and other competent authorities, with a view to ensuring coherent oversight when SoHO change regulatory status, as provided for in article 14(5);	
Article 68(1), point (dd)				
842d			**(dd) providing advice on the minimum necessary evidence for the authorisation of a particular SoHO preparation, as referred to in article 22(4);**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 68(1), point (e)				
843	(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;	(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;	
Article 68(1), point (f)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
844	(f) collaborating for the effective organisation of joint inspections and joint SoHO preparation authorisations involving more than one Member State;		(f) collaborating for the effective organisation of joint inspections and joint SoHO preparation ~~authorisations~~**assessment** involving more than one Member State;	
Article 68(1), point (fa)				
844a			**(fa) providing advice to the Commission on the functional specifications of the EU SoHO Platform;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 68(1), point (fb)				
844b			**(fb) in cooperation with the Commission, supporting a coordinated approach to the implementation of emergency plans in cases where an emergency affects more than one Member States or in the case of emergencies with an effect beyond the Union, in accordance with Article 62 (6);**	
Article 68(1), point (fa)				
844c		***(fa) ensuring coordination***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		regarding continuity and sufficiency of supply of critical SoHOs;		
Article 68(1), point (g)				
845	(g) providing assistance in other matters related to the coordination as referred to above.		(g) providing assistance in other matters related to the coordination ~~as referred to above~~**or the implementation of this Regulation**.	
Article 68(1), point (ga)				
845a		***(ga) in the event of a SoHO-***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.		
Article 68(2), first subparagraph				
846	The Commission may adopt implementing acts describing criteria and procedures for the consultation of advisory groups established under other relevant Union legislation.		**2.** The Commission may adopt implementing acts describing criteria and procedures for the consultation of advisory ~~groups established~~**bodiesestablished** under other relevant Union legislation **for the performance of**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			the SCB tasks.	
Article 68(2), second subparagraph				
847	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	
CHAPTER X				
848	CHAPTER X UNION ACTIVITIES		CHAPTER X UNION ACTIVITIES	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 69				
849	Article 69 Union training and exchange of competent authorities' personnel		Article 69 Union training and exchange of competent authorities' personnel	
Article 69(1), first subparagraph				
850	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 ~~*concerned*~~.	The Commission shall**, in cooperation with SoHO National Authorities,** organise Union training ~~in cooperation with the Member States concerned~~**on the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			implementation of this Regulation.	
Article 69(1), second subparagraph				
851	In the Union training organised, the Commission shall cover at least, the following topics, as appropriate:		~~In the Union training organised, the Commission shall cover at least, the following topics, as appropriate:~~	
Article 69(1), second subparagraph, point (a)				
852	(a) the implementation of this Regulation;		(a) ~~the implementation of this Regulation;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 69(1), second subparagraph, point (b)				
853	(b) procedures relevant for the SoHO supervisory activities of the competent authorities;		(b) ~~procedures relevant for the SoHO supervisory activities of the competent authorities;~~	
Article 69(1), second subparagraph, point (c)				
854	(c) the functionality and use of the EU SoHO Platform;		(c) ~~the functionality and use of the EU SoHO Platform;~~	
Article 69(1), second subparagraph, point (d)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
855	(d) other knowledge and skills relevant to facilitate SoHO supervisory activities.		(d) ~~other knowledge and skills relevant to facilitate SoHO supervisory activities.~~	
Article 69(2)				
856	2. The Commission may provide Union training to personnel of competent authorities of EEA Member States and of countries that are applicants or candidates for Union membership and to personnel of bodies to whom specific responsibilities for SoHO activities have been delegated. It may organise aspects of the		2. The Commission may provide Union training to personnel of **SoHO** competent authorities of EEA Member States ~~and~~**,** of countries that are applicants or candidates for Union membership and to personnel of bodies to whom specific responsibilities for SoHO **supervisory** activities have been delegated. It may organise	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	training in collaboration with international organisations and regulators working in the field of SoHOs.		aspects of the training in collaboration with international organisations and regulators working in the field of SoHOs.	
Article 69(3)				
857	3. Competent authorities shall ensure that the knowledge acquired through the Union training activities referred to in paragraph 1 of this Article is disseminated as necessary and appropriately used in the personnel training activities referred to in Article 16.		3. **SoHO** competent authorities shall ensure that the knowledge **and materials** acquired through the Union training activities referred to in paragraph 1 of this Article ~~is~~**are** disseminated as necessary and appropriately used in the personnel training activities referred to in Article ~~16~~**9**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 69(4)				
858	4. The Commission may support, in cooperation with the Member States, the organisation of programmes for the exchange of competent authorities' personnel between two or more Member States and for the temporary secondment of personnel from one Member State to the other as part of personnel training.		4. The Commission may support, in cooperation with the ~~Member States~~**SoHO National Authorities**, the organisation of programmes for the exchange of **SoHO** competent authorities' personnel between two or more Member States and for the temporary secondment of personnel from one Member State to the other as part of personnel training.	
Article 69(5)				
859				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	5. The Commission shall maintain a list of the competent authority personnel that have successfully completed the Union training referred to in paragraph 1, with a view to facilitating joint activities, in particular those referred to in Articles 23, 31, and 71. The Commission shall make this list available to the Member States.		5. The Commission shall maintain a list of the **SoHO** competent authority personnel that have successfully completed the Union training referred to in paragraph 1, with a view to facilitating joint activities, in particular those referred to in Articles 23, 31, and ~~71~~**70**. -The Commission shall make this list available to the ~~Member States~~**SoHO National Authorities**.	
Article 69(6)				
860	6. The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this		6. ~~The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Regulation by laying down rules on the organisation of the training activities referred to in paragraph 1 and of the programmes referred to in paragraph 4.		~~Regulation by laying down rules on the organisation of the training activities referred to in paragraph 1 and of the programmes referred to in paragraph 4.~~	
Article 70				
861	Article 70 Commission controls in Member States		Article 70 Commission ~~controls in Member States~~**verifications**	
Article 70(1)				
862				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	1. The Commission shall perform controls, including audits, in the Member States to verify the effective application of the requirements relating to:		1. The Commission shall perform ~~controls, including audits, in the~~**verifications to confirm whether** Member States ~~to verify the effective application of~~ **effectively apply** the requirements relating to:	
Article 70(1), point (a)				
863	(a) competent authorities and delegated bodies provided for in Chapter II;		(a) **SoHO** competent authorities and delegated bodies provided for in Chapter II;	
Article 70(1), point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
864	(b) the SoHO supervisory activities provided for in Chapter III as carried out by competent authorities and delegated bodies;		(b) the SoHO supervisory activities ~~provided for in Chapter III as~~ carried out by **SoHO** competent authorities and delegated bodies;	
Article 70(1), point (c)				
865	(c) the notification and reporting requirements of this Regulation.		(c) the notification and reporting requirements of this Regulation.	
