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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Public Health (Attachés) Working Party on Public Health (Substances of Human Origin (SOHO))
Subject:	SoHO proposal - Comments from the delegations

Delegations will find in annex comments received after the Working Parties on 6 and 9 October on documents 13503/23 + COR1 from the Austrian, Belgian, Bulgarian, Cyprus, Czech, Danish, Estonian, Finnish, French, German, Italian, Latvian, Netherlands, Polish, Romanian, Slovakian, Slovenian and Swedish delegations.

Written comments by MS on Compromise text 13503/23 + COR1 after WP on 6 and 9 October	Comments included are from **AT, BE, BG, CY, CZ, DK, EE, FI, FR, DE, IT, LV, NL, PL, RO, SK, SI, SE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
CHAPTER I (General Provisions): Articles 1, 2, 3, 4			
CHAPTER I			
GENERAL PROVISIONS			
Article 1			
Subject matter			
This Regulation establishes measures setting high standards of quality and safety for all substances of human origin ('SoHOs') intended for human application and for activities related to those substances in order to ensure a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted reproduction. ~~This Regulation is without prejudice to national legislation which establishes rules relating to aspects of SoHOs other than their quality and safety and the safety of SoHO donors.~~	This Regulation establishes measures setting high standards of quality and safety for all substances of human origin ('SoHOs') intended for human application and for activities related to those substances in order to ensure a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted reproduction. ~~This Regulation is without prejudice to national legislation which establishes rules relating to aspects of SoHOs other than their quality and safety and the safety of SoHO donors.~~	CZ would like to ask for clarification and the reason for adding the part marked in green to Article 2 para 1b). The corresponding legal consequences have not been specified so far.	**CZ**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
Article 2			
Scope			
1. This Regulation shall apply to:			
(a) SoHO ~~intended for human application, to~~**and** ~~SoHO preparations~~ **intended for human application**~~,~~ **and** to **SoHOs used to manufacture** products~~;~~ **defined in other Union legislation,** ~~manufactured from SoHOs and~~ **and** intended for human application;	**(a)** SoHO ~~intended for human application, to~~**and** ~~SoHO preparations~~ **intended for direct human application**~~,~~ **and** to **SoHOs used to manufacture** products~~;~~ **defined in other Union legislation,** ~~manufactured from SoHOs and~~ **and** intended for human application;	The reading of this provision is complicated by the fact that it mentions "for human application" twice. We propose to add « **direct** » human application at the first mention. But this proposal will have to be adapted elsewhere in the regulation where necessary.	**FR**
(b) SoHO donors~~, and~~**SoHO** recipients **and offspring from medically assisted reproduction;**~~, and to the following SoHO activities;~~			
1a.(c) ~~**This regulation shall also apply to SoHO activities that have a direct impact on the safety, or quality, including, or or effectiveness of SoHO or SoHO preparations, as follows:**~~**			
(**ia**) ~~SoHO~~ donor ~~recruitment~~**registration**;	No changes are proposed, however new letter is suggested: **promotion and publicity activities**	CZ could support the actual version of the Article 2 para 1 a) on SoHO donor registration provided the CZ proposed change in the definition no. 13a on SoHO donor registration. It is a red-line for CZ. In accordance with the aim of the Regulation to regulate advertisement	**CZ**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		and its corresponding negative impacts in the context of voluntary unpaid donation CZ proposes to add point to the scope of Regulation: "promotion and publicity activities". It is a red-line for CZ. As "promotion and publicity activities" are proposed to be regulated in Article 54, it should be stated in Article 2 as it is supposed to stipulate the whole scope of the Regulation. CZ is not in favour of registration of entities that do "promotion and publicity activities" according to Article 37. We propose to add "promotion and publicity activities" as another of the exceptions in Article 37 as proposed by CZ previously to relieve the administrative burden.	
		It is still unclear who will be registered as a donor: all who come to donate, future donors (donors after death, bone marrow donors,) rejected donors. This is also not seen from definition 13a.	**SI**
(**ii**~~b~~) ~~SoHO~~ donor history review ~~**or and medical examinations** and **for** eligibility assessment~~;			
(~~e~~**iii**) ~~SoHO~~ testing ~~of **SoHO** donors for eligibility **assessment** or matching purposes, **or of persons, from whom SoHOs are collected**		Denmark can support the wording: Testing of SoHO donors	**DK**
	(iii) testing **donor and donation testing**	The use of the term "testing" alone and the	**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~**for autologous application, for safe storage**~~;		removal of details for the testing activity obscur the difference with "quality controls".	
	(c**iii**) testing of **SoHO** donors for eligibility **assessment** or matching purposes,	We have concerns regarding inclusion into the scope of the Regulation the testing of recipients to monitor the effectiveness of SoHO (e.g., biochemical pregnancy testing or blood cells count after HPSC transplantation), therefore, we propose to specify testing as it was in the initial proposal to limit it to SoHO safety and quality only.	**LV**
	~~(c~~**iii**) ~~SoHO~~ **donor** testing ~~of **SoHO** donors for eligibility **assessment** or matching purposes, **or of persons, from whom SoHOs are collected for autologous application, for safe storage(~~	It should be made clear that regulation cover testing of donors, as it is in points i and ii.	**PL**
		What is the difference between testing and quality control (in paragraph vi)?	**SI**
		The deletions in this point have made it very broad, and difficult to interpret as well as to distinguish from (vi) on quality control. We propose either to keep it as it was, or to introduce a definition of testing, where the deleted text is introduced. We also noticed	**SE**

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		that "testing" is used for **SoHO recipients** in Art 58(3)ii, and for **SoHOs** in 47(6) and Art 58(5)(ca). A definition would need to cover also those cases, if the wording in Art 58 is kept. Or should Art 47(6) and Art 58(5)(ca) rightly refer to "quality control of SoHOs" instead of "testing of SoHOs" for the sake of consistency ?	
(~~d~~**iv**) collection ~~of SoHOs from donors or patients~~;			
(~~e~~**v**) processing ~~of SoHOs~~;			
(~~f~~**vi**) quality control ~~testing of SoHOs~~ **~~or SoHO preparations~~**;	(~~f~~**vi**) quality control testing of SoHOs;	We have concerns regarding inclusion into the scope of the Regulation the testing of recipients to monitor the effectiveness of SoHO (e.g., biochemical pregnancy testing or blood cells count after HPSC transplantation), therefore, we propose to specify testing as it was in the initial proposal to limit it to SoHO safety and quality only.	**LV**
(~~g~~**vii**) storage ~~of SoHOs~~ **~~or SoHO preparations~~**;			
(~~h~~**viii**)~~SoHO~~ release ~~**of SoHOs or SoHO preparations**~~;			
(~~i~~**ix**) distribution ~~of SoHOs~~ **~~or SoHO preparations~~**;			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
(~~j~~**x**) import ~~of SoHOs~~ **~~or SoHO preparations~~**;			
(**xi**~~k~~) export ~~of SoHOs~~ **~~or SoHO preparations~~**;			
(~~l~~**xii**) human application ~~of SoHOs~~ **~~or SoHO preparations~~**;	~~human application of SoHOs~~ **~~or SoHO preparations~~**~~;~~	CZ in accordance with the previous expressed CZ comments insists on excluding of "human aplication" from the scope of the Regulation because of increasing administrative burden and the amount of entities with the obligation to register as SoHO entities. We refer to our suggestions to amend Article 37 for the purpose of narrowing down the amount of registered entities as SoHO entities and the corresponding obligation to designate a responsible person in such case. It is a red-line for CZ.	**CZ**
		We had proposed a limitation that the human application is only covered insofar that the criteria for vigilance and traceability are applied. Since the human application as a SoHO activity is now still mentioned without restriction, we proposed to clarify this in a recital and to clarify also that the Regulation does not specify how the applying physician has to behave during the treatment of his patients. The medical action and the medical freedom of therapy are not subject of the regulation.	**DE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		This proposal has been implemented by the council presidency in compromise text 13655/23-.	
	(~~l~~**xii**) human application registration ~~of SoHOs~~ ~~**or SoHO preparations**~~;	Suggestion to clarify here that it is not about the 'act' (e.g. surgical procedure) itself, but only on the registration of applications. So use the same wording as in (m): human application **registration**.	**NL**
(~~m~~**xiii**)~~SoHO~~ clinical outcome **monitoring registration** ~~monitoring~~.	~~SoHO~~ clinical outcome monitoring ~~**registration**~~ **of SoHOs in clinical studies or of SoHO preparations with a conditional permission**	CZ refers to the previous expressed suggestions on this point of the scope of the Regulation. Term "registration" is confusing in the context of monitoring and clinical outcomes. Therefore, monitoring is proposed to be narrowed only on monitoring in clinical studies or on the case of conditional permission of SoHO preparations and not on each case. Therefore, change of wording is suggested. It is a red-line for CZ. The CZ proposed text has to be stipulated either here or in the definition 22 clinical outcome monitoring (the definition is prefered by CZ).	**CZ**
	(~~m~~**xiii**)~~SoHO~~ clinical outcome **monitoring** ~~**registration**~~ ~~monitoring~~.	Clarification on why the term was changed to "clinical outcome monitoring registration" What exactly is meant by 'registration'	**DE**
		We consider that the wording is not clear and anticipate confusion in the	**RO**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		interpretation, at least after translation. Which is the activity?! The registration of the results obtained by monitoring the recepient post-application?	
~~1b~~1a. This Regulation shall not apply to:			
(i) organs intended for transplantation within the meaning of Article 3, points (h) and (q), of Directive 2010/53/EU.;	**(i) organs intended for transplantation within the meaning of Article 3, points (h) ~~and (q),~~ of Directive 2010/53/EU.;**	In principle, the explicit exclusion of organs from the scope is supported. Only the reference to the letter of Directive 2010/53/EU is unclear. Under Art. 3 point q the term "transplantation" is defined. From our point of view to reference to the definitions of organs in Art.. 2 point h is sufficient.	**DE**
	organs ~~intended for transplantation~~ within the meaning of Article 3, point~~s~~(h) ~~and (q)~~, of Directive 2010/53/EU.;	Suggestion to remove "for transplantation" as superfluous. The scope already mentions this regulation only applies to soho intended for application of soho.	**NL**
~~1ba This Regulation shall not apply to~~			
breast milk when used exclusively for feeding the own child.	(ii) breast milk when used exclusively for feeding the own child, **without any processing"** ou "breast milk when used exclusively for feeding the own child, **unless pasteurized.**	**Red line for FR** Processing operations involve risks that make it necessary to apply the regulation, even in the case of mother's own milk. From a practical point of view, if personal donations (the equivalent of autologous donations) are excluded, compared with what is done in France today, this means that the most important part of the products	**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		and some of the services currently controlled (in-house lactariums that only do personalised donations) will be excluded. However, in terms of risk, **whether it's personalised or anonymous donations, the risks are the same as soon as there is a transformation operation.** In France, **lactariums are authorised and inspected in the same way whether they are for internal use (LUI) (mother's milk for her own child)** (article D2323-4 of the public health code) or for internal and external use (LUIE) (mother's milk for her own child or for a child other than her own). **There are 13 LUI (~8,400 litres collected in 2022**) and 20 LUIE (~77,000 litres collected in 2022). In 2021, for all lactariums combined, **breast milk of the mother for her own child accounted for 41.6% of the milk collected.** This provision would lead to a review of the management of lactariums in France and to 2 different statuses for breast milk in LUIEs. We therefore propose to amend this provision to take into account the pasteurised breast milk (= from lactariums) of the mother for her own child in this regulation.	
		The definition is too broad.	**SI**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~1e1b~~. **This Regulation is without prejudice to national legislation which establishes rules relating to aspects of SoHOs other than their quality and safety ~~which are not governed by the provisions of this Regulation. other than their quality and safety and the safety of SoHO donors~~.**	~~1e1b~~. **This Regulation is without prejudice to national legislation which establishes rules relating to aspects of SoHOs other than their quality, and safety and effectiveness ~~which are not governed by the provisions of this Regulation. other than their quality and safety and the safety of SoHO donors~~.**	Efficiency requirements are found in many articles of the regulation	**FR**
1ba. By way of derogation, the provisions of this Regulation concerning the publication of information, specifically the publication obligations in Articles 4(2), 8, 17, 21(3), 31, 33, 39, 44, 62, 63, 66, 77, 81(3) may not apply when such publication might imply a risk to public security or national security and defence.	**1ba. By way of derogation, the provisions of this Regulation concerning the publication of information, specifically the publication 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 might imply a risk to public security or national security and defence.**	Only the 81 (3b) refers to transmission to the Soho Platform.	**FR**
		The exception for conflicting secrecy interests can be supported in order to protect defence and national security. With regard to public safety, we oppose the exemption. It still has not been explained, despite repeated requests, why we need an exemption for this field as well. We cannot provide an exemption if we cannot justify it	**DE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		and the impact may be unknown. Also the corresponding recital just refers to military organisations. Furthermore, the exemption does not cover another important issue for DE. This concerns the possibility of deviating from the Regulation in order to ensure the supply of SoHO preparations during military operations. This may, for example, require a deviation from the specifications for manufacturing. Such an exception should be possible if this is justified for the tasks of the special military tasks and the protection of the health of the donors and recipients is sufficiently safeguarded. This situation is not yet addressed in Regulation, although we have presented this problem several times. Either the exemption should therefore be extended at this point or a separate exemption should be provided in the	