Article 70(2)				
866				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	2. The Commission shall organise the controls referred to in paragraph 1 in cooperation with the Member States, and shall carry them out in a manner that avoids unnecessary administrative burden.		2. The Commission shall organise the ~~controls~~**verifications** referred to in paragraph 1 in cooperation with the ~~Member States~~**SoHO National Authorities**, and shall carry them out in a manner that avoids unnecessary administrative burden.	
Article 70(3)				
867	3. When performing the controls referred to in paragraph 1, the Commission experts shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c), on inspection, vigilance and		3. When performing the ~~controls~~**verifications** referred to in paragraph 1, the Commission ~~experts~~ shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c), on	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	any other SoHO supervisory activities as needed.		~~inspection, vigilance and any other~~ SoHO supervisory activities ~~as needed~~.	
Article 70(4)				
868	4. Experts from the Member States may assist the Commission experts in carrying out the controls referred to in paragraph 1. The Commission shall select the experts from the Member States, whenever possible from the list referred to in Article 69(5), and shall give them the same rights of access as the Commission experts.		4. ~~Experts from the Member States may assist~~ The Commission ~~experts~~**,** in carrying out the ~~controls~~**verifications** referred to in paragraph 1~~. The Commission shall select the~~**, may be supported by** experts from the ~~Member States~~**SoHO competent authorities selected**, whenever possible**,** from the list referred to in Article 69(5)~~, and~~**. Experts from the SoHO competent authorities**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			shall ~~give them~~**be given** the same rights of access as the Commission ~~experts.~~	
Article 70(5)				
869	5. Following each control, the Commission shall:		5. Following each ~~control~~**verification**, the Commission shall:	
Article 70(5), point (a)				
870	(a) prepare a draft report on the findings and, where appropriate, include recommendations on how		(a) prepare a draft report on the findings and, where appropriate, include recommendations ~~on how~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	best to address the shortcomings;		~~best to address~~**addressing** the shortcomings **identified**;	
Article 70(5), point (b)				
871	(b) send a copy of the draft report referred to in point (a) to the concerned Member State for its comments;		(b) send a copy of the draft report referred to in point (a) to the concerned ~~Member State~~**SoHO National Authority** for its comments;	
Article 70(5), point (c)				
872	(c) take the comments of the Member State referred to in point		(c) take the comments ~~of the Member State~~ referred to in point	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(b) into account in preparing the final report; and		(b) into account in preparing the final report; and	
Article 70(5), point (d)				
873	(d) make publicly available the final report referred to in point (c) and the comments of the Member State referred to in point (b).		(d) make publicly available ~~the final report referred to in point (c) and the comments~~**a summary** of the ~~Member State referred to in point (b)~~**final report on the EU SoHO Platform**.	
Article 71				
874				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 71 Cooperation with the EDQM		Article 71 Cooperation with the EDQM	
Article 71, first paragraph				
875	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***	The ~~Commission~~**Union** shall establish and maintain **a framework of** cooperation with the EDQM**, notably** in relation to the guidelines published by the EDQM.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		be without prejudice to Union law and shall take into account Union principles on transparency and stakeholder participation.		
Article 71, first paragraph a				
875a		***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.***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 72				
876	Article 72 Assistance by the Union		Article 72 Assistance by the Union	
Article 72(1)				
877	1. To facilitate the fulfilment of the requirements provided for in this Regulation, the Commission shall support implementation by:		1. To facilitate the fulfilment of the requirements provided for in this Regulation, the Commission shall support implementation by:	
Article 72(1), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
878	(a) providing secretariat and technical, scientific and logistic support to the SCB and its working groups;		(a) providing secretariat and technical, scientific and logistic support to the SCB and its working groups;	
Article 72(1), point (b)				
879	(b) funding Commission controls in Member States, including the costs of Member State experts assisting the Commission in such controls;		(b) funding Commission ~~controls~~**verifications** in Member States, including the costs of Member State experts assisting the Commission ~~in such controls~~;	
Article 72(1), point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
880	(c) providing funding from the relevant Union programme in support of public health to:		(c) providing funding from the relevant Union ~~programme~~**programmes** in support of public health to:	
Article 72(1), point (c)(i)				
881	(i) support collaborative work between competent authorities and organisations representing groups of SoHO entities and SoHO professionals with the aim to facilitate effective and efficient implementation of this Regulation, including for training activities;		(i) support collaborative work between **SoHO** competent authorities and organisations representing groups of SoHO entities and SoHO professionals with the aim to facilitate effective and efficient implementation of this Regulation, including for training activities **referred to in**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			article 69(1) and programmes for the exchange of SoHO competent authorities' personnel referred to in article 69(4);	
Article 72(1), point (c)(ii)				
882	(ii) co-finance a cooperation agreement with the EDQM to support the development and updating of technical guidelines supporting the coherent implementation of this Regulation.		(ii) ~~co-finance a cooperation agreement~~**if applicable, support financially in accordance** with the ~~EDQM to support~~**relevant Union programmes,** the development and updating of technical guidelines ~~supporting the coherent~~**with a view to contributing to the** implementation of this Regulation.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 72(1), point (ca)				
882a			**(ca) establishing, managing and maintaining the EU SoHO Platform.**	
Article 72(1), point (cb)				
882b			**(cb) facilitating the cooperation between the SCB and advisory bodies established by other Union legislation as referred to in Article 2(3), in particular through the organisation of joint meetings on the experience acquired with the application of**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Article 68(1)(b).	