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		chapter on continuity of supply. We had already submitted a wording Proposal for the supple continuity chapter. We have submitted it again in our comments for the meeting on October 9. **Red Line DE!**	
	1ba. By way of derogation, the provisions of this Regulation concerning the publication of information, specifically the publication obligations in Articles 4(2), 8, 17, 21(3), 31, 33, 39, 44, 62, 63, 66, 77, 81(3) may not apply can be derived from when such publication might imply a risk to public security or national security and defence.	SE can in general support this addition. We would however like a clarification of the wording "may not apply". If it is up to the Member State to decide, it would be better to state this. Another option could be to use "can be derived from", if the intention if for the entity/establishment to apply the provision directly.	**SE**
2. In case~~s~~ of **SoHO intended for** autologous ~~use~~ **application use,** ~~of SoHOs~~ where:			
(a) SoHO~~s~~ ~~**or SoHO preparations**~~ are ~~processed and~~ **processed or** stored before application, this Regulation shall apply in ~~**full**~~**relevant parts**~~full~~;			
~~(b) SoHOs are processed and~~ **but** ~~not stored before application,~~ ~~**this Regulation shall apply in full, except for the provisions of this Regulation that are relevant to the SoHO activities referred to in paragraph (1a) points (a), (b), (c), (g), (h), (i), (j) and (k)**~~ ~~only the provisions on vigilance referred to in~~			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~Article 35, on SoHO rapid alerts 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;~~			
(c) SoHO~~s~~ are not processed and not stored before application, this Regulation shall not apply.	(c) SoHO~~s~~ are not neither processed and not nor stored before application, this Regulation shall not apply.	Minor editorial suggestion for enhanced clarity.	**SE**
~~**(d) SoHOs are used to manufacture products in accordance with other Union legislation, as referred to in paragraph (3), only the provisions of this Regulation that are applicable to the SoHO activities referred to in Article 2(1) points (c) and (d) shall apply.**~~			
3. ~~For~~ **In case of** SoHO~~s~~ ~~**or SoHO preparations**~~ that are used to manufacture products **regulated by**~~**defined in**~~ **other** ~~in accordance with~~Union legislation**,**~~on medical devices, regulated by~~ **in particular, medical devices, as defined in** Regulation (EU) 2017/745~~ **(on medical devices)**, **Regulation (EU) 2017/746 (on in vitro diagnostic medical devices),** on medicinal products, regulated by~~ **medicinal products, as defined in** ~~Regulation (EC) No 726/2004 and~~ Directive 2001/83/EC~~ **(on medicinal products)**, including on advanced therapy medicinal products, regulated by~~ **advanced therapy**	3. ~~For~~ **In case of** SoHO~~s~~ ~~**or SoHO preparations**~~ that are used to manufacture products **regulated by**~~**defined in**~~ **other** ~~in accordance with~~Union legislation**,**~~on medical devices, regulated by~~ **in particular, medical devices, as defined in** Regulation (EU) 2017/745~~ **(on medical devices)**, **Regulation (EU) 2017/746 (on in vitro diagnostic medical devices),** on medicinal products, regulated by~~ **medicinal products, as defined in** ~~Regulation (EC) No 726/2004 and~~ Directive 2001/83/EC **(on medicinal products)**, ~~including on advanced therapy medicinal products, regulated by~~ **advanced therapy medicinal products, as**	Editorial change in order to clarify the text.	**CZ**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
medicinal products, as defined in Regulation (EC) No 1394/2007 ~~**(on advanced therapy medicinal products)**~~, ~~**Regulation (EU) No 536/2014 (on clinical trials on medicial products),**~~ ~~or on food, regulated by Regulation (EC) No 1925/2006~~ **~~(on food)~~**, ~~or as the starting and raw material thereof~~, ~~the provisions of~~ **the provisions of** this Regulation **~~shall apply for all SoHO to the extent that the activities to which they the SoHOs used to manufacture such products are subjected, including the provisions of this Regulation that are~~ applicable to the SoHO activities referred to in paragraph (1a) point (~~h~~i), (~~i~~ii), (~~j~~iii) and (~~k~~iv), shall apply in all cases. I~~i~~nsofar ~~are not regulated by~~ as the activities of SoHO referred to in paragraph (a) point (vii), (viii), (x) and (xi) relate to SoHO until their distribution to a manufacturer regulated by ~~the~~ other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.~~legislative frameworks is not applicable. NonethelessBy way of derogation, the provisions of this Regulation that are relevant applicable to the SoHO activities referred to in paragraph (1a) points (a), (b), (c) and (d) shall apply at all timesin all cases.~~ ~~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.~~	**defined in** Regulation (EC) No 1394/2007 ~~**(on advanced therapy medicinal products)**~~, **Regulation (EU) No 536/2014 (on clinical trials on medicial products),** ~~or on food, regulated by Regulation (EC) No 1925/2006~~ **~~(on food)~~**, ~~or as the starting and raw material thereof~~, ~~the provisions of~~ **the provisions of** this Regulation **~~shall apply for all SoHO to the extent that the activities to which they the SoHOs used to manufacture such products are subjected, including the provisions of this Regulation that are~~ applicable to the SoHO activities referred to in paragraph (1a) point (~~h~~i), (iii), (~~j~~iii) and (~~k~~iv), shall apply in all cases. I~~i~~nsofar ~~are not regulated by~~ as the SoHO activities ~~of SoHO~~ referred to in paragraph 1 point (c) point (vii), (viii), (x) and (xi) relate to SoHO until their distribution to a manufacturer regulated by ~~the~~ other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.~~legislative frameworks is not applicable. NonethelessBy way of derogation, the provisions of this Regulation that are relevant applicable to the SoHO activities referred to in paragraph (1a) points (a), (b), (c) and (d) shall apply at all timesin all cases.~~ ~~applicable to the activities of SoHO donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, and collection of SoHOs from donors or patients shall apply. Insofar as the activities of SoHO release, distribution,~~		

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~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.~~	~~import and export relate to SoHOs prior to their distribution to an operator regulated by the other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.~~		
		The reference to the IVD-regulation would add also the clarity of the text.	**FI**
	applicable to the SoHO activities referred to in paragraph ~~(1a)~~ (c) point (~~hi~~), (iii), (~~jiii~~) and (~~kiv~~), **to in paragraph ~~(a)~~ (c)**	Error of reference	**FR**
	3. ~~For~~ **In case of** SoHO~~s~~ **~~or SoHO preparations~~** that are used to manufacture products **regulated by~~defined in~~ other** ~~in accordance with~~Union legislation**,**~~on medical accordance with~~Union legislation**,**~~on medical devices, regulated by~~ **in particular, medical devices, as defined in** Regulation (EU) 2017/745 **~~(on medical devices)~~**, **~~Regulation (EU) 2017/746 (on in vitro diagnostic medical devices),~~** ~~on medicinal products, regulated by~~ **medicinal products, as defined in** ~~Regulation (EC) No 726/2004 and~~ Directive 2001/83/EC **~~(on medicinal products)~~**, ~~including on advanced therapy medicinal products, regulated by~~ **advanced therapy medicinal products, as defined in** Regulation (EC) No 1394/2007 **~~(on~~**	Deletion of Regulation (EU) No. 1925/2006 or the non-incorporation of Regulation (EC) No 178/2002 has the consequence that the relationship of the foodstuff legislation to the SoHO legislation is unclear. Breast milk, which, in contrast to breastfeeding one's own child, is to be given for the purpose of feeding other infants, is a foodstuff within the meaning	**DE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	~~advanced therapy medicinal products)~~, **~~Regulation (EU) No 536/2014 (on clinical trials on medicial products),~~** ~~or on food, regulated by Regulation (EC) No 1925/2006 (on food)~~, ~~or as the starting and raw material thereof~~, ~~the provisions of~~ **the provisions of** this Regulation **~~shall apply for all SoHO to the extent that the activities to which they the SoHOs used to manufacture such products are subjected, including the provisions of this Regulation that are~~ applicable to the SoHO activities referred to in paragraph (1c~~a~~) point (~~hi~~), (iii), (~~j~~iii) and (~~k~~iv), shall apply in all cases. Iinsofar ~~are not regulated by as~~ the activities of SoHO referred to in paragraph (~~a~~ c) point (vii), (viii), (x) and (xi) relate to SoHO until their distribution to a manufacturer regulated by ~~the~~ other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.~~legislative frameworks is not applicable. NonethelessBy way of derogation, the provisions of this Regulation that are relevant applicable to the SoHO activities referred to in paragraph (1a) points (a), (b), (c) and (d) shall apply at all timesin all cases.~~ ~~applicable to the activities of SoHO donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, and collection of SoHOs from donors or patients shall apply. Insofar as the activities of SoHO release, distribution, import and export relate to SoHOs prior to their~~	of Regulation (EC) No. 178/2002. According to Article 2 of Regulation (EC) No. 178/2002 means food or foodstuff any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. Breastmilk fullfills this definition an therefore falls under the scope of Regulation (EC) No. 178/2002. According to Article 1 (3) sentence 2 of Regulation (EC) No. 178/2002 only the primary production for private domestic use or for the domestic processing, handling or storage of food for private domestic consumption is excluded. Thus, the transfer of breast milk to other than own infants is placing food on the market according to this Regulation.	

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	~~distribution to an operator regulated by the other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.~~	Breast milk has been subject to food law for years. Therefore, a functioning monitoring system already exists in this area. Food law offers those who handle food (in this case breast milk) a secure legal framework through which safety and quality are guaranteed. In addition, food law offers the responsible authorities a catalogue of measures to ensure that the requirements are adhered to or that identified violations are remedied and prevented in the future (see Articles 137, 138 of Regulation (EU) 2017/625 on official controls) As soon as the SoHO Regulation comes into force, breast milk will also be classified as SoHO. This has an impact on two different szenarios: 1. Implifications on breast milk banks: Breast milk must first and foremost meet the general requirements for	

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		foodstuffs. Compliance with these requirements is checked as part of inspections. Additionally, the SoHO Regulation will be applied. This establishes authorisation and inspection obligations. 2. Implifications on products manufactured from breast milk. Such products currently on the market in Germany are classified as food for special medicinal purposes (FSMP) according to Del. Regulation 2016/128 and are used in hospitals to feed premature infants. There should be clarity on the legal provisions to be applied and on the extent of their application. It is our understanding that the Regulation on foodstuff be applied in addition to the SoHO Regulation. Therefore, this should be made clear in the Regulation and in the Recitals.	

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		For DEU it is important to keep it that way. Otherwise, FSMP containing human milk for premature infants may disappear from the market or would need to be regulated as medicinal product. **Red Line for DE!**	
	3. ~~For~~ **In case of** SoHOs~~**or SoHO preparations**~~ that are used to manufacture products **regulated by**~~**defined in**~~**other** ~~in accordance with~~Union legislation**,**~~on medical devices, regulated by~~ **in particular, medical devices, as defined in**Regulation (EU) 2017/745 ~~**(on medical devices)**~~, ~~**Regulation (EU) 2017/746 (on in vitro diagnostic medical devices),**~~ ~~on medicinal products, regulated by~~ **medicinal products, as defined in** ~~Regulation (EC) No 726/2004 and~~ Directive 2001/83/EC ~~**(on medicinal products)**~~, ~~including on advanced therapy medicinal products, regulated by~~ **advanced therapy medicinal products, as defined in**Regulation (EC) No 1394/2007 ~~**(on advanced therapy medicinal products)**~~, ~~**Regulation (EU) No 536/2014 (on clinical trials on medicial products),**~~ ~~or on food, regulated by Regulation (EC) No 1925/2006~~ ~~**(on food)**~~, ~~or as the starting and raw material~~	**Suggestion** to remove the list of activities that might be applicable as some activities, like processing, are left out in both para 3 & 4.	**NL**

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	~~thereof~~, ~~the provisions of~~ **the provisions of**this Regulation **~~shall apply for all SoHO to the extent that the activities to which they the SoHOs used to manufacture such products are subjected, including the provisions of this Regulation that are~~applicable to the SoHO activities referred to in paragraph (1a) point (~~h~~i), (iii), (~~j~~iii) and (~~k~~iv), shall apply in all cases.~~I~~insofar ~~are not regulated by~~ as the activities of SoHO referred to in paragraph (a) ~~point (vii), (viii), (x) and (xi) that~~ relate to SoHO until their distribution to a manufacturer regulated by ~~the~~other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.~~legislative frameworks is not applicable.NonethelessBy way of derogation, the provisions of this Regulation that arerelevant applicable to the SoHO activities referred to in paragraph (1a) points (a), (b), (c) and (d) shall applyat all timesin all cases.~~applicable to the activities of SoHO donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, and collection of SoHOs from donors or patients shall apply. Insofar as the activities of SoHO release, distribution, import and export relate to SoHOs prior to their distribution to an operator regulated by the other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.~~		

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	~~For~~ **In case of** SoHO~~s~~ **~~or SoHO preparations~~** that are used to manufacture products **regulated by~~defined in~~ other** ~~in accordance with~~Union legislation**,**~~on medical devices, regulated by~~ **in particular, but not limited to, medical devices, as defined in** Regulation (EU) 2017/745**~~ (on medical devices)~~**, **~~Regulation (EU) 2017/746~~**…	- Proposal to clarify that the list of other union legislation is not comprehensive. This is important also since reference is made to Art 2(3) in other parts of the regulation. It should be clear that also other products can be covered here, also for the future-proofing of the regulation. If such an addition is made, SE can accept the deletion in the list of other legal framworks. - SE would still like some more clarity when it comes to the relation between the SoHO regulation and the EU legislation on food. The definition of food in (EG) no. 178/2002 is very broad and per definition that regulation also covers HBM. Our preliminary analysis gives that there are no conflicts between the two regulations and that they thus could be applicable in parallell. Has the presidency made a similar analysis and come to the same conclusion? Otherwise there would be a need to make one of them subsidiary to the other. It would probably be useful to have a recital clarifying the relation between the regulation on food and the SoHO	SE

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		regualtion. - There should also be a clear delineation between the SoHO Regulatoin and the Reglation (EG) 609/2013 (on foods for infants and young children, foods for special medical porposes etc) in cases the HBM is used to manufacture such products. There are no references to the activities *processing* or *distribution* in the list of activities to which the regulation shall apply, if carried out before distribution for manufacture. If simpler processing is carried out before a SoHO is subjected to another Union legislation, what is to apply for that processing? SE agrees that it is correct to exempt such SoHO-preparations from the provisions of SoHO preparation authorisation. It would however be more convenient to regulate that in those articles, rather than taking such processing out of the scope of the regulation. We would strongly suggest to introduce a reference to, at least, processing here.	
~~By way of derogation from the first subparagraph, in cases where SoHOs, SoHO preparations, or products manufactured from SoHOs~~ **~~or SoHO preparations~~**~~, as referred to in that subparagraph, are exclusively for autologous use, only those provisions of this~~		If the possibility for manufacturers regulated by other Union legislation to import the SoHOs intended for manufacturing of products under authorization under this other legislation is excluded, this is a substantial burden to all SoHO CAs and also	**LV**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~Regulation that~~ **~~are relevant to the SoHO activity referred to in paragraph (1a) point (d)~~** ~~concern the collection of SoHOs from patients shall apply.~~		to manufacturers of such products (e.g., PDMPs) as it will be in contrary to flexibilities already in place and established by GMP Annex 14 requiring only 1 authorizatation for each actor (either manufacturing licence for fractionator, or SoHO establishment authorization for BE and their cooperation (incl. tasks and responsibilities, specifications, etc.) regulated by means of Technical Agreement). As pharma legislation allows technical agreements also with parties established in nonEEA countries, requirement to obtain authorization for SoHO imports will be considerable additional burden. We consider that this para 3 is adressed to situations when operators, other than manufacturers, perform import of SoHOs and then distribute them further to a manufacturer regulated by other Union legislation.	
4. Where non-viable SoHO~~s~~ or their derivatives, as defined in 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 SoHO~~s~~ or their derivatives is principal and not ancillary to that of the device, **this Regulation shall apply in full on** the non-viable SoHO~~s~~ or their derivatives ~~shall be governed by this Regulation~~. If the action of the non-viable	Where non-viable SoHO~~s~~ or their derivatives, as defined in 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 SoHO~~s~~ or their derivatives is principal and not ancillary to that of the device, **this Regulation shall apply in full on** the non-viable SoHO~~s~~ or their derivatives ~~shall be governed by this Regulation~~. If the action of the non-viable SoHO~~s~~ or their	Editorial change in order to clarify the text.	**CZ**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
SoHO~~s~~ or their derivatives is ancillary to that of the device and not principal, **the provisions of this Regulation applicable to the SoHO activities referred to in paragraph (1a) point (i), (ii), (iii) and (iv), shall apply in all cases. Insofar as the activities of SoHO referred in parragraph (1a) point (vii), (viii), (x) and (xi) relate to SoHO until their distribution to the manufacturer regulated by Regulation (EU) 2017/745, the provisions of this Regulation shall also apply.~~this Regulation shall apply for all SoHO activities to which the non-viable SoHOs or their derivatives are subjected, insofar as the extent that the activities to which the SoHOs or their derivatives are subjected are not regulated by Regulation (EU) 2017/745 is not applicable and the final product shall be subject to the provisions of that Regulation. By way of derogation, the provisions of this Regulation that are applicable to the SoHO activities referred to in paragraph (1a) points (a), (b), (c) and (d) shall apply in all cases.~~ 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.	derivatives is ancillary to that of the device and not principal, **the provisions of this Regulation applicable to the SoHO activities referred to in paragraph (1~~a~~) point c) (i), (ii), (iii) and (iv), shall apply in all cases. Insofar as the activities of SoHO referred in parragraph (1~~a~~) point c) (vii), (viii), (x) and (xi) relate to SoHO until their distribution to the manufacturer regulated by Regulation (EU) 2017/745, the provisions of this Regulation shall also apply.~~this Regulation shall apply for all SoHO activities to which the non-viable SoHOs or their derivatives are subjected, insofar as the extent that the activities to which the SoHOs or their derivatives are subjected are not regulated by Regulation (EU) 2017/745 is not applicable and the final product shall be subject to the provisions of that Regulation. By way of derogation, the provisions of this Regulation that are applicable to the SoHO activities referred to in paragraph (1a) points (a), (b), (c) and (d) shall apply in all cases.~~ 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.		
	4. Where non-viable SoHO~~s~~ or their derivatives, as defined in Article 2, point **(16)** **and** (17), of Regulation (EU) 2017/745, incorporate, as an integral part, a medical		**DE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	device, and where the action of the non-viable SoHOs or their derivatives is principal and not ancillary to that of the device, **this Regulation shall apply in full on** 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 applicable to the SoHO activities referred to in paragraph (1ca) point (i), (ii), (iii) and (iv), shall apply in all cases. Insofar as the activities of SoHO referred in parragraph (1a) point (vii), (viii), (x) and (xi) relate to SoHO until their distribution to the manufacturer regulated by Regulation (EU) 2017/745, the provisions of this Regulation shall also apply.** ~~**this Regulation shall apply for all SoHO activities to which the non-viable SoHOs or their derivatives are subjected, insofar as the extent that the activities to which the SoHOs or their derivatives are subjected are not regulated by Regulation (EU) 2017/745 is not applicable and the final product shall be subject to the provisions of that Regulation. By way of derogation, the provisions of this Regulation that are applicable to the SoHO activities referred to in paragraph (1a) points (a), (b), (c) and (d) shall apply in all cases.** 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		