Article 72(2)				
883	2. With regard to the support referred to in paragraph 1, point (a), the Commission shall, in particular, organise the meetings of the SCB and its working groups, the travel of members of the SCB, reimbursement and special allowances for scientific experts that participate in those meetings, and ensure the appropriate follow-up.		2. With regard to the support referred to in paragraph 1, point (a), the Commission shall, in particular, organise the meetings of the SCB and its working groups, the travel ~~of members of the SCB~~, reimbursement and special allowances for ~~scientific experts that participate~~**participants** in those meetings~~, and ensure the appropriate follow-up~~.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 72(3)				
884	3. Upon request from Member States, technical support may be provided, through the Technical Support Instrument established by Regulation (EU) 2021/240 of the European Parliament and of the Council[1], for the reform of national or regional SoHO supply supervision, provided those reforms aim to achieve compliance with this Regulation. _____ 1. Regulation (EU) 2021/240 of the European Parliament and of the Council of 10 February 2021 establishing a Technical Support		3. Upon request from Member States, technical support may be provided, through the Technical Support Instrument established by Regulation (EU) 2021/240 of the European Parliament and of the Council[1], for the reform of national or regional SoHO supply supervision, provided those reforms aim to achieve compliance with this Regulation. _____ 1. Regulation (EU) 2021/240 of the European Parliament and of the Council of 10 February 2021 establishing a Technical Support	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Instrument (OJ L 57, 18.2.2021, p. 1).		Instrument (OJ L 57, 18.2.2021, p. 1).	
Article 72(4)				
885	4. In order to perform the activities referred to in paragraph 1 to the mutual benefit of the Commission and of the beneficiaries, relating to preparation, management, monitoring, audit, and control, as well as to support expenditure, the Commission shall have recourse to the technical and administrative assistance it might need.		4. In order to perform the activities referred to in paragraph 1 to the mutual benefit of the Commission and of the beneficiaries, relating to preparation, management, monitoring~~, audit, and control~~ **and verifications**, as well as to support expenditure, the Commission shall have recourse to the technical and administrative assistance it might need.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
CHAPTER XI				
886	CHAPTER XI EU SoHO PLATFORM		CHAPTER XI EU SoHO PLATFORM	
Article 73				
887	Article 73 Establishment, management and maintenance of the EU SoHO Platform		Article 73 Establishment, management and maintenance of the EU SoHO Platform	
Article 73(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
888	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.	1. The Commission shall establish, manage and maintain ~~the EU SoHO~~ **a digital** platform ~~-~~ to facilitate effective and efficient exchange of information concerning SoHO activities in the Union, as provided for in this Regulation **("EU SoHO Platform")**.	
Article 73(2)				
889	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	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	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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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~~.	~~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.~~	
Article 73(3)				
890	3. The processing of personal data by the Member States and the Commission through the EU SoHO Platform and any one of its components shall only be carried out for the purpose of performing SoHOs related activities in		3. The processing of personal data**, including health data,** by the **SoHO entities, the SoHO competent authorities, the** Member States and the Commission through the EU SoHO Platform ~~and any one of its~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	accordance with this Regulation and in compliance with the applicable data protection legislation.		~~components shall only be carried out~~**shall only be carried out in cases where it is necessary** for the ~~purpose of performing SoHOs related activities in accordance with~~**performance of the tasks, the achievement of the objectives and the fulfilment of obligations as laid down in** this Regulation**. The processing of personal data, including health data, shall be carried out in accordance** ~~and in compliance~~ with the applicable **Union** data protection legislation.	
Article 73(4)				
891	4. The Commission shall adopt	4. The Commission shall adopt	4. ~~The Commission shall adopt~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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***.	~~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.~~	
Article 73(5)				
892	5. The Commission shall provide instructions for SoHO entities and		5. The Commission shall provide instructions**, materials and**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	competent authorities on the correct use of the EU SoHO Platform.		**training on the correct use of the EU SoHO Platform** for SoHO ~~entities and competent authorities~~**competent authorities via their SoHO National Authority. The Commission, where appropriate and in cooperation with their SoHO National Authority, shall provide instructions and training for SoHO entities** on the correct use of the EU SoHO Platform. **Those training materials shall be available on EU SoHO Platform.**	
Article 73(5a)				
892a		***5a. In order in particular to***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).		
Article 74				
893	Article 74 General functionalities of the EU SoHO Platform		Article 74 General functionalities of the EU SoHO Platform	
Article 74(1)				
894	1. The EU SoHO Platform shall		1. The EU SoHO Platform shall	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	enable SoHO entities, competent authorities, Member States and the Commission to process information, data and documents concerning SoHOs, including the submission, retrieval, storage, management, handling, exchange, analysis, publication and deletion of such data and documents as provided for in this Regulation.		enable SoHO entities, **SoHO** competent authorities, Member States and the Commission to process information, data and documents concerning ~~SoHOs~~**SoHO, and SoHO activities**, including the submission, retrieval, storage, management, handling, exchange, analysis, publication**, tracking** and deletion of such data and documents as provided for in this Regulation.	
Article 74(2)				
895	2. The EU SoHO platform shall also provide a secure environment	2. The EU SoHO platform shall also provide a secure environment	2. The EU SoHO Platform shall ~~also~~ provide a secure ~~environment~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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*** ~~*and rapid*~~ 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.	~~for the~~ **channel for restricted** exchange of information ~~between competent authorities and the Commission~~**and data**, 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.~~**:**	
Article 74(2), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
895a			**(a) between Member States' SoHO National Authorities;**	
Article 74(2), point (b)				
895b			**(b) between two SoHO competent authorities within the Member State or between a SoHO competent authority and its SoHO National Authority;**	
Article 74(2), point (c)				
895c				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			(c) between SoHO National Authorities and the Commission, in particular in relation to activity data concerning SoHO activities of SoHO entities, the summaries of notifications and investigation reports of confirmed SAR or SAE, SoHO rapid alerts and SoHO supply alerts;	
Article 74(2), point (d)				
895d			**(d) between SoHO National Authorities and the SCB;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 74(2), point (e)				
895e			**(e) between SoHO National Authorities and the ECDC, in relation to alerts related to communicable diseases, where applicable; and**	
Article 74(2), point (f)				
895f			**(f) between SoHO entities and their respective SoHO competent authorities, when the SoHO competent authorities choose to use the EU SoHO Platform for such exchanges.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 74(2a)				
895g			**2a. The EU SoHO Platform shall provide public access to information regarding:**	
Article 74(2a), point (a)				
895h			**(a) the registration and authorisation status of SoHO entities and their identification code and the SoHO establishment identification code;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 74(2a), point (b)				
895i			**(b) authorised SoHO preparations;**	
Article 74(2a), point (c)				
895j			**(c) the annual Union SoHO Activity Report and annual Union SoHO vigilance report, in aggregated and anonymised formats, after their approval by SoHO National Authorities;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 74(2a), point (d)				
895k			**(d) relevant best practices agreed and documented by the SCB;**	
Article 74(2a), point (e)				
895l			**(e) technical guidelines for quality management published by the EDQM;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 74(2a), point (f)				
895m			**(f) technical guidelines concerning the prevention of communicable and non-communicable diseases published by the ECDC and the EDQM, and concerning SoHO donor, SoHO recipient and offspring protection;**	
Article 74(2a), point (g)				
895n			**(g) the name, the institution of origin and the declaration of interest of each SCB member**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			and alternate;	
Article 74(2a), point (h)				
895o			**(h) the SoHO compendium.**	
Article 74(2a)				
895p		***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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.		