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	~~SoHOs from donors or patients, shall apply~~.		
	4. Where non-viable SoHOsor their derivatives, as defined in 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 SoHOsor their derivatives is principal and not ancillary to that of the device, **this Regulation shall apply in full on** the non-viable SoHOsor their derivatives ~~shall be governed by this Regulation~~. If the action of the non-viable SoHOsor their derivatives is ancillary to that of the device and not principal, **the provisions of this Regulation applicable to the SoHO activities referred to in paragraph (1a) point (i), (ii), (iii) and (iv), shall apply in all cases. Insofar as the activities of SoHO referred in parragraph (1a) ~~point (vii), (viii), (x) and (xi)~~ that relate to SoHO until their distribution to the manufacturer regulated by Regulation (EU) 2017/745, the provisions of this Regulation shall also apply.~~this Regulation shall apply for all SoHO activities to which the non-viable SoHOs or their derivatives are subjected, insofar as~~the extent that the activities to which the SoHOs or their derivatives are subjected are not regulated by Regulation (EU) 2017/745 is not applicable and the final product shall be subject to the provisions of that Regulation. By way of derogation, the provisions of this Regulation that are applicable to the SoHO activities**	**Suggestion** to remove the list of activities that might be applicable as some activities, like processing, are left out in both para 3 & 4.	**NL**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	~~referred to in paragraph (1a) points (a), (b), (c) and (d) shall apply in all cases.~~~~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~~.		
4a. By way of derogation from paragraphs 3 and 4, when SoHO are used to manufacture products under other Union legislation for the exclusive therapeutic use on the person from whom SoHO are collected, only the provisions of this Regulation relating to the SoHO activities referred to in Article 2(1) (c) (iii and iv) shall apply.			
Article 3			
Definitions[1]			
~~[(1) 'blood' means the liquid that circulates in arteries and veins carrying oxygen to and carbon dioxide from the tissues of the body;]~~			
~~[(2) 'blood component' means a constituent of blood such as red cells, white cells, platelets and plasma, that can be separated from it;]~~			
~~[(3) 'cell' means a mass of cytoplasm with~~			

[1] Only definitions not revised along with the corresponding sections and chapters during ES PRES are included.

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~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;]~~			
~~[(4) 'tissue' means a group of cells that function together as a unit;]~~			
(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**, including SoHO preparations resulting from the processing of that substance;**~~. For the purposes of this Regulation, SoHO does not include organs in the sense of Article 3, point (h), of Directive 2010/53/EU;~~	'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**, including SoHO preparations resulting from the processing of that ~~substance~~ SoHO;**~~. For the purposes of this Regulation, SoHO does not include organs in the sense of Article~~	Editorial change in order to clarify the text.	**CZ**
		Denmark supports keeping this definition	**DK**
	(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**, including SoHO preparations resulting from the processing of that substance;**~~. For the purposes of this Regulation, SoHO does not include organs in the sense of Article 3, point (h), of Directive 2010/53/EU;~~	Deleting "in whatever manner" could be prejudicial to fecal collection.	**FR**
(6) 'human application' means inserted, implanted, injected, infused, transfused, transplanted, ingested, transferred ~~(as in transfer to the uterus or fallopian tube of a~~			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~woman)~~**,** inseminated or otherwise added to the human body in order to create a biological~~,~~ ~~mechanical~~ [~~or physiological~~] interaction with that body;			
(7) 'SoHO activity' means an action, or series of actions, that has a direct impact on the safety, quality or ~~efficacy~~ **effectiveness** of SoHOs, as listed in Article 2(1**c**);	(7) 'SoHO activity' means an action, or series of actions, ~~that has a direct impact on the safety, quality or efficacy~~**effectiveness**~~of SoHOs,~~ as listed in Article 2(1**c**);	Suggestion to delete part of the definition as is already mentioned in article 2(1c)	**NL**
(7a) 'Effectiveness' means the extent to which SoHO quality ensures that the intended ~~biological effect~~outcome is achieved in the recipient;	**'Effectiveness' means the extent to which SoHO quality ensures that the intended ~~biological effect~~outcome is achieved in the SoHO recipient;**	Editorial change in order to clarify the text.	**CZ**
	(7a) 'Effectiveness' means the capacity of a ~~extent to which~~ SoHO with its own specifications to reach an expected ~~quality ensures that the intended~~ biological ~~effect~~ or clinical outcome ~~is achieved in the recipient~~;	The definition of the term "effectiveness" should not mention quality in these terms, as it is not quality that ensures clinical outcome.	**FR**
	(7a) 'Effectiveness of SoHO' means the extent to which SoHO quality ensures that the intended ~~biological effect~~outcome is achieved in the recipient;	We propose a clarification of the proposed definition that would be more in line with the interpretation of the definition	**LV**
	(7a) 'Effectiveness' means the extent to which SoHO quality ensures that the intended ~~biological effect~~ clinical **outcome is achieved in the recipient;**	Proposal to add "clinical" to harmonise with other parts of the Regulation (for example recital 28, Art 3(22) and Art 41.)	**SE**
(15) 'processing' means any operation involved in the handling of SoHOs~~,~~ including**,**		We still have concerns on this definition with regard to our previous request	**BE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
but not limited to, washing, shaping, separation, fertilisation, decontamination, sterilisation, preservation and packaging;**except for the handling of SoHOs for immediate application ~~within the sterile field~~ during a surgical intervention, without ~~here~~ these SoHOs being removed from the surgical field before they are applied ~~are either released or for autologous application;~~**		on a bedside exception. In the current definition of 'processing', it is still not clear what surgical field exactly means, which could cause issues. On the other hand, it is still possible there is a release step during bedside processing in an autologous procedure. There are two points: 1) In the case of additional adaptation of a SoHO preparation for immediate application, where the preparation has previously been processed and released, this definition of processing ensures that this type of adaptation is not seen as processing, so no additional preparation authorization or release step is required. We support this. However, this derogation is based on the provision that the preparation may not leave the surgical field, to still fall under 'immediate application'. However, this creates another problem, namely that of possible contamination of the surgical field (including the patient), e.g.: the commission used the example of a released "bone" or similar materials, which a surgeon would	

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		have to "adapt" (i.e. cut/saw) before use. My experts inform me that this is often done with an electric saw - in that case, bone splinters can contaminate the "surgical field". A solution must be found for this. E.g. What exactly is meant by surgical field, can this be more clearly defined? And furthermore, would it not be easier to explicitly state that this exception applies to materials that have already been released and that need to be modified, before they can be applied? This would be less confusing. 2) We want to avoid that every hospital that processes a SoHO for immediate application during an autologous application in the same surgical procedure, makes a release step and therefore has to apply for authorization as an establishment. We agree that it is necessary to ensure that these products, even if they are autologous and prepared immediately, even within the surgical field, would have to be seen as "SoHO Preparations" and require an authorisation, such as platelet-Rich Plasma (PRP) (to use an example the Commission used	

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		earlier). However: a. This means that that kind of processing, would still need to be viewed as processing; b. This kind of 'Processing' during autologous application in the same surgical procedure should, however, not require a release step - and requesting authorization as an establishment would be too far-reaching here. As such, this issue is not solved by letting this type of bedside processing of an autologous SoHO also fall under the derogation in the definition of processing (point 1): this doesn't solve the "release" problem, and creates a new risk – as there is no processing, there might not be a requirement to have the preparation itself be authorised. After all, there is processing, but the processing is of such an immediate nature that no release step is necessary or wanted. Regarding this, we think it is important to fix this issue via the articles regarding release (see our comment on article 60, document 13586/23.	
		- What does the term "surgical field" mean in this context"? The term is new to SoHO regulation. The current legislation refers to the procedure, not	**FI**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		the physical area in which the processing is done. Does this create an incentive or need to move equipment into the surgical room to be included in this definition and therefore be exempt from following the regulation?	
	(15) 'processing' means any operation involved in the handling of SoHOs~~,~~ including**, but not limited to,** washing, shaping, separation, fertilisation, decontamination, sterilisation, preservation and packaging;~~**except for the handling of SoHOs for immediate application within the sterile field during a surgical intervention, without here these SoHOs being removed from the surgical field before they are applied are either released or for autologous application;**~~	We understand thaht the part of the sentence "except for the handling of SoHO for immediate application (...) before they are applied" is used to exclude autologous products from the scope without being processed during surgery. It seems that this is to limit the scope of application and not to define the word "processing". In this case, it would be preferable to specify this in Article 2. Moreover, SoHO can be processed autologously even during surgery (this is what we call perioperative processing in France). However, this part of the sentence seems to exclude manipulations at the patient's bedside, whereas France argues that this should be included in the scope of the regulation. France is therefore in favour of deleting the addition "except". In any event, if this part of the sentence is retained, the notion of autologous donation	**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		should be reinstated, because if it is deleted, it could be imagined that a donor and a recipient are in the same room and that the Regulation does not apply.	
	(15) 'processing' means any operation involved in the handling of SoHOs~~,~~ including**,** **but not limited to,** washing, shaping, separation, fertilisation, decontamination, sterilisation, preservation and packaging;**except for the handling of SoHOs ~~for immediate application~~ ~~within the sterile field during a surgical intervention, without here these SoHOs being removed from the surgical field before they are applied~~ ~~are either released or for autologous application;~~**	We agree in principle. However, containment by 'immediate application' is not necessary. It should be sufficient that the retransfer of the SoHO takes place within the same procedure. The criterion of 'immediate application' raises questions such as whether the retransfer after a short lay down within the sterile operating field can still be considered an immediate application.	**DE**
		Clarifications on the exact meaning of "surgical field" are requested.	**IT**
		We would appreciate clarification on "removed from surgical field" in Recitals.	**LV**
	'processing' means any operation involved in the handling of SoHOs~~,~~ including**, but not limited to,** washing, shaping, separation, ~~**fertilisation**~~, decontamination, sterilisation, preservation and packaging;**except for the handling of SoHOs for immediate application ~~within the sterile field during a surgical intervention, without here these SoHOs being removed from the surgical field before they are applied~~ ~~are either released or for~~**	In line with the government's position, Poland proposes to remove the word fertilization from the definition. Even if you remove fetilisation, the definition contains an open catalogue and this will not change its scope.	**PL**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	~~autologous application;~~		
	‘processing’ means any operation involved in the handling of SoHOs~~,~~ including**, but not limited to,** washing, shaping, separation, **filtration,** fertilisation, decontamination, sterilisation, ~~preservation~~ **storage** and packaging;**except for the handling of SoHOs for immediate application ~~within the sterile field~~ during a surgical intervention, without ~~here~~ these SoHOs being removed from the surgical field before they are applied ~~are either released or for autologous application;~~**	To include “filtration”, to have a frequently used process in the blood establishments-leucodepletion mentioned in the regulation. To replace “preservation”, which was deleted from the definitions with “ storage”.	**RO**
	‘processing’ means any operation involved in the handling of SoHOs~~,~~ including**, but not limited to,** washing, shaping, separation, ~~fertilisation~~, decontamination, sterilisation, preservation and packaging; **except for the handling of SoHOs for immediate application ~~within the sterile field~~ during a surgical intervention, without ~~here~~ these SoHOs being removed from the surgical field before they are applied ~~are either released or for autologous application;~~**	In support of the PL proposal	**SK**
		The use of phrase surgical field is not clear.	**SI**
	“… before they are applied, and except for the mixing of released breast milk with medicines, food or fortifiers before **human** application”	It is important that the mixing of released HBM with medicines or nutrients before application to a premature child is not considered processing in a way that this activity would require a preparation authorisation. We are not sure if this is safeguarded by the wording in 40.1, where	**SE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		the need for a prepartion authorisation is connected to release. (The mixing would be performed with already released SoHOs). To ensure this is correctly interpreted, we propose it is clarified here, that a SoHO preparation authorisation is not needed when HBM is used as a medium to give medicines or nutrients to the recipient baby. See also, as a possible alternative, our proposal for a recital in document for comments on 13655.	
~~**(15a) 'preservation' means modifying the conditions of SoHOs in such a manner as to prevent deterioration over time of certain properties critical for their safety or quality, including placing SoHOs in an environment where the temperature differs from ambient;**~~			
(17) 'storage' means the maintenance of SoHO~~s~~ under appropriate controlled conditions **until they are transferred to another ~~authorised~~ SoHO entity** ~~until distribution~~;	'storage' means the maintenance of SoHO~~s~~ under appropriate controlled conditions **until they are transferred to another ~~authorised~~ SoHO entity or transferred for application** ~~until distribution~~;	CZ considers it important to change the wording of the definition no. 17 on storage in accordance with the final version of the scope of the Regulation. Provided exluding of "human application" from the scope of the Regulation, changes of wording are suggested.	**CZ**
		Denmark supports the wording: 'storage' means the maintenance of SoHOs under appropriate controlled conditions.	**DK**
	(17) 'storage' means the maintenance of SoHO~~s~~ under appropriate controlled conditions	France supports the Presidency's proposal, announced at the group meeting on 6	**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	~~until they are transferred to another authorised SoHO entity~~ ~~until distribution;~~	October, to remove the end of the definition from "until".	
		We would like to have a practical example how (15) and (17) definitions exclude hospital blood banks from being SoHO establishments or a Recital referring to this.	**LV**
		We understood from the Presidency's explanation that the last underlined part of this definition is going to be deleted. SE would support a clarification on the definition, as the present wording indicates that it is only storage if the SoHO is transferred to another entity. It should also cover cases when SoHOs are stored until distribution or export.	**SE**
(19) 'distribution' means ~~transportation and delivery~~ **the procedures for providing**, ~~within the Union, of~~**,within the Union,** released SoHO~~s~~**:**		This definition is very different from the one in the directives and from the original one. We ask to restore the original definition that was removed, while appreciating the subsequent specifications that have been introduced (a, b, c).	**IT**
		Support for the compromise text. Did the PRE however consider to include in the definition that re-distribution is possible? Or is it in the opinion of the PRE legally sound enough to only mention this in the recitals?	**NL**
(a) ~~or SoHO preparations~~ intended for human application **to a specific SoHO**	~~or SoHO preparations~~ intended for human application **to a specific SoHO recipient in the**	CZ refers to previously expressed CZ comments on the scope of the Regulation,	**CZ**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
recipient in the same or another SoHO entity;	**same or another SoHO entity or transferred for application**	particularly human application. Similarly to the definition no. 17 on storage change of wording should be reflected in this definition.	
		For the transfusion field: is it correct to understand that this " distribution" situation corresponds/is equivalent to the "issuing" activity?! (specific for HBB, BEs)	**RO**
(b) intended for human applications in general, without the prior identification of a specific recipient, in the same or another SoHO entity;	**intended for human applications in general, without the prior identification of a specific SoHO recipient, in the same or another SoHO entity;**	Editorial change in order to clarify the text.	**CZ**
(c) ~~or~~ **intended** for the manufacture of products regulated under **other** ~~other~~ Union legislation, **as referred to in Article 2(3),** ~~or as the starting and raw material thereof,~~ ~~[~~***~~within the Union~~***~~]~~including within the same ~~organisation when SoHOs are delivered from a SoHO entity to a unit responsible for human application~~**to a manufacturer of such products;**			
~~[(30) 'non-viable' means having no potential for metabolism or multiplication.]~~			
~~[(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~~			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~SoHO preparation that is considered to be acceptable as a means to comply with regulatory standards;~~]			
(61) 'reproductive ~~cells~~**SoHO'** means **human sperm, oocytes, ovarian ~~or~~and testicular tissue ~~and any preparation resulting from the processing of those SoHO, including embryos,~~** ~~all cells~~ intended to be used for the purpose of medically assisted reproduction. **For the purposes of this Regulation, embryos are also considered reproductive SoHO even if they are not collected from the human body;**	'reproductive SoHO' means human sperm, oocytes, ovarian and testicular tissue intended to be used for the purpose of medically assisted reproduction **or hormonal recovery**. For the purposes of this Regulation, embryos are also considered reproductive SoHO even if they are not collected from the human body;	Denmark propose to add the text in bold, since some hormone producing reproductive tissues not only are transplanted for the purpose of medically assisted reproduction	**DK**
		Support of the wording in this compromiss text. The other wording in the compromise text 13655/23 is not support (see comments on Art. 3 (61) of the compromise text 13655/23).	**DE**
	reproductive ~~cells~~**SoHO'** means **human sperm, oocytes, ovarian ~~or~~and testicular tissue ~~and any preparation resulting from the processing of those SoHO, including embryos,~~** ~~all cells~~ intended to be used for the purpose of medically assisted reproduction or for restoring of endocrinal functionality. **For the purposes of this Regulation, embryos are also considered reproductive SoHO even if they are not collected from the human body**	We request to add the reference to the recovery of endocrine function.	**IT**
		We support DK proposal to add "for hormonal recovery".	**LV**
		Poland supports the definition in the	**PL**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		wording proposed by PREZ.	
[(68) 'plasma for transfusion' means plasma separated from whole blood or collected by apheresis for the purpose of transfusion to a recipient;]			
[(69) 'plasma for fractionation' means plasma separated from whole blood or collected by apheresis and used as the starting material for manufacturing of plasma-derived medicinal products;]			
[(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 4			
More stringent Member State measures			
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. **Apart from provisions concerning the organisation and delivery of medical services and healthcare,** Member States may maintain or introduce within their territories **specific** measures **concerning SoHO** 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.	*Measures pertinent to the organisation and delivery of health services and medical care should be distinguished from the category of "more stringent protective measures" in the area of SoHO. The national rules on hospital care for example should remain outside of the scope of this Regulation. Art. 4, on the other hand, regulates the category of more stringent measures within the scope*	**BG**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		of the Regulation itself (SoHO).	
2. Member States shall make available to the public details of **the more stringent** 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 **such** more stringent measure**s** to the EU SoHO Platform ~~referred to in Chapter XI.~~	2. Member States shall make available to the public details of **the more stringent** 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 **such** more stringent measure**s** to the EU SoHO Platform ~~referred to in Chapter XI.~~	We ask for clarification : how should we interpret this obligation?! Do you mean the institution website?!	**RO**
CHAPTERS III, IV & V and related recitals and definitions organised by sections:			
Section VII – Authorisation of SoHo preparations: Recitals 27, 28, 29, 30; Articles 3(12), 3(22), 3(22a), 3(25), 3(39), 3(43), 3(57), 3(58), 3(59), 20, 21, 22, 22a, 23, 24, 40, 41			
Recitals:			
(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 **effectiveness** ~~efficacy~~ is achieved consistently by the application of that specific series of activities, performed in that specific manner. When SoHOs are prepared	(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 **effectiveness** ~~efficacy~~ is achieved consistently by the application of that specific series of activities, performed in that specific		**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
with newly developed and validated collection, testing or processing methods, consideration should be given to the demonstration of safety and **effectiveness** ~~efficacy~~ in **SoHO** 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 **SoHO** recipients (or offspring in the case of medically assisted reproduction), the vigilance reporting requirements provided for in this Regulation should be adequate to ~~demonstrate~~ **verify** 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.	manner. When SoHOs are prepared with newly developed and validated collection, testing or processing methods, **or for a new indication**, consideration should be given to the demonstration of **positive benefit and risk ratio (**safety and **effectiveness** ~~efficacy~~ in **SoHO** 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 uncertainties existing on the benefit risk ratio** ~~of risk associated with the activities performed~~ for that SoHO preparation and use. Where **clinical data are available or can be extrapolated from another comparable SoHO** ~~a new or modified SoHO preparation poses negligible risks for **SoHO** recipients (or offspring in the case of medically assisted reproduction)~~, the vigilance reporting requirements provided for in this Regulation should be adequate to ~~demonstrate~~ ~~**verify**~~ **confirm there is no new safety signal and so confirm** 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.		
(28) With regard to SoHO preparations that pose a certain level of risk (low, moderate or high), the applicant should propose a plan for	(28) With regard to SoHO **for which there is a certain level of uncertainty regarding the benefit-risk ratio** ~~preparations that pose a~~		**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
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 pro-active clinical follow-up for a defined number of **SoHO recipients** ~~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 **endpoints** ~~end-points~~. In case of high risk, these should include a comparison with standard **therapy** ~~treatments~~, ideally in a study with **SoHO recipients** ~~subjects~~ allocated to test and control groups in a 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.	~~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~~**level of uncertainties**. 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 uncertainties on**~~level of risk~~ ~~of~~ the SoHO preparation. In the case of low ~~risk~~ **incertainties**, in addition to the mandatory continuous vigilance reporting, the applicant should organise pro-active clinical follow-up for a defined number of **SoHO recipients** ~~patients~~. For moderate and high ~~risk~~**uncertainties**, in addition to the mandatory vigilance reporting and the clinical follow-up, the applicant should propose **to limit the** clinical investigation studies with monitoring of pre-defined clinical **endpoints** ~~end-points~~. In case of high risk, these should ~~include~~ **limit the availability of the product to certain pre-identified entities in order to guarantee the safety of recipients and completeness of the monitoring.** **In parallel with the monitoring plan** a comparison with standard **therapy** ~~treatments~~, ideally in a study with **SoHO recipients** ~~subjects~~ allocated to test and control groups in a randomised manner**, may be in place**.	Comparison with existing treatments is not mandatory to demonstrate the B/R in an indication but this gives the place in a therapeutic strategy. The response provided by the monitoring plan and the comparison	

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	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.	with the standards of care is not the same.	
	(28) With regard to SoHO preparations that pose a certain level of risk (low, moderate or high), the applicant should propose a plan for clinical outcome monitoring that should fulfil different requirements appropriate to the risk indicated. The most up-to-date guidance of the European Directorate for the Quality of Medicines & HealthCare (EDQM, a Directorate of the Council of Europe) should be considered relevant in the design of clinical follow-up studies proportionate in extent and complexity to the identified level of risk of the SoHO preparation. In the case of low risk, in addition to the mandatory continuous vigilance reporting, the applicant should organise pro-active clinical follow-up for a defined number of **SoHO recipients** ~~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 **endpoints** ~~end-points~~. In case of high risk, these should include a comparison with standard **therapy** ~~treatments~~, ideally in a study with **SoHO recipients** ~~subjects~~ allocated to test and control groups in a randomised manner. The **SoHO** competent authority should approve the plans before they are implemented and should assess	To whom goes the responsibility to asses the risk?! If it is the responsibility of the applicant, which it seems obvious from the text, will the CA accept it without assessment of the risk analysis? Maybe an additional sentence giving the CA the right to ask for additional actions to be taken as part of the plan, if it is considered necessary, would be usefull.	**RO**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	the outcome data as part of a SoHO preparation authorisation.		
(29) In the interests of efficiency, it should be permitted to conduct clinical outcome studies using the established framework in the pharmaceutical sector for clinical trials, as set out in Regulation (EU) No 536/2014 of the European Parliament and of the Council[2], when **SoHO entities** ~~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 **SoHO** competent authority, or are certified by an external institution, in terms of the reliability of their data **quality** management procedures.			
(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 **recipients** ~~patients~~. Such sharing could allow **SoHO competent** authorities to accept	(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 **recipients** ~~patients~~. Such sharing could allow **SoHO competent** authorities to accept previous	Does it mean that a CA may ask another one the information about an already authorised SOHO preparation, directly, without going through the National Authority to intermediate communication?! Is is mandatory for the MS to provide any information or some limitations have been foreseen?!	**RO**

[2] 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).