Article 74(2b)				
895q		***2b. In the event of a SoHO-related health emergency or for the purpose of preventing***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.		
Article 74(2c)				
895r		***2c. The EU SoHO Platform shall contain a record of SoHO clinical studies and their results, as referred to in Article 36a.***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 74(3), first subparagraph				
896	The Commission shall adopt implementing acts laying down technical specifications for the EU SoHO Platform, including its functions, the roles and responsibilities of each of the parties listed in paragraph 1, the retention periods for personal data and the technical and organisational measures to ensure the safety and security of personal data processed.	The Commission shall adopt ~~*implementing acts*~~***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	**3.** The Commission shall adopt implementing acts laying down technical specifications for the EU SoHO Platform, ~~including its~~ **covering its management, maintenance,** functions, **including its minimal functionalities,** 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**, including health data**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		ensure the safety and security of personal data processed.		
Article 74(3), second subparagraph				
897	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	*deleted*	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	
Article 74(3a)				
897a			**3a. When the minimal operational functionalities required for the functioning of**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			the EU SoHO Platform as defined through the procedure in paragraph 3 have been fulfilled, the Commission shall publish a notice to that effect in the Official Journal of the European Union.	
CHAPTER XII				
898	CHAPTER XII PROCEDURAL PROVISIONS		CHAPTER XII PROCEDURAL PROVISIONS	
Article 75				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
899	Article 75 Confidentiality		Article 75 Confidentiality	
Article 75(1)				
900	1. Unless otherwise provided for in this Regulation or in national legislation on confidentiality, and without prejudice to Regulation (EC) No 1049/2001 of the European Parliament and of the Council[1], each party involved in the application of this Regulation shall respect the confidentiality of information and data obtained in		1. Unless otherwise provided for in this Regulation or in national legislation on confidentiality, and without prejudice to Regulation (EC) No 1049/2001 of the European Parliament and of the Council[1], each party involved in the application of this Regulation shall respect the confidentiality of information and data obtained in	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	carrying out their tasks in order to protect the following: _____ 1. 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).		carrying out their tasks in order to protect the ~~following:~~**effective implementation of this Regulation, in particular for the purpose of authorisations, inspections, investigations or Commission verifications.** _____ 1. 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).	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 75(1), point (a)				
901	(a) personal data in accordance with Article 76;	(a) ***natural persons with regard to the processing of*** personal data in accordance with Article 76;	(a) ~~personal data in accordance with Article 76;~~	
Article 75(1), point (b)				
902	(b) the effective implementation of this Regulation, in particular for the purpose of authorisations, inspections, investigations or Commission controls.		(b) ~~the effective implementation of this Regulation, in particular for the purpose of authorisations, inspections, investigations or Commission controls.~~	
Article 75(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
903	2. Information may be exchanged on a confidential basis between competent authorities and between competent authorities and the Commission, but shall not be disclosed without the prior agreement of the authorities from whom that information originates.		2. Information **and data** may be exchanged on a confidential basis between **SoHO** competent authorities and between ~~competent~~**SoHO National** Authorities and the Commission, ~~but~~**and** shall not be disclosed without the prior agreement of the **SoHO competent** authorities from whom that information originates.	
Article 75(3)				
904	3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States	3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States	3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	and competent authorities with regard to the exchange of information and the dissemination of alerts, nor the obligations of persons to provide information under national criminal law ***or other applicable law, including on access to information***.	and **SoHO** 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.	
Article 75(4)				
905	4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries as necessary and proportionate for the protection of human health.		4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries **with which they have concluded bilateral or multilateral confidentiality arrangements,** as	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			necessary and proportionate for the protection of human health.	