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
previous authorisations granted to other **SoHO** entities, including in other Member States and to thus significantly reduce the requirements to generate evidence.	authorisations granted to other **SoHO** entities, including in other Member States and to thus significantly reduce the requirements to generate evidence.		
CHAPTER I			
GENERAL PROVISIONS			
Article 3			
Definitions			
(12) 'SoHO preparation' means a ~~particular~~ type of SoHO**,** that:		France reiterates the comment it has made on several occasions: the link between this definition of SoHO preparations (or is intended for distribution for manufacture of a product regulated by other Union legislation, as referred to in Article 2(3)) and the requirement for an authorisation for SoHO preparations means that an authorisation must be issued for SoHO used in the manufacture of another health product. France considers this inappropriate, since the finished product will be authorised under its own regulations (see proposed amendment to Article 20).	**FR**
(a) has been subjected to one or more SoHO activities, **as listed in Article 2(1a), point c, ~~at least,~~** including processing, in	(a) has been subjected to ~~one or more SoHO activities, as listed in Article 2(1a), point c, at least, including~~ processing, in	Proposal for simplification. The SoHO activity 'processing' is decesive for the classification as SoHO preparation.	**DE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
accordance with defined quality**,** ~~and~~ safety **and effectiveness** parameters **in this Regulation**; **and**	accordance with defined quality**,** ~~and~~ safety **and effectiveness** parameters **in this Regulation**; **and**		
	(a) has been subjected to one or more SoHO activities, **as listed in Article 2(1a), point c, ~~at least,~~** at least including processing, in accordance with defined quality**,** ~~and~~ safety **and effectiveness** parameters **in this Regulation**; **and**	Support for the remark made by HUN that it is not yet clear that it is a prerequisite that soho is processed to become a SoHO preparation. See suggestion	**NL**
~~(b) meets a pre-defined specification; and~~			
(c) is intended for application to a **SoHO** recipient for a specific clinical indication or is intended for distribution for manufacture of a product regulated by other Union legislation, **as referred to in Article 2(3)** ~~or as the starting and raw material thereof~~;		As we see it SoHO preparations can include processed SoHO that are intended for manufacture for products reguled in other Union legislation. It must, nevertheless, be clarified that there is no requirement for SoHO preparation authorisations for the processing of SoHO which are distributed for manufacture of products regulated in other Union legislation. See also comments under Section VII.	**SE**
(22) 'clinical outcome **monitoring** ~~monitoring~~ **registration**' means **evaluation of the health of a SoHO recipient for the purpose of following-up the results of a SoHO preparation application, maintaining care and demonstrating safety and effectiveness** ~~recording information on results from clinical outcome monitoring as referred in~~		The clinical outcome cannot be monitored by a Blood Establishment. The treating physician is responsible for a transfused patient and their health. Therefore the blood established will onlly have a report from the physician when an adverse reaction occurs or sth that the physician wants to highlight as a result of a transusion.	**CY**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~**Article 41, including transferring such information to other registries** 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~~];	clinical outcome **monitoring** ~~**registration**~~ **' of SoHOs or SoHO preparations in clinical studies or of SoHO preparations with a conditional permission** means **evaluation of the health of a SoHO recipient for the purpose of following-up the results of a SoHO preparation application, maintaining care and demonstrating safety and effectiveness** ~~**recording information on results from clinical outcome monitoring as referred in Article 41, including transferring such information to other registries** 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~~];	In accordance with the previously expressed comments to Article 22a and to the scope of the Regulation, CZ is of the opinion that the proposed version of the definition no. 22 on clinical outcome monitoring registration is confusing. We recommend not combining "monitoring", "clinical outcome" and "registration" terms in one. A change in wording is suggested. Monitoring should be narrowed into monitoring in clinical studies or in conditional persmission on SoHO preparations. If changes are not made in the Article related to the scope of the Regulation (Article 2 para 1 c)) CZ considers it important to change the definition no. 22.	**CZ**
	(22) 'clinical outcome monitoring registration' means **evaluation of impact on the health/ disease of a SoHO recipient** ~~**for the purpose of following-up the results of**~~ **after a SoHO preparation application**~~**, maintaining care and demonstrating safety and effectiveness**~~		**FR**
		(included definition from document 13503/23 + COR 1) – no comments	**NL**
(22a) clinical outcome monitoring plan' means a programme for monitoring, including the lasting of monitoring safety, effectiveness and indicators of effectiveness;		It is not sufficiently clear from this definition that the soHo entity must collect clinical monitoring data and that this collection is carried out according to a plan that it has drawn up and which is authorised	**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		by the competent authority.	
	(22a) clinical outcome monitoring plan' means a programme for monitoring, including the lasting of monitoring safety and effectiveness ~~and indicators of effectiveness~~	It is not comprehensible why the 'indicators of effectiveness' are mentioned separately.	**DE**
	~~**(22a) clinical outcome monitoring plan' means a programme for monitoring, including the lasting of monitoring safety, effectiveness and indicators of effectiveness;**~~	Suggestion to delete as already sufficiently explained in the articles on clinical outcome monitoring.	**NL**
	The definition could use some clarification as the wording is not completely clear. It may be considered sufficiently described in the Articles? Is the definition needed?	**SE**	
~~(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;~~			
~~[(39) 'assessors' means personnel performing the assessment of SoHO preparations as referred to in Article 22;]~~			
~~[(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;]~~			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~[(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;]~~			
~~[(58) 'equipment qualification' means establishing documented evidence that provides a high degree of assurance that a specific piece of equipment will consistently perform to predetermined specifications;]~~			
~~(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;~~			
CHAPTER III			
SoHO SUPERVISORY ACTIVITIES			
Article 20			
SoHO preparation authorisation system			
SoHO ~~C~~competent authorities shall establish and maintain a system for **granting** ~~receiving and processing requests for the~~ authorisations of SoHO preparations **to SoHO entities**	**1. (…) territory, excepted for SoHO preparations intended for distribution for manufacture of a product regulated by other Union legislation, as refered to in Article 2(3).**	Important point for France **The authorisation should be limited to SoHO preparations intended for direct therapeutic use and**	**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
located on their territory. The system **shall include the reception and processing of requests and the approval of clinical outcome monitoring plans for the generation of evidence required for authorisation, where necessary, and** shall allow for the suspension or withdrawal of authorisations.		**exclude those intended for use in another health product.** Furthermore, from an editorial point of view, France considers that the term "processing" in the sentence "the system shall include the reception and processing of requests" is too close to the term used in definition 15 for SoHOs. Couldn't another term be used?	
	1. **SoHO** ~~C~~competent authorities shall establish and maintain a system for **granting** ~~receiving and processing requests for the~~ authorisations of SoHO preparations **to SoHO entities located on their territory.** The system **shall include the** ~~**reception**~~ **submission and processing of requests and the approval of clinical outcome monitoring plans for the generation of evidence required for authorisation, where necessary, and** shall allow for the suspension or withdrawal of authorisations.		**SI**
2. **SoHO c**~~C~~ompetent authorities shall authorise SoHO preparations pursuant to Articles 21, 22 and, where applicable, Article 23.			
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 to Article 21 (2), point (d)** or until ~~a~~ **the**			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
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 **until ~~it has verified~~ the SoHO entity authorised for the SoHO preparation has demonstrated to that Member State the compliance with that more stringent measure** ~~pending verification that the more stringent measure has been met.~~			
~~4. The Commission may adopt implementing acts concerning the compatibility and comparability of the SoHO preparation authorisation system.~~			
~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).~~			
Article 21		***Further DE commets on Art. 22 and 22a you can find in the specific new process document for theses Articles***	**DE**
Authorisation of SoHO preparations		Denmark supports the new compromise text presented at the meeting Oct. 10	**DK**
1. **SoHO** ~~C~~competent authorities shall ~~have procedures in place to allow that applications for the authorisation of SoHO~~			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~preparations are submitted in accordance with Article 41. They shall~~ provide guidelines and templates for the submission of applications for SoHO preparation authorisation, **in accordance with Article 41, and ~~including those~~ for the design of clinical outcome monitoring plans proposed, in accordance with Article 22a ~~that are proportionate to the level of risk assessed by the applicant.~~** When developing these guidelines and templates, **SoHO** competent authorities **shall use the ~~models~~ templates and** shall **take into account** ~~consult~~ the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c). **SoHO** ~~C~~**c**ompetent authorities may establish simplified procedures for applications concerning modifications to previously authorised SoHO preparations.			
SoHO competent authorities may use the secure communicaction channel on the EU SoHO Platform for the exchange, with the SoHO entity, of documents relating to the application and authorisation of SoHO preparations~~, including those for the design of clinical outcome monitoring plans that are proportionate to the level of risk~~.			
2. Upon receipt of an application for the authorisation of a **SoHO** preparation, **SoHO** competent authorities shall:	2. Upon ~~receipt~~ submission of an application for the authorisation of a **SoHO** preparation, **SoHO** competent authorities shall:		**SI**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
(a) acknowledge receipt of the application **without undue delay** ~~within 14 working days;~~	~~(a) acknowledge receipt of the application **without undue delay** within 14 working days;~~ a) review submitted application persuant to Article 41 and request the applicant to provide supplementary information and documentation , if needed;		**SI**
(b) assess the SoHO preparation pursuant to Article 22 and examine agreements between the applicant ~~SoHO entity~~ and **other SoHO entities or** ~~any~~ third parties contracted ~~by~~ **to perform** ~~that SoHO entity concerning~~ SoHO activities, **in relation to the SoHO preparation** where applicable;	(b) assess the SoHO preparation pursuant to Article 22 and examine agreements between the applicant ~~SoHO entity~~ and **other SoHO entities or** ~~any~~ third parties contracted ~~by~~ **to perform** ~~that SoHO entity concerning~~ SoHO activities, **in relation to the SoHO preparation** where applicable; and **request ~~to~~ the applicant ~~SoHO entity~~ to provide supplementary information and documentation , if needed;**	(ba) is merged with (b)	**SI**
	(b) assess the SoHO preparation pursuant to Article 22 and examine agreements between the applicant ~~SoHO entity~~ and **other SoHO entities or** ~~any~~ third parties contracted ~~by~~ **to perform** ~~that SoHO entity concerning~~ ~~SoHO~~ activities, **in relation to the SoHO preparation** where applicable;	There is a reference in this point to "third parties preforming SoHO activities". As we undestood the explanation from the Presidency, third parties are such parties that are performing activities for an entity, that are not SoHO activities. This should be corrected here for the sake of clarity. See proposal.	**SE**
(ba) request ~~to~~ the applicant ~~SoHO entity~~ to provide supplementary information, if needed;	~~**(ba) request to the applicant SoHO entity to provide supplementary information and documentation , if needed;**~~	(ba) is merged with (b)	**SI**
(c) grant **or refuse the approval for** ~~a conditional authorisation for the use of the~~			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~SoHO preparation in all cases where~~ clinical outcome **monitoring plans, as appropriate** ~~data is required for authorisation~~, pursuant to Article 22(4), points (d) and (e); **and indicate any conditions that ~~may~~ apply, as well as ~~and~~ a time limit for the applicant to submit the results of the approved clinical outcome monitoring;**			
(d) **on the basis of the assessment performed in point (b), and the results of the clinical outcome monitoring referred to in point (c),** grant or refuse the authorisation for the SoHO preparation **and, if any**, ~~as~~ appropriate,~~**taking into accout the assessment performd in point (b), and the results of the clinical outcome monitoring referred to in point (c), if required, indicating which conditions apply, if any**~~.	(d) **on the basis of the assessment performed in point (b), ~~and the results of the clinical outcome monitoring referred to in point (c),~~** grant or refuse the authorisation for the SoHO preparation **and, if any**, ~~as~~ appropriate,~~**taking into accout the assessment performd in point (b), and the results of the clinical outcome monitoring referred to in point (c), if required, indicating which conditions apply, if any**~~.	France would like to see a clearer distinction made in this article between the time of submission of : - on the one hand, the clinical results monitoring plan (and its approval by the competent authority) and - the application for authorisation to prepare SoHO (and its authorisation/refusal by the competent authority). Otherwise, there is a risk that (d) will be misunderstood. It would be preferable for the wording to clearly state that these applications are made sequentially.	**FR**
3. **SoHO** ~~C~~**c**ompetent authorities shall submit information regarding **the** ~~granted~~ **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		Only positive outcome (granted authorisations) will be submitted to the Platform?	**SI**
		As we have already put forward in previous comments, we do not understand the reason for the deletion of the	**SE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
preparation, amend accordingly the authorisation **information** ~~status~~ of the SoHO entity **concerned** ~~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.~~		requirement to submit evidence used to authorise the preparation If a preparation is to be authorised under Art 22(3), can it not be helpful for the SoHO compentent authority performing such assessment to have access to such evidence? Furthermore, recital 30 seems to contradict a deletion in this Article.	
4. **SoHO** ~~C~~**c**ompetent authorities shall conclude the SoHO preparation authorisation ~~steps~~, referred to in paragraph 2 of this Article, ~~**whitout undue delay and**~~ ~~within 3 months from receipt of the application,~~ **in accordance with national legislationi,** ~~excluding the time needed for clinical outcome monitoring or~~ ~~**for the performance of additional validation or the gerneration of additional quality data as requested by the SoHO competent authority prior to the authorisation**~~ ~~studies~~. **SoHO competent authorities** ~~They~~ may suspend this time limit for**:**	"legislation"	"legislationi" – probably typo.	**EE**
		France would have liked the Regulation to provide for harmonised application assessment times at EU level, especially in the context of a Regulation that provides for joint assessments. The absence of deadlines could act as a brake on these joint assessments. Furthermore, from an editorial point of view, insofar as the time limit for assessment by the competent authorities has been removed, the words "*SoHO competent authorities may suspend this time limit for:"* are not appropriate.	**FR**
	4. **SoHO** ~~C~~**c**ompetent authorities shall conclude the SoHO preparation authorisation ~~steps~~, referred to in paragraph 2 of this Article, ~~**whitout undue delay and**~~ ~~within 3 months from receipt of the application,~~ **in accordance with national legislationi,** ~~excluding the time needed for clinical outcome monitoring or~~ ~~**for the performance of additional validation or the**~~	For greater clarity of the text, a modification of the wording is proposed.	**IT**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	~~**gerneration of additional quality data as requested by the SoHO competent authority prior to the authorisation** studies. **SoHO competent authorities** They may suspend this time limit for:~~ **The time limit foreseen for the authoritation in the national law may be extended for:**		
	4. **SoHO** ~~C~~competent authorities shall conclude the SoHO preparation authorisation ~~steps~~, referred to in paragraph 2 of this Article, ~~**whitout undue delay and**within 3 months from receipt of the application,~~ **in accordance with national legislationi,** ~~excluding the time needed for clinical outcome monitoring or **for the performance of additional validation or the gerneration of additional quality data as requested by the SoHO competent authority prior to the authorisation**studies~~. **SoHO competent authorities** ~~They~~ may suspend th~~is~~eirtime limit for**:**	Minor text suggestion needed as there is no specified time limit anymore	**NL**
		In this new wording the time-limit is deleted and changed into "in accordance with national legislation". However, there is still a reference to a suspension of the time-limit for certain reasons. This seems inconsistent and needs a clarification.	**SE**
(a) the duration of the consultation processes referred to in Article 14(1)~~and.~~ (2) **and (3),**			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
(b) ~~and in case of~~ a request for additional information to the SoHO entity,	(b) a request for additional information to the SoHO entity, **including the performance of additional validation or the generation of additional quality and safety data as requested by the SoHO competent authority."**	The b) and d) could be joined	**FR**
(c) the time needed to perform clinical outcome monitoring, or		Same as above	**CY**
		The plan is not implemented while the application is being assessed. The Competent Authority authorises the preparation as part of a plan to monitor the clinical results (and therefore the plan) for a certain period of time and then either the Competent Authority assesses a new application with the results of the plan, or it assesses the results of the plan in a specific procedure which is different from the initial assessment.	**FR**
(d) the performance of additional validation or the generation of additional quality and safety data as requested by the SoHO competent authority.	**~~(d) the performance of additional validation or the generation of additional quality and safety data as requested by the SoHO competent authority.~~**	See comments under b)	**FR**
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 ~~appropriate certification of~~ that the medical		FR notes that in this provision only certification by the notifying body is mentioned and not the derogation situations in Article 59 of Regulation 2017/745 or the "in house" possibility in Article 5.	**FR**
	4a. For SoHO preparations that incorporate a medical device as an integral	The CE certificates are issued by the *notified body*, we suggest the wording used in	**LV**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
device has been certified by the competent body.	**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 ~~appropriate certification of~~ that the medical device has been certified by the notified body.**	Regulation (EU) 2017/745.	
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** competent authorities receiving the request shall **provide an opinion regarding compliance of the SoHO preparation part with the provisions of this Regulation, pursuant to Annex IX (5) (3)(1) of Regulation (EU) 2017/745** ~~follow the relevant procedure of that Regulation~~, and inform the SCB of the opinion provided.			
6. **SoHO** Competent authorities may, in accordance with national legislation, suspend the authorisation of a SoHO preparation**, or the realisation 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:**	6. **SoHO** Competent authorities may, in accordance with national legislation, suspend the authorisation of a SoHO preparation**, or the ~~realisation~~execution 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:**	Minor text suggestion for more suitable wording	**NL**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
(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~~			
(b) **do not comply with the provisions of this Regulation; or**~~**and such**~~	(b) **do not comply with the provisions of this Regulation; and such** ~~**or**~~**and such**	By changing "and" into "or" (c) has no value anymore as it is already covered with (b). This is however not desireable. Suggestion to change "or" in (b) back to "and" that makes this measure proportional to the non-compliance.	**NL**
(c) that non-compliance**, or suspected non-compliance,** imply~~ie~~s **or might imply** a risk to the safety of SoHO donors, recipients or offspring from medically assisted reproduction **or** ~~**unnecessary**~~ **wastage of SoHO preparations.**	**that** non-compliance**, or suspected non-compliance,** imply~~ie~~s **or might imply** a risk to the safety of SoHO donors, SoHO recipients or offspring from medically assisted reproduction **or** ~~**unnecessary**~~ **wastage of SoHO preparations.**	Editorial change in order to clarify the text.	**CZ**
	(c) ~~**that non-compliance, or suspected non-compliance,**~~ imply~~ie~~s **or might imply** a risk to the safety of SoHO donors, recipients or offspring from medically assisted reproduction **or** ~~**unnecessary**~~ **wastage of SoHO preparations.**	Important point for France France reiterates its comment, which it considers to be very important and which has already been made on numerous occasions: the condition of non-compliance with the authorisation or regulation should be separated from the condition of risk to the safety of donors or recipients. The activities carried out may comply with the authorisation or regulations, but involve a risk for donors and recipients. Or it may be that the preparation is not carried out in accordance with the requirements of the	**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		regulations without the risk being established and proven at the time the decision to suspend the authorisation is taken.	
	(c) that ~~non-compliance, or~~ suspected non-compliance, impl**~~i~~**es **or might imply** a risk to the safety of SoHO donors, recipients or offspring from medically assisted reproduction	Deletion of 'non-compliance'. The 'non-compliance with the conditions of the authorisation or the requirements of the Regulation is already regulated under point (a) and (b) and therefore does not need to be additionally regulated in (c). In (c), only suspected cases with safety risks for donors, recipients and offspring from MAR can be referred to.	**DE**
	(c) ~~that~~ non-compliance**, or suspected non-compliance,** impl**~~i~~**es **or might imply** a risk to the safety of SoHO donors, recipients or offspring from medically assisted reproduction **or ~~unnecessary~~ wastage of SoHO preparations.**	See above	**NL**
SoHO ~~C~~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.			
7. In cases where SoHO **competent authorities have** ~~entities are not able to rectify~~ confirmed non-compliances referred to in paragraph 6 **and SoHO entities are not able to rectify ~~them~~** in the specified time period,		The distinction between paragraphs 7 and 8 is unclear. In both cases, it is a question, for example, of the approval being revoked if the conditions of the approval have not been met. To what extent are different situations	**DE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
SoHO competent authorities shall, in accordance with national legislation, withdraw the authorisation of the SoHO preparation **from the SoHO entities** concerned.		regulated here?	
		Not sure what the additiona value of para 7 is next to para 8.	**NL**
8. **SoHO** ~~C~~competent authorities may, in accordance with national legislation, withdraw the authorisation of a SoHO preparation if the **SoHO** competent authorities have confirmed that the SoHO preparation in question does not comply with ~~subsequently~~ updated criteria for authorisation or the SoHO entity has ~~repeatedly~~ failed to comply with the conditions of its authorisation, **~~and~~or ~~that~~ a risk to SoHO donors, recipients or offspring from medically assisted reproduction is identified and that risk cannot be resolved during a suspension.**	**SoHO** ~~C~~competent authorities may, in accordance with national legislation, withdraw the authorisation of a SoHO preparation if the **SoHO** competent authorities have confirmed that the SoHO preparation in question does not comply with ~~subsequently~~ updated criteria for authorisation or the SoHO entity has ~~repeatedly~~ failed to comply with the conditions of its authorisation, **~~and~~or ~~that~~ a risk to SoHO donors, SoHO recipients or offspring from medically assisted reproduction is identified and that risk cannot be resolved during a suspension.**	Editorial change in order to clarify the text.	**CZ**
	8. **SoHO** ~~C~~competent authorities may, in accordance with national legislation, withdraw the authorisation of a SoHO preparation if the **SoHO** competent authorities have confirmed that the SoHO preparation in question does not comply with ~~subsequently~~ updated criteria for authorisation or the SoHO entity has ~~repeatedly~~ failed to comply with the conditions of its authorisation, **~~and~~or ~~that~~ a unacceptable /intolerable risk to SoHO donors, recipients or offspring from medically assisted reproduction is identified and that risk cannot be resolved during a suspension.**	There is always a risk, but the important thing is that it does not outweigh the benefit.	**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		Paragraph 7 and 8 just differ with regard to the last alternative in paragraph 8. We understand that the authorisation can be withdrawn if a risk exists despite compliance with the requirements of the Regulation and the authorisation. However, there is hardly any room for this if the requirements for recipient protection have been complied with. So do we need this alternative?	**DE**
	8. **SoHO** ~~C~~competent authorities may, in accordance with national legislation, withdraw the authorisation of a SoHO preparation or prohibit the execution of its clinical outcome monitoring planif the **SoHO** competent authorities have confirmed that the SoHO preparation in question does not comply with ~~subsequently~~updated criteria for authorisation or the SoHO entity has ~~repeatedly~~failed to comply with the conditions of its authorisation, **~~and~~or ~~that~~a risk to SoHO donors, recipients, ~~or~~offspring from medically assisted reproduction or wastage of SoHOis identified and that risk cannot be resolved during a suspension.**	Suggestion to align para 8 with para 6 and make it possible for SCA to prohibit the execution of its clinical outcome monitoring plan. Also suggestion to include the risk for wastage of SoHO as this could also, in our view, justify the withdrawal of authorisation.	**NL**
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 **information ~~for~~** ~~status~~ of the SoHO entity concerned in the EU SoHO	9. In cases of authorisation suspension or withdrawal of SoHo preparation , as referred to in paragraphs 6, 7 and 8, **SoHO** competent authorities shall, without undue delay, amend accordingly the authorisation **information ~~for~~** ~~status~~ of the SoHO ~~entity~~ preparation concerned	Articles 6,7 and 8 are describing SoHo preparation authorisation and because of that authorisation of SoHo entity concerned is not changing . Change is in information about SoHo	**SI**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
Platform ~~as referred to in Chapter XI.~~	in the EU SoHO Platform ~~as referred to in Chapter XI.~~	preparation.	
9a. By way of derogation from this Article, SoHO competent authorities may authorise, at the request of a prescribing physician or the SoHO entity responsible for that application, the application of SoHO preparations for a defined group of SoHO recipients within their territory in cases where the procedures referred to in this Article have not been carried out, provided that:	(Note from DG SANTE, this cell was empty and no change was proposed for 9a)	Editorial change in order to clarify the text.	**CZ**
	9a. By way of derogation from this Article, SoHO competent authorities may authorise, at the request of a prescribing physician or the SoHO entity responsible for that application, the application of SoHO preparations for a specific ~~defined group of~~ SoHO recipient~~s~~ within their territory in cases where the procedures referred to in this Article have not been carried out, provided that:	France is not in favour of adding the words "for a defined group of SoHO recipients" as this could compete with the implementation of a clinical results monitoring plan. The idea here was to be able to authorise the preparation of SoHO by name for reasons linked to the urgency of the patient's state of health. With this addition, the competent authority would be issuing an authorisation in advance for a given duration or a given number of patients, without knowing what would prevent a "normal" authorisation from being issued.	**FR**
	9a. By way of derogation from this Article, SoHO competent authorities may authorise, at the request of ~~a prescribing physician or~~ the SoHO entity responsible for that application, the application of SoHO preparations for a defined group of SoHO recipients within their territory in cases where the procedures referred to in this Article have not been carried out, provided that:	Competetnt authority issue authorisation of SoHo preparation to the SoHo entity. Any application concerning any change of SoHo preparation or any application of SoHo preparation can be done only by the entity (future owner of the SoHo preparation). Only the (future) owner of SoHo preparation authorisation is legaly allowed to submit application. A request or submission of application cannot be done by prescribing physician since a person cannot be in possession of	**SI**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		SoHO preparation authorization. In well justified emergency situation it should be possible to use SoHo preparation, not yet authorized, on the responsibility of entity and prescribing physician . Competent authority should be notified prior treatment.	
(a) the use of those SoHO preparations is foreseen for a ~~given~~ specific SoHO recipient, in cases where ~~that~~ the SoHO recipient has no therapeutic alternative, where treatment cannot be postponed or where the SoHO recipient's prognosis is life-threatening;	**the use of those SoHO preparations is foreseen for ~~a given specific SoHO recipient, in~~ cases where ~~that~~ the SoHO recipients ~~has~~ have no therapeutic alternative, where treatment cannot be postponed or where the SoHO recipient's prognosis is life-threatening;**	CZ supports changes in para 9a) point 2 b) and d) as CZ proposals were included. Relating to para 9a) point a), we consider this part not in accordance with para 9a introductory provision itself (a defined group of SoHO recipients vs. a given specific SoHO recipient). Therefore, change of wording is proposed in order to clarify which recipients are considered.	**CZ**
		The wording of (a) clearly shows that the system concerns a given patient, which is not consistent with the addition to the previous paragraph. If the idea is to target a group of patients, the reference should be to a defined indication and not a defined patient.	**FR**
	the use of those SoHO preparations is foreseen for a ~~given~~~~specified~~defined SoHO recipient, in cases where ~~that~~ theSoHO recipient has no therapeutic alternative, where treatment cannot be postponed or where the SoHO recipient's prognosis is life-threatening;	Minor text suggestion in (a)	**NL**
(b) the safety and effectiveness of the			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
SoHO preparation is presumed on the basis of the available clinical data; ~~and~~			
(c) there is ~~a~~ the conformity of the SoHO entity ~~establishment~~ responsible for the SoHO preparation; and		Please specify to which requirements/discipline the compliance refers.	**IT**
	(e) there is ~~a~~ the conformity of the SoHO entity ~~establishment~~ responsible for the SoHO preparation; and	Conformity related to what? It is not clear.	**LV**
	there is ~~a~~~~the conformity~~no objection of the SoHO entity ~~establishment~~ responsible for the SoHO preparation; and	Suggestion for better wording in (c)	**NL**
(d) the SoHO recipient concerned are informed of the scarcity of the available data and of the still experimental nature of the proposed treatment as well as its therapeutic objectives.	**the SoHO recipient concerned ~~are~~ is informed by the prescribing physician of the scarcity of the available data and of the still experimental nature of the proposed treatment as well as its therapeutic objectives.** **The prescribing physician gives his written concent before the release of the product.**	The blood establishment has no interaction with the recipient. Is the treating physician's responsibility to inform the recipient of the risks and why there is no alternative.	**CY**
	the SoHO recipients concerned are informed of the scarcity of the available data and of the still experimental nature of the proposed treatment as well as its therapeutic objectives.	Editorial change in order to clarify the text.	**CZ**
	(f) the SoHO recipient concerned are informed of the scarcity of the available data and of the still experimental nature of the proposed treatment as well as its therapeutic objectives. **(h) the SoHO entity responsible for that application for a group of recipients commits**	If, despite the comment made above, this provision is extended to a group of patients, France would like the applicant to undertake, when submitting an application on the basis of Article 21.9 a, to submit the	**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	to submit the corresponding SoHO preparation authorisation request accompanied by a monitoring plan within a defined deadline	corresponding application for authorisation of SoHO preparation, accompanied by a monitoring plan, within a defined period. The aim of this addition is to ensure that the derogation system is not implemented over too long a period, so that the derogation system is only transitory and does not compete with the plan for monitoring clinical results. The idea would be to use the early access authorisations that exist in France for medicinal products, with a commitment to submit a marketing authorisation application.	
SoHO competent authorities shall indicate the period of time or a maximum number of SoHO recipients for which the application of those SoHO preparations is authorised ~~authorisation is granted~~.	**SoHO competent authorities shall indicate the period of time ~~or a maximum number of SoHO recipients~~ for which the application of those SoHO preparations is authorised ~~authorisation is granted~~.**	CZ is of the opinion that it could be complicated for competent authorities to indicate a maximum number of SoHO recipients. Therefore, CZ recommends deleting this part.	**CZ**
	SoHO competent authorities shall indicate the period of time ~~or a maximum number of SoHO recipients~~ for which the application of those SoHO preparations is authorised	Adding a number of patients is not appropriate because if there is a need, we are not going to deprive patients of a SoHO.	**FR**
SoHO competent authorities shall inform the SoHO National Authority of ~~the~~ that authorisation.	**~~SoHO competent authorities shall inform the SoHO National Authority of the that authorisation~~**	For a smoother system operation, it is suggested to remove this point.	**IT**
10. ~~Competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point~~			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~(c).~~			
11. The Commission may adopt implementing acts concerning the procedures to authorise SoHO preparations pursuant to this Article.			
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
Article 22		Benefit-risk concept (assessment) Related to the art. 22 /22a; art. 41, art. 64 Benefit risk assessment is a methodologically challenging process, and should be transparent and defined concerning e.g. what information needed for the regulatory assessment. It should be based on the evidence based data. There is always some uncertainty around the actual benefits and risks of a product, because they can only be determined by looking at the information that is available at a given point in time. The terminology is well established in the field of pharmaceuticals including the obligation to demonstrate efficacy (and safety) of the product. Therefore, while lacking the methodologic guidance and taking into account the large spectrum of SOHO preparations, we hesitate to use benefit risk assessment concept in provisional text of the SOHO for time being or alternatively define the concept explicitly.	**FI**
Assessment of SoHO preparations			
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 **effectiveness** ~~efficacy~~ of the SoHO preparation.			
2. The assessment of SoHO preparations shall be carried out by **SoHO preparation**			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
assessors meeting the requirements set out in Article 24.			
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 Member State **or by the transitional provisions referred to in Article 82**, **SoHO** competent authorities may authorise that SoHO preparation ~~in the applicant SoHO entity~~, provided that the **SoHO** competent authorities have verified 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 **effectiveness** ~~efficacy~~ results **of the SoHO preparation** will be equivalent to those demonstrated in the SoHO entity where the SoHO preparation was first authorised.	3. In cases where **an equivalent** ~~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 Member State **or by the transitional provisions referred to in Article 82**, **SoHO** competent authorities may authorise that SoHO preparation ~~in the applicant SoHO entity~~, provided that ~~the SoHO competent authorities have verified~~ **the applicant demonstrates** that ~~the SoHO activities performed~~ **and the steps of the processing applied and the controls** for the SoHO preparation are carried out by the applicant ~~SoHO entity~~ in a manner such that the safety, quality and **effectiveness** efficacy results of the SoHO preparation will ~~be equivalent to those demonstrated in the SoHO entity where the SoHO preparation was first authorised.~~**meet at least the defined quality criteria in the EDQM SoHO monograph.**	The level of quality of the preparation authorised for a first SoHO entity could be much higher than that considered sufficient by the competent authorities to issue the authorisation. In this case, this provision would oblige the competent authorities to refuse authorisations requested by subsequent entities, even if the preparations are considered by the competent authority to be of satisfactory quality. This system could therefore prevent the development of a preparation by other SoHO entities when it is already authorised for a first entity, potentially reducing the volume of preparations available, as well as the number of operators with these preparations. It might therefore be preferable to define, at least in certain cases, a quality level below which authorisation cannot be given, via the ECDC or EDQM technical guidelines. Preparations whose quality level complies with these guidelines could be authorised even if they already exist in other SoHO entities. In this way, a balance should be struck between the data protection to which SoHO entities are entitled and the "pooling" of authorisations for SoHO preparations. In addition, the wording at the beginning of	**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		the provision needs to be clarified as it is confusing. If the same SoHO is already authorised in another MS, it will not be re-authorised (because the authorisation is recognised throughout the EU). On the other hand, if another establishment submits an application for a SoHO that is equivalent to a SoHO already authorised for another establishment, then this article may apply. Finally, a rewording is necessary to specify that it is up to the applicant to demonstrate equivalence in his application.	
	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 Member State **or by the transitional provisions referred to in Article 82**, **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 enities, 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 **effectiveness** ~~efficacy~~ results **of the SoHO preparation** will be equivalent to those demonstrated in the	For comparing documentation and reveiling information competent authorities need consent of the entity who already has authorised SoHo preparation (located in the same country or not). Withough consent of the entity who already has authorised SoHo preparation submitted application cannot be reviewed and compared. Entities-applicants should be aware of required consent before submitting applications (less administrative burden if entity-applicant does not get a consent) . EU SoHo Platform will have only summaries of SoHO preparation but this will	**SI**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	SoHO entity where the SoHO preparation was first authorised.	not be enough to assess required information (SoHo activities performed, steps of processing applied in a manner such that the safety, quality and effectiveness results of the SoHO preparation will be equivalent to those demonstrated in the SoHO entity where the SoHO preparation was first authorised.) If summaries on the EU SoHo Platform will have data required to compare documentation of applicant with content of the Summary , correction of paragraph 3 is not needed. Entities should be than notified in this Regulation which information will be publicly available	
		SE can support the deletion of the added part on transitional provisions that was proposed in the new version of Art 22.3 that was shared with the delegations on the 10th of October.	**SE**
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**:			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
(a) ~~shall~~ assess **the adequacy of** ~~all~~ the information provided by the applicant pursuant to Article 41**(2) point (a);**			
(b) ~~shall review the SoHO preparation dossier referred to in Article 41(2), point (a);~~			
(c) ~~shall~~ initiate the consultation described in Article 14~~(1)~~, if during the review of the **information** ~~SoHO preparation dossier~~ referred to in point (~~a~~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;			
(d) ~~shall review and~~ evaluate the **results of a benefit** risk assessment **carried out** ~~performed~~ by the applicant as pursuant to Article 41(2), point (b);	d) ~~shall review and~~ evaluate the **results of a benefit** risk assessment **carried out in the indication** ~~performed~~ by the applicant as pursuant to Article 41(2), point (b);		**FR**
(e) shall evaluate the plan for clinical outcome monitoring and its proportionality to the level of risk of the SoHO preparation **according to Article 22a** ~~paraghap 4a as referred to in Article 41(3), points (a), (b) and (c), as applicable;~~	~~**shall**~~ evaluate the plan for clinical outcome monitoring and its proportionality to the level of risk of the SoHO preparation **according to Article 22a** ~~paraghap 4a as referred to in Article 41(3), points (a), (b) and (c), as applicable;~~	Editorial change in order to clarify the text.	**CZ**
	(e) shall evaluate the plan for clinical outcome monitoring and its proportionality to the level of ~~risk of~~**incertainties on** the SoHO preparation **in the claimed indication according to Article 22a** ~~paraghap 4a as~~		**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	~~referred to in Article 41(3), points (a), (b) and (c), as applicable;~~		
	~~shall~~ evaluate the plan for clinical outcome monitoring and its proportionality to the level of risk of the SoHO preparation **according to Article 22a** ~~paraghap 4a as referred to in Article 41(3), points (a), (b) and (c), as applicable;~~	We suggest to remove "shall" since it is already present at paragraph 4, before the list of SCA's tasks	**IT**
(f) ~~shall 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**;			
(g) ~~shall~~ assess, in the case of **an approved clinical outcome monitoring plan** ~~a conditional authorisation~~ pursuant to Article 21(2), point (c), the results of **that plan** ~~that plan the clinical outcome monitoring~~ **upon submission by the applicant**.		Same as above	**CY**
	(g) ~~shall~~ assess, in the case of **an previously approved clinical outcome monitoring plan** ~~a conditional authorisation~~ pursuant to Article 21(2), point (c), the results of **that plan** ~~that plan the clinical outcome monitoring~~ **upon submission by the applicant**.		**FR**
~~**4a. When evaluating clinical outcome monitoring plans, as referred to in paragraph 4 point (e), SoHO competent authorities shall verify that the plan proposes clinical outcome monitoring as follows:**~~			
~~**(a) in cases of low risk, pro-active clinical follow-up of a defined number of SoHO recipients;**~~			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~**(b) in cases of moderate risk, in addition to point (a), a clinical study of a pre-defined number of SoHO recipients assessing pre-defined clinical endpoints;**~~			
~~**(c) in cases of high risk, in addition to point (a), a clinical study of a pre-defined number of SoHO recipients assessing pre-defined clinical endpoints with a comparison to standard therapy.**~~			
5. When assessing the SoHO preparation pursuant to paragraph 4, points (e) and (g), **SoHO** competent authorities shall **verify** ~~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 that the~~ registry has data quality management procedures in place that ensure **adequate** accuracy and completeness ~~of data~~.		These registers are the clinical registers of learned societies and reference centres that the competent authorities cannot assess, as this is not within their area of competence.	**FR**
6. **SoHO c**~~C~~ompetent authorities shall conduct the assessment ~~steps~~ referred to in paragraphs 3 and 4 of this Article by means of a remote document review. **SoHO c**~~C~~ompetent authorities may also, as part of the SoHO preparation assessment, carry out inspections pursuant to Articles 29, 30 and 31. **Member States shall ensure communication and cooperation between SoHO preparation**			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
assessors and inspectors pursuant to Article 13.			
7. When conducting the assessment steps referred to in paragraph 4 **and 4a** of this Article, **SoHO** competent authorities shall **take into account** ~~consult~~ the best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).	When conducting the assessment steps referred to in paragraph 4 ~~**and 4a**~~ of this Article, **SoHO** competent authorities shall **take into account** ~~consult~~ the best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).	Editorial change in order to clarify the text.	**CZ**
	7. When conducting the assessment steps referred to in paragraph 4 ~~**and 4a**~~ of this Article, **SoHO** competent authorities shall **take into account** ~~consult~~ the best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).	Minor text suggestion	**NL**
Article 22a		Same as above	**CY**
Clinical outcome monitoring plans		Denmark supports the new compromise text presented at the meeting Oct. 10	**DK**
1. As a basis for the assessment of an authorisation for a new SoHO preparation a clinical outcome monitoring plan shall be approved by the SoHO compentent authority.	**1. As a basis for the assessment of an authorisation for a new SoHO preparation, in case of uncertainty about the benefit -risk ratio of the SoHO in the claimed indication, a clinical outcome monitoring plan shall be approved by the SoHO compentent authority.**	France would like to extend the scope of clinical results monitoring plans to situations where there is insufficient clinical data in a given indication.	**FR**
	1. As a basis for the assessment of an authorisation for a new SoHO preparation a clinical outcome monitoring plan of the applicant SoHO entity shall be approved by the SoHO compentent authority.	Minor text suggestion to clarify that the clinical outcome monitoring plan is owned by the applicant SoHO entity.	**NL**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
2. The clinical outcome monitoring plan shall include:			
(a) clinical outcome monitoring according to 22a (3) point c, where scientific data for clinical use are not available or sparse, where benefit and risk are not evaluable, or when a negative benefit-risk analysis based on current knowledge is confirmed.		CZ points out that in the actual version of the Regulation is referred to the Article 22a para 3 c) which is not the part of the Regulation. We would like to ask for the clarification.	*CZ*
	(a) clinical outcome monitoring according to 22a ~~(3)~~ (4) point c, where ~~scientific data for clinical use are not available or sparse, where benefit and risk are not evaluable, there are uncertainties on the benefit -risk ratio or when a negative benefit-risk analysis based on current knowledge is confirmed~~	France is strongly in favour of deleting the end of the negative sentence "when a negative benefit-risk analysis based on current knowledge is confirmed". These words would be tantamount to allowing patients to be treated in the event of a negative benefit-risk analysis. This cannot be envisaged. A presumption of favourable benefit/risk must be demonstrated when the competent authority authorises a preparation with a follow-up plan. Furthermore, there is a reference error in 2(a): "according to 22a (3) point c" --> "according to 22a (4) point c".	**FR**
		The correct reference should be at article 22 a (4) point c	**IT**
	clinical outcome monitoring according to 22a ~~(3)~~(4) point c, where scientific data for clinical use are not available or sparse, where benefit and risk are not evaluable, or when a negative benefit-risk analysis based on current knowledge is confirmed.	minor text suggestion in (a) and (b)	**NL**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
(b) clinical outcome monitoring according to 22a (3) point a, in a case of a relevant risk despite a positive benefit-risk analysis.		Please see the comment above.	CZ
	~~(b) clinical outcome monitoring according to 22a (3) point a, in a case of a relevant risk despite a positive benefit-risk analysis.~~	Whatever the risk, there is no need for a monitoring plan when the B/R can be established as positive without uncertainty in an indication.	FR
		The correct reference should be at article 22 a (4) point a	IT
	clinical outcome monitoring according to 22a ~~(3)~~(4) point a, in a case of a relevant risk despite a positive benefit-risk analysis.	minor text suggestion in (a) and (b)	NL
3. The design of clinical outcome monitoring plan referred to in paragraph 1, shall be proportionate to the level of risk assessed by the applicant and shall take into account the guidance and templates provided by their SoHO competent authority, in accordance with Article 21(1).	**3. The design of clinical outcome monitoring plan referred in paragraph 1, shall be proportionate to level of uncertainties on the benefit-risk ~~to the level of risk~~ assessed by the applicant and shall take into account the guidance and templates provided by their SoHO competent authority, in accordance with Article 21(1).**		FR
4. The clinical outcome monitoring plan shall include the clinical outcome monitoring as follows:			
(a) in cases of low benefit risk, pro-active clinical follow-up of a defined number of SoHO recipients;	**in cases of low ~~benefit~~ risk, pro-active clinical follow-up of a defined number of SoHO recipients;**	**Benefit-risk ratio is usually evaluated to be positive or negative and not low, moderate or high. Paragraph 2 of article 22a is addressing benefit-risk ratio question in sufficient way. Paragraph 4 should only address the risks that can be minimised using the risk minimizing**	EE