Article 75(5)				
906	5. Competent authorities may publish or make otherwise available to the public the outcome of SoHO supervisory activities regarding individual SoHO entities provided that the following conditions are met:		5. **Without prejudice to national legislation on the publication of the outcome of SoHO supervisory activities, SoHO** competent authorities may publish or make otherwise available to the public the outcome of SoHO supervisory activities regarding individual SoHO entities provided that the following conditions are met:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 75(5), point (a)				
907	(a) the SoHO entity concerned is given the opportunity to comment on the information that the competent authority intends to publish or make otherwise available to the public, prior to its publication or release, taking into account the urgency of the situation;		(a) the SoHO entity concerned is given the opportunity to comment on the information that the **SoHO** competent authority intends to publish or make otherwise available to the public, prior to its publication or release, taking into account the urgency of the situation;	
Article 75(5), point (b)				
908	(b) the information which is published or made otherwise		(b) the information **or data** which is published or made otherwise	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	available to the public takes into account the comments expressed by the SoHO entity concerned or is published or released together with such comments;		available to the public takes into account the comments expressed by the SoHO entity concerned or is published or released together with such comments;	
Article 75(5), point (c)				
909	(c) the information concerned is made available in the interest of public health protection and is proportionate to the severity, extent and nature of the associated risk.		(c) the information **or data** concerned is made available in the interest of public health protection and is proportionate to the severity, extent and nature of the associated risk~~.~~**;**	
Article 75(5), point (ca)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
909a			**(ca) the information or data made available to the public does not unnecessarily undermine the protection of legal rights of the SoHO entity or any other natural or legal person;**	
Article 75(5), point (cb)				
909b			**(cb) the information or data made available to the public does not undermine the protection of court proceedings and legal advice.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 75(6)				
910	6. Regarding information or data that is, by its nature, covered by professional secrecy and that is obtained by competent authorities in carrying out SoHO supervisory activities, competent authorities may only publish or make that information or data available to the public, provided that the following conditions are met:		6. Regarding information or data that is, by its nature, covered by professional secrecy and that is obtained by **SoHO** competent authorities in carrying out SoHO supervisory activities, **SoHO** competent authorities may only publish or make that information or data available to the public, **without prejudice to national legislation,** provided that the ~~following conditions are met:~~**conditions described in paragraph 5 points (c) apply.**	
Article 75(6), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
911	(a) the information or data made available to the public is in the interest of public health protection and is necessary and proportionate to the severity, extent and nature of the associated risk;		(a) ~~the information or data made available to the public is in the interest of public health protection and is necessary and proportionate to the severity, extent and nature of the associated risk;~~	
Article 75(6), point (b)				
912	(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;~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 75(6), point (c)				
913	(c) the information or data made available to the public does not undermine the protection of court proceedings and legal advice.		(c) ~~the information or data made available to the public does not undermine the protection of court proceedings and legal advice.~~	
Article 75(7)				
914	7. The provisions of this Article shall also apply to delegated bodies.		7. ~~The provisions of this Article shall also apply to delegated bodies.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 76				
915	Article 76 Data protection		Article 76 Data protection	
Article 76(1)				
916	1. Personal data required for the application of Articles 5(5) and 6(2), Article 18(3), point (a), Articles 19(2) and 21(3), Article 27(2), Article 28(2), Articles 35 and 36, Article 53(1), points (f) and (g), Article 53(3), Article 58(11), and Articles 63 and 75 shall be collected for the purpose of		1. Personal data required for the application of Articles 5(5) and ~~6(2)~~**10(2a)**~~, Article 18(3), point (a),~~ Articles ~~19(2) and 21(3)~~**35 and 36**, Article ~~27(2), Article 28(2), Articles 35 and 36~~**37 (1a), (1b)**, Article ~~53(1), points (f) and (g)~~**37a, Article 38, Article 41(2)(-a)**, Article ~~53(3), Article 58(11)~~**49(2),**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	identifying the relevant contact persons within the relevant SoHO entities, competent authorities or delegated bodies, and shall only be processed further for the purpose of ensuring the administration and transparency of the supervisory activities and SoHO activities concerned.		, and -Articles 63 and ~~75~~**67(3)** shall be collected for the purpose of identifying the relevant contact persons within the relevant SoHO entities, **SoHO** competent authorities or delegated bodies, and shall only be processed further for the purpose of ensuring the administration and transparency of the **SoHO** supervisory activities and SoHO activities concerned.	
Article 76(2)				
917	2. Personal data, including data concerning health, required for the application of Articles 74 and 75 shall be processed in the interest of		2. Personal data, including data concerning health, **exchanged through the EU SoHO Platform and** required for the application of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	public health and, in particular, for the following purposes:		Articles ~~74 and 75~~**73 and 74** shall**, where absolutely necessary,** be processed in the interest of public health and~~, in particular,~~ for the following purposes:	
Article 76(2), point (a)				
918	(a) to help to identify and evaluate risks associated with a particular SoHO donation or SoHO donor;		(a) to help to identify and evaluate risks associated with a particular SoHO donation or SoHO donor;	
Article 76(2), point (b)				
919	(b) to process relevant information		(b) to process relevant information	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	on clinical outcome monitoring.		on clinical outcome monitoring.	
Article 76(3)				
920	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	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	3. Personal data, including data concerning health, required for the application of Articles 35, 36**, 41, 45 and 47,** ~~, 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	supervisory activities and SoHO activities concerned and be limited to the extent necessary and proportionate for that purpose.	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).***	of the supervisory activities and SoHO activities concerned and be limited to the extent necessary and proportionate for that purpose.	
Article 76(4)				
921	4. All information shall be processed by the Commission,		4. All information shall be processed by the Commission,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Member States, competent authorities, including SoHO National Authorities, delegated bodies and SoHO entities, including any third party contracted by a SoHO entity, as applicable, in such a way that the personal data of the subjects remain protected in accordance with the applicable legislation on personal data protection. The Commission, Member States, competent authorities, including SoHO National Authorities, delegated bodies and SoHO entities, including any third party contracted by a SoHO entity, shall, in particular, minimise the risk that subjects can be identified and shall limit the information processed to elements necessary and appropriate		Member States, **SoHO** competent authorities, including SoHO National Authorities, delegated bodies ~~and~~**,** SoHO entities~~,~~ ~~including~~ **and** any third party contracted by a SoHO entity, as applicable, in such a way that the personal data of the subjects remain protected in accordance with the applicable legislation on personal data protection. ~~The Commission, Member States, competent authorities, including SoHO National Authorities, delegated bodies and SoHO entities, including any third party contracted by a SoHO entity,~~**They** shall, in particular, minimise the risk that subjects can be identified and shall limit the information processed to elements necessary	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	for carrying out their tasks and fulfilling their obligations under this Regulation.		and appropriate for carrying out their tasks and fulfilling their obligations under this Regulation.	
Article 76(5)				
922	5. The Commission, Member States, competent authorities, including SoHO National Authorities, delegated bodies and SoHO entities, including any third party contracted by a SoHO entity, shall implement appropriate technical and organisational measures to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination,		5. The Commission, Member States, **SoHO** competent authorities, including SoHO National Authorities, delegated bodies ~~and ~~**,** SoHO entities~~,~~ ~~including~~ **and** any third party contracted by a SoHO entity, shall implement appropriate technical and organisational measures to protect information and personal data processed**, including health data,** against unauthorised or	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	alteration, destruction or accidental loss, in particular where the processing involves transmission over a network.		unlawful access, disclosure, dissemination, alteration, destruction or accidental loss, in particular where the processing involves transmission over a network.	
Article 76(6)				
923	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	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	6. In relation to their responsibilities to process personal data to comply with the obligations of this Regulation, ~~the~~ SoHO entities and **SoHO** competent authorities of the Member States shall be regarded as controllers as defined in Article 4, point (7), of Regulation (EU) 2016/679 ~~and~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	they are bound by the rules of that Regulation.	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.***	~~they are bound by the rules of that Regulation~~.	