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		methods.	
	(a) in cases of low uncertainties on benefit risk, pro-active clinical follow-up of a defined number of SoHO recipients assessing pre-defined clinical endpoints;	France understands the compromise as follows: it introduces the notion of benefit/risk where previously (in the Commission's text) only the notion of risk appeared (which was based on "quality" aspects). France is in favour of adding the notion of benefit/risk. However, it makes no sense to refer to low, moderate or high benefit/risk. Benefit/risk is either favourable or unfavourable. France therefore proposes changes to points (a), (b) and (c). Clinical evaluation criteria should also be added to (a), so that results can be assessed.	**FR**
(b) in cases of moderate benefit risk, in addition to point (a), a clinical study of a pre-specified number of SoHO recipients assessing pre-defined clinical endpoints;	**in cases of moderate ~~benefit~~ risk, in addition to point (a), a clinical study of a pre-specified number of SoHO recipients assessing pre-defined clinical endpoints;**	**Benefit-risk ratio is usually evaluated to be positive or negative and not low, moderate or high. Paragraph 2 of article 22a is addressing benefit-risk ratio question in sufficient way. Paragraph 4 should only address the risks that can be minimised using the risk minimizing methods.**	**EE**
	(b) in cases of moderate uncertainties on benefit risk, in addition to point (a), a clinical study of a pre-specified number of SoHO recipients assessing pre-		**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	defined clinical endpoints;		
	in cases of moderate benefit risk, in addition to point (a), a clinical study of a pre-specified number of SoHO recipients required to be able to assess~~ing~~ pre-defined clinical endpoints;	Minor text suggestion to clarify that the pre-specified number should be determined in such a way that it is statistically justified.	**NL**
(c) in cases of high benefit risk, in addition to point (a), a clinical study of a pre-specified number of SoHO recipients assessing pre-defined clinical endpoints with a comparison to standard therapy.	**(c) in cases of high ~~benefit~~ risk, in addition to point (a), a clinical study of a pre-specified number of SoHO recipients assessing pre-defined clinical endpoints with a comparison to standard therapy.**	**Benefit-risk ratio is usually evaluated to be positive or negative and not low, moderate or high. Paragraph 2 of article 22a is addressing benefit-risk ratio question in sufficient way. Paragraph 4 should only address the risks that can be minimised using the risk minimizing methods.**	**EE**
	(c) in cases of high uncertainties on benefit risk, in addition to point (a), a clinical study of a pre-specified number of SoHO recipients assessing pre-defined clinical endpoints with, limitation of the availability of the product to certain pre-identified SoHO entities in order to enhance the safety of recipients and completeness of the monitoring. **In parallel with the monitoring plan, where appropriate, a comparison to standard therapy.**	In (c), the key point should not be the comparison with the standard of care. This certainly makes it possible to validate the interest of an SoHO in the set of alternatives available in a given indication, but has nothing to do with the risk-benefit ratio for a given product in a given indication. France would like to see this added to the comparison.	**FR**
	in cases of high benefitrisk, in addition to point (a), a clinical study of a pre-specified number of SoHO recipients required to be able to assess~~ing~~pre-defined clinical	Minor text suggestion to clarify that the pre-specified number should be determined in such a way that it is statistically justified.	**NL**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	endpoints with a comparison to standard therapy.		
5. To record the clinical data generated during the clinical outcome monitoring, the applicant shall record those data via their own registries or existing clinical registries. In cases where the applicant SoHO entity chooses to use existing clinical registries, those registries shall be verified by the SoHO competent authority, or shall be certified by an external institution, in terms of the reliability of their data quality management procedures.	**The applicant remains responsible for collecting the data and must be able to have this data available upon request from SoHO competent authority at any time during the plan.**		**FR**
6. In case where vigilance reports indicate a risk for SoHO donors, SoHO recipients or offspring from medically assisted reproduction, SoHO competent authorities may stop clinical outcome monitoring.	**In case where vigilance reports indicate a risk for SoHO donors, SoHO recipients or offspring from medically assisted reproduction, SoHO competent authorities may stop clinical outcome monitoring and use of the SoHO in question.**	**The use of the SoHO in question should be stopped as well – see suggested addition highlighted in yellow.**	**EE**
	6. In case where vigilance reports indicate a risk for SoHO donors, SoHO recipients or offspring from medically assisted reproduction, SoHO competent authorities may stop clinical outcome monitoring by suspension or	It is not clear how monitoring shall be stopped.	**LV**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	revocation/withdrawal of the authorization for preparation process.		
		Which are the vigilance reports referred to here? We can only find a reference to vigilance reports in Art 35(11), but this probably rather refers to the inspection report described in Article 29(14)? A clarification might be needed here. It is also not completely clear how this provision (on stopping clinical outcome monitoring) relates to Article 21(6) (on suspending the realisation of a clinical outcome monitoring plan). Is there a duplication here, or is it two different measures that are described? It could be useful to regulate this issue in one place in the Regulation.	**SE**
Article 23			
Joint SoHO preparation assessments			
1. At the request of one or more **SoHO** competent authorities, **via their SoHO National Authority to another SoHO National Autority, or a SoHO entity,** SoHO preparation assessments as referred to in Article 22 may be carried out by **SoHO preparation assessors assigned by** ~~competent authorities from~~ more than one Member State,	At the request of one or more SoHO competent authorities, via their SoHO National Authority to another SoHO National Autority, **or a SoHO entity**, SoHO preparation assessments as referred to in Article 22 may be carried out by SoHO preparation assessors assigned by more than one Member State, as a joint SoHO preparation assessment.	Denmark agrees that it should not be an option for a SoHO entity to request a joint SoHO preparation assessment.	**DK**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
as a joint SoHO preparation assessment.	1. At the request of one or more **SoHO** competent authorities, **via their SoHO National Authority to another SoHO National Autority, ~~or a SoHO entity~~,** SoHO preparation assessments as referred to in Article 22 may be carried out by **SoHO preparation assessors assigned by** ~~competent authorities from~~ more than one Member State, as a joint SoHO preparation assessment.	France does not wish to open up the possibility for entities to apply for a joint assessment for the following reasons: Firstly, national authorisations must de facto be recognised by the other competent authorities for SoHO. Consequently, an entity that wants its SoHO preparation to be used in several Member States does not "need" a joint assessment. This procedure should not be used to "challenge" the assessments of the competent authorities or to "distort" the fact that it is the competent authority of a Member State that must authorise products prepared by an establishment located on its territory. On the other hand, the wording "The SoHO competent authority receiving a request for a joint SoHO preparation assessment shall make all reasonable efforts to accept such request, taking into account their..." does not give the competent authority much leeway to refuse a request for a joint assessment. The wording does not specify the criteria on the basis of which a competent authority could decide whether or not to carry out a joint	**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		assessment, i.e. in which cases such an approach would be necessary or possible (e.g. highly innovative products, particular risks, etc.). Conversely, when the request for a joint assessment is initiated by the competent authorities, it can be set up if it is felt that a dossier raises a particular issue that a competent authority might not be able to manage on its own. In the end, France prefers the Commission's initial wording for Article 23: "1. At the request of one or more competent authorities, the assessments of a preparation based on substances of human origin referred to in Article 22 may be carried out by the competent authorities of several Member States as part of a joint assessment. 2. The competent authority which receives a request for a joint assessment of a preparation based on substances of human origin may accept such a request, and coordinate and facilitate that assessment, if it agrees that there are reasonable grounds for carrying out a joint assessment." However, if we really need to review our position, France could accept that entities	