Article 76(7)				
924	7. In relation to its responsibility to establish and manage the EU SoHO Platform, as referred to in Article 73 and the processing of personal data that might result from that activity, the Commission		7. In relation to its responsibility to establish and manage the EU SoHO Platform, as referred to in Article 73 and the processing of personal data**, including health data,** that might result from that	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	shall be regarded as controller as defined in Article 3, point (8), of Regulation (EU) 2018/1725 and it is bound by the rules of that Regulation.		activity, the Commission shall be regarded as controller as defined in Article 3, point (8), of Regulation (EU) 2018/1725~~ and it is bound by the rules of that Regulation~~.	
Article 76(8)				
925	8. For the purposes of this Article, the Commission is empowered to adopt delegated acts in accordance with Article 77 supplementing this Regulation by laying down the retention periods for personal data as appropriate to their purpose and specific criteria that would allow identification of data relevant for public health protection as referred		8. For the purposes of this Article, the Commission is empowered to adopt delegated acts in accordance with Article 77 supplementing this Regulation by laying down the retention periods for personal data**, including health data,** as appropriate to their purpose and specific criteria that would allow identification of data relevant for	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	to in paragraph 2.		public health protection as referred to in paragraph 2.	
Article 77				
926	Article 77 Exercise of the delegation		Article 77 Exercise of the delegation	
Article 77(1)				
927	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this		1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article.		Article.	
Article 77(2)				
928	2. The power to adopt delegated acts referred to in Articles 28(10), 42(3), 53(6), 58(15), 69(6), 73(4), and 76(8) shall be conferred on the Commission for an indeterminate period of time from … [OP please insert the date = date of entry into force of this Regulation].	2. The power to adopt delegated acts referred to in ~~*Articles 28(10), 42(3), 53(6), 58(15), 69(6), 73(4), and*~~***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].	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].	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 77(3)				
929	3. The delegation of power referred to in Articles 28(10), 42(3), 53(6), 58(15), 69(6), 73(4), and 76(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in ~~*Articles 28(10), 42(3), 53(6), 58(15), 69(6), 73(4), and*~~***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	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***~~Official Journal of the European Union~~ or at a later date specified therein. It shall not affect	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		the ***Official Journal of the European Union*** ~~*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.	the validity of any delegated acts already in force.	
Article 77(4)				
930	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.		4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 77(5)				
931	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	
Article 77(6)				
932	6. A delegated act adopted pursuant to the provisions listed in paragraph 2 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of		6. A delegated act adopted pursuant to the provisions listed in paragraph 2 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.		notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.	
Article 78				
933	Article 78 Urgency procedure		Article 78 Urgency procedure	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 78(1)				
934	1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.		1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.	
Article 78(2)				
935	2. Either the European Parliament or the Council may object to a		2. Either the European Parliament or the Council may object to a	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	delegated act in accordance with the procedure referred to in Article 77(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.		delegated act in accordance with the procedure referred to in Article 77(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.	
Article 79				
936	Article 79 Committee procedure		Article 79 Committee procedure	
Article 79(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
937	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.		1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	
Article 79(2)				
938	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.		2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. **Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU)**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			No 182/2011 shall apply.	
Article 79(3)				
939	3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.		3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.	
Article 80				
940	Article 80 Penalties		Article 80 Penalties	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 80, first paragraph				
941	Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, by … [OP please insert the date = 3 years after the date of entry into force of this Regulation], notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent		Member States shall **take the necessary legal measures to** lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, by … [OP please insert the date = ~~3~~ **5** years after the date of entry into force of this Regulation], notify the Commission of those rules and of those measures and shall notify it,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	amendment affecting them.		without delay, of any subsequent amendment affecting them.	
CHAPTER XIII				
942	CHAPTER XIII TRANSITIONAL PROVISIONS		CHAPTER XIII TRANSITIONAL PROVISIONS	
Article 81				
943	Article 81 Transitional provisions concerning establishments designated, authorised, accredited or licensed		Article 81 Transitional provisions concerning establishments designated, authorised, accredited or licensed	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	under Directives 2002/98/EC and 2004/23/EC		under Directives 2002/98/EC and 2004/23/EC	
Article 81(1)				
944	1. Blood establishments designated, authorised, accredited or licensed based on Article 5(1) of Directive 2002/98/EC and tissue establishments designated, authorised, accredited or licensed on the basis of Article 6(2) of Directive 2004/23/EC before the date of application of this Regulation shall be deemed to be registered as SoHO entities and deemed to be authorised as SoHO establishments, in accordance with		1. Blood establishments designated, authorised, accredited or licensed based on Article 5(1) of Directive 2002/98/EC and tissue establishments designated, authorised, accredited or licensed on the basis of Article 6(2) of Directive 2004/23/EC before the date of application of this Regulation shall be deemed to be registered as SoHO entities and deemed to be authorised as SoHO establishments, in accordance with	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.		this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.	
Article 81(2)				
945	2. Tissue establishments that are designated, authorised, accredited or licensed as importing tissue establishments on the basis of Article 6(2) of Directive 2004/23/EC before the date of application of this Regulation shall be deemed to be authorised as importing SoHO entities in accordance with this Regulation and shall, as such, be subject to the		2. Tissue establishments that are designated, authorised, accredited or licensed as importing tissue establishments on the basis of Article ~~6(2)~~**9(2)** of Directive 2004/23/EC before the date of application of this Regulation shall be deemed to be authorised as importing SoHO ~~entities~~**establishments** in accordance with this Regulation	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	relevant obligations provided for under this Regulation.		and shall, as such, be subject to the relevant obligations provided for under this Regulation.	
Article 81(3)				
946	3. For blood establishments referred to in paragraph 1, competent authorities shall:		3. For blood establishments referred to in paragraph 1, **SoHO** competent authorities shall:	
Article 81(3), point (a)				
947	(a) verify whether those establishments meet the definition of SoHO establishment in Article		(a) verify whether those establishments meet the definition of SoHO establishment in Article	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	3, point (40);		3, point (40);	
Article 81(3), point (b)				
948	(b) submit the information referred to in Article 18(3), points (a) and (d), and information regarding the registration and authorisation status according to the verification referred to in point (a) of this paragraph to the EU SoHO Platform as referred to in Chapter XI.		(b) submit the information referred to in Article ~~18(3)~~**37(1b)**, points (a) and (d), and information regarding the registration and authorisation status according to the verification referred to in point (a) of this paragraph to the EU SoHO Platform as referred to in Chapter XI.	
Article 81(4)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
949	4. For tissue establishments referred to in paragraph 1, the Commission shall:		4. For tissue establishments referred to in ~~paragraph 1~~**paragraphs 1 and 2**, the Commission shall:	
Article 81(4), point (a)				
950	(a) verify whether those establishments meet the definition of SoHO establishment in Article 3, point (40);		(a) verify whether those establishments meet the definition of SoHO establishment in Article 3, point (40);	
Article 81(4), point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
951	(b) transfer the relevant information from the EU Tissue Establishment Compendium of the EU Coding Platform laid down in Directive 2006/86/EC, including the information regarding the registration and authorisation status according to the verification referred to in point (a) of this paragraph, to the EU SoHO Platform as referred to in Chapter XI of this Regulation;		(b) transfer the relevant information from the EU Tissue Establishment Compendium of the EU Coding Platform laid down in Directive 2006/86/EC, including the information regarding the registration and authorisation status according to the verification referred to in point (a) of this paragraph, to the EU SoHO Platform ~~as referred to in Chapter XI of this Regulation~~;	
Article 81(4), point (c)				
952	(c) inform the competent		(c) inform the **SoHO** competent	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorities of the establishments that do not meet the definition of SoHO establishment according to the verification referred to in point (a).		authorities of the establishments that do not meet the definition of SoHO establishment according to the verification referred to in point (a).	
Article 81(5)				
953	5. Competent authorities shall inform those establishments not meeting the definition of SoHO establishment, according to the verification referred to in paragraph 3, point (a), and paragraph 4, point (a) and based on the information referred to in paragraph 4, point (c), that they are deemed to be registered as SoHO		5. **SoHO** competent authorities shall inform those establishments not meeting the definition of SoHO establishment, according to the verification referred to in paragraph 3, point (a), and paragraph 4, point (a) and based on the information referred to in paragraph 4, point (c), that they are deemed to be registered as SoHO	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	entities only and that they, as such, are subject to the obligations relevant for SoHO entities provided for under this Regulation.		entities only and that they, as such, are subject to the obligations relevant for SoHO entities provided for under this Regulation.	
Article 81(6)				
954	6. For tissue establishments referred to in paragraph 2 of this Article, the Commission shall transfer the relevant information from the EU Tissue Establishment Compendium of the EU Coding Platform laid down in Directive 2006/86/EC to the EU SoHO Platform as referred to in Chapter XI of this Regulation.		6. ~~For tissue establishments referred to in paragraph 2 of this Article, the Commission shall transfer the relevant information from the EU Tissue Establishment Compendium of the EU Coding Platform laid down in Directive 2006/86/EC to the EU SoHO Platform as referred to in Chapter XI of this Regulation.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 82				
955	Article 82 Transitional provisions concerning SoHO preparations		Article 82 Transitional provisions concerning SoHO preparations	
Article 82(1)				
956	1. The preparations resulting from tissue and cell preparation processes designated, authorised, accredited or licensed on the basis of Article 6(2) of Directive		1. The preparations resulting from tissue and cell preparation processes designated, authorised, accredited or licensed on the basis of Article 6(2) of Directive	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	2004/23/EC before the date of application of this Regulation shall be deemed to be authorised as the corresponding SoHO preparations in accordance with this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.		2004/23/EC before the date of application of this Regulation shall be deemed to be authorised as the corresponding SoHO preparations in accordance with this Regulation ~~and shall, as such, be subject to the relevant obligations provided for under this Regulation~~.	
Article 82(2)				
957	2. Blood components that were verified by competent authorities as complying with applicable quality and safety requirements for blood components on the basis of Article 5(3) and Article 23 of Directive 2002/98/EC or with the		2. Blood components that were verified by **SoHO** competent authorities as complying with applicable quality and safety requirements for blood components on the basis of Article 5(3) and Article 23 of Directive 2002/98/EC	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	blood component monographs included in the edition of the Guide to the preparation, use and quality assurance of blood components of the EDQM indicated on the EU SoHO Platform on … [OP please insert the date = two years after the date of entry into force of this Regulation], or that were otherwise designated, authorised, accredited or licensed under national legislation before the date of application of this Regulation, shall be deemed to be authorised as the corresponding SoHO preparations in accordance with this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.		or with the blood component monographs included in the edition of the Guide to the preparation, use and quality assurance of blood components of the EDQM indicated on the EU SoHO Platform on … [OP please insert the date = ~~two years after the~~ date of ~~entry into force~~**application** of this Regulation], or that were otherwise designated, authorised, accredited or licensed under national legislation before the date of application of this Regulation, shall be deemed to be authorised as the corresponding SoHO preparations in accordance with ~~this Regulation and shall, as such, be subject to the relevant obligations provided for under~~ this Regulation.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 82(3)				
958	3. Competent authorities shall submit the information referred to in paragraphs 1 and 2 to the EU SoHO Platform, and link those entries to the respective SoHO entities.		3. **SoHO** competent authorities shall submit the information referred to in paragraphs 1 and 2 to the EU SoHO Platform, and link those **SoHO preparations, authorised pursuant to transitional provisions,** ~~entries~~ to the respective SoHO entities.	
Article 82(4), first subparagraph				
959	The Commission may adopt		**4.** The Commission may adopt	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	implementing acts in order to establish uniform procedures for ensuring that SoHO preparations deemed to be authorised pursuant to paragraphs 1 and 2 are fully documented in line with the requirements for SoHO preparation authorisation in this Regulation.		implementing acts in order to establish uniform procedures for ensuring that SoHO preparations deemed to be authorised pursuant to paragraphs 1 and 2 are fully documented in line with the requirements for SoHO preparation authorisation in this Regulation.	
Article 82(4), second subparagraph				
960	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 82a				
960a			**Article 82a** **Transitional provisions concerning SoHO not addressed expressly in Directives 2002/98/EC nor 2004/23/EC**	
Article 82a, first subparagraph				
960b			**1. Organisations carrying out one or more of the SoHO activities as listed in Article 2(1c), point(i), (iv), (v), (vi), (vii), (viii), (ix) and (xii) with SoHO not addressed expressly in**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Directives 2002/98/EC nor 2004/23/EC, before …[OP please insert the date = of application of this Regulation] shall be allowed to continue their activities regarding those SoHO until [OP please insert the date = one year after the date of application of this Regulation], without applying this Regulation, except for the following requirements:	
Article 82a(1), first subparagraph, point (a)				
960c			**(a) registration as SoHO entities pursuant to Article 37;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 82a(1), first subparagraph, point (b)				
960d			**(b) application for any and all relevant SoHO preparation authorisation, where required pursuant to Article 40;**	
Article 82a(1), first subparagraph, point (c)				
960e			**(c) application for a SoHO establishment authorisation, where required pursuant to Article 48;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 82a(1), first subparagraph, point (d)				
960f			**(d) compliance with the standards referred to in Chapters VI and VII for the SoHO activities carried out during the transition phase.**	
Article 82a(1), second subparagraph				
960g			**Such SoHO entities shall comply with the requirements referred to in points (b) and (c) before [[OP please insert the date =**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			three months after the date of application of this Regulation].	
Article 83				
961	Article 83 Status of SoHOs released for distribution, distributed or in storage before the application of this Regulation		Article 83 Status of SoHOs released for distribution, distributed or in storage before the application of this Regulation	
Article 83(1)				
962	1. SoHOs already released for		1. ~~SoHOs~~**SoHO** already ~~released~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	distribution before … [OP please insert the date = date of application of this Regulation] shall not be subject to the relevant obligations provided for under this Regulation, provided those SoHOs are distributed at the latest by … [OP please insert the date = one year after the date of application of this Regulation] and under the condition that those SoHOs were fully compliant with the applicable Union legislation and national law in force at the time when those SoHOs were released for distribution.		~~for distribution~~ **in storage** before … [OP please insert the date = date of application of this Regulation] shall not be subject to the relevant obligations provided for under this Regulation, provided those ~~SoHOs are distributed at the latest by …~~**SoHO are released and distributed before** [OP please insert the date = ~~one year~~**two years** after the date of application of this Regulation]~~ and~~ under the condition that those SoHOs were fully compliant with the applicable Union legislation and national law in force at the time when those SoHOs were ~~released for distribution~~**collected**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 83(2)				
963	2. SoHOs which have been distributed before … [OP please insert the date = date of application of this Regulation] and kept under appropriate control conditions until that date shall not be subject to the relevant obligations provided for under this Regulation.		2. SoHOs which have been distributed before … [OP please insert the date = date of application of this Regulation] and kept under appropriate control conditions until that date shall not be subject to the relevant obligations provided for under this Regulation.	
Article 83(3)				
964	3. SoHOs already in storage before … [OP please insert the date = date of application of this		3. SoHOs already in storage before … [OP please insert the date = date of application of this	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Regulation], and for which no alternative SoHOs are available, in particular because the SoHOs are autologous, intended for within couple use or highly matched for a specific recipient, shall only be subject to Article 61. Those SoHOs shall be subject to that Article from… [OP please insert date = date of application of this Regulation].		Regulation], and **not distributed according to paragraph 1, and** for which no alternative ~~SoHOs~~**SoHO** are available, in particular because the ~~SoHOs~~**SoHO** are autologous, intended for within couple use or highly matched for a specific **SoHO** recipient, shall only be subject to Article 61. Those SoHOs shall be subject to that Article from… [OP please insert date = date of application of this Regulation].	
Article 84				
965	Article 84		Article 84	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Transitional measures for the adoption of certain delegated and implementing acts		Transitional measures for the adoption of certain delegated and implementing acts	
Article 84, first paragraph				
966	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	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)*~~***Article 42(3), Article 67(7), Article 73(4) and Article 74(3)*** and the implementing acts referred to in ~~*Articles 26(4), 43(6), 44(3), 46(3), 67(7) and 74(3)*~~***Article 26(4),***	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	***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.	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.	
CHAPTER XIV				
967	CHAPTER XIV FINAL PROVISIONS		CHAPTER XIV FINAL PROVISIONS	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 85				
968	Article 85 Repeals		Article 85 Repeals	
Article 85, first paragraph				
969	Directives 2002/98/EC and 2004/23/EC are repealed with effect from … [OP please insert the date = two years after the date of entry into force of this Regulation].		Directives 2002/98/EC and 2004/23/EC are repealed with effect from … [OP please insert the date = ~~two~~**three** years after the date of entry into force of this Regulation].	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 86				
970	Article 86 Evaluation		Article 86 Evaluation	
Article 86, first paragraph				
971	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.	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.***	European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.	
Article 86, second paragraph				
972	The Commission shall use aggregated and anonymised data and information gathered from supervisory and SoHO activities and information submitted to the EU SoHO Platform for the purposes of the evaluation report.		The Commission shall use aggregated and anonymised data and information gathered from supervisory and SoHO activities and information submitted to the EU SoHO Platform for the purposes of the evaluation report.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 86, third paragraph				
973	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.***	Member States shall provide the Commission with additional information necessary and proportionate for the preparation of the evaluation report.	
Article 87				
974				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 87 Entry into force and application		Article 87 Entry into force and application	
Article 87(1), first subparagraph				
975	This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		This Regulation shall enter into force on the twentieth day following that of its publication in the ***Official Journal of the European Union***~~Official Journal of the European Union~~.	
Article 87(1), second subparagraph				
976				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Unless otherwise provided for in paragraph 2, it shall apply from … [OP please insert the date = two years after the date of entry into force of this Regulation].		Unless otherwise provided for in paragraph 2, it shall apply **as from six months after the publication of the notice referred to in article 74(4) but in any event no earlier than**~~from~~ … [OP please insert the date = ~~two~~ **four** years after the date of entry into force of this Regulation].	
Article 87(2), first subparagraph				
977	Article 81(3) to (6) and Article 82(3) shall apply from … [OP please insert the date = three years after the date of entry into force of this Regulation].		Article **80,** 81(3) to (6) and Article 82(3) shall apply from … [OP please insert the date = ~~three~~**five** years after the date of entry into force of this Regulation].	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 87(2), second subparagraph				
978	This Regulation shall be binding in its entirety and directly applicable in all Member States.		This Regulation shall be binding in its entirety and directly applicable in all Member States.	
Formula				
979	Done at Brussels,		Done at Brussels,	
Formula				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
980	For the European Parliament		For the European Parliament	
Formula				
981	The President		The President	
Formula				
982	For the Council		For the Council	
Formula				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
983	The President		The President	