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		can make this type of joint assessment request if and only if this possibility is regulated and limited to a specific field (similar to what is done for medicinal products that must be assessed under the "centralised procedure" by the EMA on the basis of Regulation 726/2004, the annex to which lists the medicinal products concerned).	
	At the request of one or more **SoHO** competent authorities, **in accordance with ~~via~~ their SoHO National Authority to another SoHO National Autority, or a SoHO entity,** SoHO preparation assessments as referred to in Article 22 may be carried out by **SoHO preparation assessors assigned by** ~~competent authorities from~~ more than one Member State, as a joint SoHO preparation assessment.	It is proposed to replace 'Via' with 'in accordance with' in order to emphasize the need for a broad delegation authority of SNAs over SCAs.	**IT**
	1. At the request of one or more **SoHO** competent authorities, **via their SoHO National Authority to another SoHO ~~National Autority~~ competent authority, or a SoHO entity,** SoHO preparation assessments as referred to in Article 22 may be carried out by **SoHO preparation assessors assigned by** ~~competent authorities from~~ more than one Member State, as a joint SoHO preparation assessment.	Editorial.	**LV**
2. **With the previous consent of the SoHO National Authority, t**~~T~~he **SoHO** competent authority receiving a request for a	~~**With the previous consent of**~~ **Prior comunication to the SoHO National Authority, t**~~T~~he **SoHO** competent authority	It is proposed to replace 'With the previous consent of' with 'Prior communication to' in order to streamline the system.	**IT**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
joint SoHO preparation assessment **shall make all reasonable efforts to accept such request, taking into account their available resources** ~~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~~.	receiving a request for a joint SoHO preparation assessment **shall make all reasonable efforts to accept such request, taking into account their available resources** ~~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~~.		
2a. The SoHO competent authority receiving a request for a joint SoHO preparation assessment and in charge of the authorisation of the SoHO preparation shall be the leader of the joint SoHO preparation assessment.	**The SoHO competent authority ~~receiving a request for a joint SoHO preparation assessment~~ and in charge of the authorisation of the SoHO preparation shall be the leader of the joint SoHO preparation assessment.**	CZ considers part marked in yellow redundant as it is an excessive detail and might lead to confusion. Therefore, this part is proposed to be deleted.	**CZ**
	The SoHO competent authority sending a request for a joint SoHO preparation assessment and in charge of the authorisation of the SoHO preparation shall be the leader of the joint SoHO preparation assessment.	**It would make sense that the initating competent authority would be in charge and lead the assessment process as they are more likely to be more involved with the SoHO preparation in question. The competent authority receiving a request could help with the knowlegde and technical input and would be more likely to contribute to the joint assessement if not put in charge. See change highlighted in yellow.**	**EE**
3. **The SoHO** ~~C~~competent authorities participating in a joint **SoHO preparation**			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
assessment shall conclude a prior written agreement **to carry out** ~~on~~ the joint assessment. **Such written** ~~The~~ agreement shall **specify** at least ~~defines~~ the following:			
(a) the scope of the joint assessment;			
(b) the roles of the participating assessors during and following the assessment, ~~including the designation of an authority leading the assessment;~~			
(c) the powers and responsibilities of each of the **SoHO competent** authorities **involved.**			
The SoHO competent authorities participating in the joint SoHO preparation assessments shall commit themselves in that agreement to jointly accept the results of ~~the~~ that assessment.			
The agreement shall be signed by all the participating SoHO competent authorities, including the respective SoHO National Authorities, according to the ~~requisites~~ requirements developed by the SCB.			
4. Member States may set up joint **SoHO preparation** assessment programmes to facilitate frequent or routine joint assessments. **Member States may operate such programmes under a single written agreement as referred to** ~~In such cases, competent authorities may sign a single written~~	~~4. Member States may set up joint **SoHO preparation** assessment programmes to facilitate frequent or routine joint assessments. **Member States may operate such programmes under a single written agreement as referred to** In such cases, competent authorities may sign a single written~~	We treat joint assessment as an action in exceptional situations. Therefore, provisions allowing for routine assessments should not be introduced.	**PL**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~agreement provided that agreement meets the requirements~~ in paragraph 3.	~~agreement provided that agreement meets the requirements in paragraph 3.~~		
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).			
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			
Specific obligations concerning SoHO preparation assessors			
1. **SoHO preparation** ~~A~~**a**ssessors shall:		In the other legislative like Pharmaceutical or CTR or MD there is no definition of the training of assesors, there is no diploma for it in the European legislative landscape. This would eventually establish the training of assessors for all areas.	**AT**
(a) **be in** possess**ion of** a diploma, certificate or other evidence of formal		Relevant field : Is up to MS to define which field is relevant? And if so, a MS has to	**CY**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
qualifications in ~~the field of medical~~ , **~~pharmaceutical~~** ~~or~~ **~~life~~** ~~biological sciences~~ **a relevant field**, awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned;		accept another MSs assessor if he/she are not of the relevant field the MS decides? We believe the definition should be : biological or life science defined as: Microbiology, Biology, Biochemistry, Chemistry, Haematology, Genetics, Cytology, Histology, Medical Laboratory Sciences, Molecular Biology, Virology. In all articles of the regulation, not just for the assessors.	
	(b) have **field** expertise **or assesmment expertise** in the processes being assessed ~~and~~ **or** the human applications for which the SoHO preparations will be used.		**FR**
		This si too wide definiton of formal qualification for assesors (also use of diploma from life sciences is too wide definition).	**SI**
(b) have expertise in the processes being assessed ~~and~~ **or** the human applications for which the SoHO preparations will be used.			
2. The assessment of SoHO 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.			
3. In exceptional cases, **SoHO** competent authorities may consider that a person's considerable and relevant experience may			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
exempt this person from the requirements set out in paragraph 1.			
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.			
5. **SoHO** ~~C~~**c**ompetent authorities shall ensure that the specific induction training is complemented by specialised training for 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** ~~C~~**c**ompetent 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).			
6. **SoHO preparation** ~~A~~**a**ssessors 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.			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
CHAPTER IV			
GENERAL OBLIGATIONS ON SOHO ENTITIES			
Article 40			
SoHO preparation authorisation			
1. SoHO entities shall not release or, in an autologous context **as referred to in Article 2(2)(a),** prepare and apply ~~immediately~~ 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 SoHO preparation.~~	1. SoHO entities shall not ~~release~~ **collect** or, in an autologous context as referred to in Article 2(2)(a), prepare and apply ~~immediately~~ 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 SoHO preparation.**	It is not ethical to allow a SoHO entity to start collecting and preparing before the authorisation is obtained knowing that requests for changes could be made by the competent authority which would oblige the SoHO entity to remove its SoHO stock. It is important that any change to the activity be subject to a new authorisation. In addition, as on the same date, if the planned change is likely to have an impact on the quality and safety of the preparation, the change must be authorised. **(comment FR)**	
	SoHO entities shall not release or, in an autologous context **as referred to in Article 2(2)(a),** prepare and apply ~~immediately~~ to a **SoHO** recipient, SoHO preparations without prior SoHO preparation authorisation, except for	- Release and application needs to be carried out within the clinical outcome monitoring. This should be specified, for enhanced clarity. - SoHO preparations are released also	**SE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	when a SoHO preparation: (a) is released or applied in an autologous context as a part of the realisation of a clinical outcome monitoring plan, as referred to in Article 22a; or (b) is released before distribution for manufacture of a product regulated by other Union legislation, as referred to in Article 2(3).	when they are distributed for the manufacture of products regulated under other Union legislation. To avoid the impression that SoHO preparations released for distribution for manufacture would need a preparation authorisation, we propose that this is to be clarified in this paragraph. See proposal!	
2. SoHO entities may request **an opinion** ~~advice~~ 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.			
3. SoHO entities may request to their **SoHO** competent authorities a derogation from the requirement for a SoHO preparation authorisation in ~~the~~ **emergency situations** ~~exceptional circumstances~~ referred to in Article 64.	3. SoHO entities may request to their **SoHO** competent authorities a derogation from the requirement for a SoHO preparation authorisation in ~~the~~ **emergency situations** ~~exceptional circumstances~~ referred to in Article 64 **or in situations referred to in Article 21 9(a)**.	We suggest refer also to the Article 21 9(a). **9a. By way of derogation from this Article, SoHO competent authorities may authorise, at the request of a prescribing physician or the SoHO entity responsible for that application, the application of SoHO preparations for a defined group of SoHO recipients within their territory in cases where the procedures referred to in this Article have not been carried out, provided that:**	**LV**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
Article 41			
Application for ~~the authorisation of~~ SoHO preparation authorisation			
1. SoHO entities shall send applications for ~~the authorisation of a~~ SoHO preparation **authorisation** to the~~ir~~ **SoHO** competent authorit~~y~~ies **of their territories**. ~~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).~~	SoHO entities shall send applications for ~~the authorisation of a~~ SoHO preparation **authorisation** to the~~ir~~ **SoHO** competent authorit~~y~~ies **of their ~~territories~~ territory**. ~~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).~~	Editorial change in order to clarify the text.	**CZ**
	1. SoHO entities shall ~~send~~ submit applications for ~~the authorisation of a~~ SoHO preparation **authorisation** to the~~ir~~ **SoHO** competent authorit~~y~~ies **of their territories**. ~~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).~~		**SI**
2. The **applications for SoHO preparation authorisation** ~~applicant~~ shall **include** ~~provide~~ the following:			
(-a) the name and contact details of the ~~prospective~~ applicant SoHO entity ~~preparation authorisation~~ responsible for the SoHO preparation authorisation;	(-a) the name and contact details of the **SoHO preparation authorisation holder;**	The wording is complicated. The notion of "holder" should be introduced because the person in charge is the person responsible for the activities, the notion of the person	**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		responsible for a preparation does not exist.	
(a) ~~a SoHO preparation dossier describing the~~ details of the SoHO activities performed for that SoHO preparation and including at least:			
(-i) a description of the SoHO used for the preparation;	**a description of the SoHO used for the SoHO preparation;**	Editorial change in order to clarify the text.	**CZ**
(i) **a summary of** ~~any specific~~ SoHO donor eligibility **~~or~~and** SoHO donor testing procedures;	(a) **a list of soho donor eligibility criteria including testings and a summary of** ~~any specific~~ SoHO donor eligibility **criteria** **~~or~~and** SoHO donor testing procedures;	We need summaries for the procedures, but we also need all the criteria and tests in full.	**FR**
(ii) **a summary of** ~~any specific~~ SoHO collection procedures **and any specific controls carried out on the collected SoHO prior to processing**;	(ii) **a summary of** ~~any specific~~ SoHO collection procedures **and any specific quality? controls carried out on the collected SoHO prior to processing**;	Editorial.	**LV**
(iii) a description of the **steps of the** processing applied including **details of relevant materials and equipment used, environmental conditions and the process parameters and controls at each step** ~~details s of the air quality standards maintained in the processing facilities and the rationale for the air quality standard applied;~~			
(iv) a description of equipment, reagents and materials **coming into direct contact with the SoHO during processing** ~~used~~ and their certification status in accordance with Regulation (EU) 2017/745 **or Regulation (EU)**		Please clarify the meaning of "justification". Can it be considered equivalent to "evidence"?	**IT**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
2017/746, when applicable, and, in the case of the use of in-house developed equipment, reagents or materials, a justification of the validation of their quality;			
(v) any specific storage **and transport** conditions and storage time limits **including validation of those conditions and limits**;			
(vi) **a specification of the SoHO preparation including** ~~any~~ quality control and**,** ~~**where relevant,**~~ release parameters;	(vi) a specification of the SoHO preparation including **any** quality control and~~, where relevant,~~ release parameters ;	There are always specifications and release parameters that have to be predefined, which does not rule out checks.	**FR**
(vii) data ~~concerning procedures performed for~~ **resulting from** process validation and equipment qualification;	(vii) data ~~concerning procedures performed for~~ **resulting from** process validation ~~and equipment qualification;~~	The results of equipment qualification are a concern systematically seen in inspections and not in product authorisation dossiers.	**FR**
(viii) details of any **SoHO entities or** third parties contracted ~~by the SoHO entity~~ to perform activities **or relevant steps of the processing applied** for the SoHO preparation;			
(ix) the clinical indications for which the SoHO preparation is to be applied **and the ~~scientific rationale~~ clinical data justifying this indication**;	**(x) non-clinical data demonstrating the efficacy and toxicity of the product.**	Addition of a paragraph (x) on non-clinical data	**FR**
(b) the results of a **benefit-**risk assessment conducted on the combination of SoHO activities performed for the SoHO preparation,	(b) the results of a **benefit-**risk assessment conducted on ~~the combination of SoHO activities performed for the~~ **the** specified SoHO	This is the same wording as the risk analysis presented in Article 41 of the Commission proposal. So there seems to be confusion	**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
together with the intended clinical indication for which **application for authorisation is submited** ~~it is **authorised**~~ ~~intended~~ to be applied, taking into account:	preparation, ~~together with the~~**in** intended clinical indication for which **application for authorisation is submited** ~~it is **authorised**~~ ~~intended~~ to be applied, taking into account:	between risk analysis and benefit/risk analysis. In France's view, the different levels of the monitoring plan should be determined on the basis of this benefit/risk analysis.	
	the results of a **benefit-**risk assessment conducted on the combination of SoHO activities performed for the SoHO preparation, together with the intended clinical indication for which **application for authorisation is submited**~~it is **authorised**~~~~intended to be applied~~, taking into account:	Minor text suggestion	**NL**
(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 point (b)**;			
(ii) whether the SoHO preparation meets the defined quality criteria in the EDQM SoHO monograph referred to in point (i) and is intended to be used for the indication and with the mode of application to which that monograph refers, where such details are provided in that monograph **or meets national requirements as referred to in Article 59(4) point (b)**;	"(…) or meets national **or international** requirements as referred to in Article 59(4) point (b);"	Insofar as Article 59(4) point (b) refers to national or international standards, international standards should be added here.	**FR**
(iii) information regarding previous use and authorisation of the SoHO preparation in other SoHO entities, as available in the EU SoHO	(iii) information regarding previous use and authorisation of the SoHO preparation **or a comparable SoHO preparation** in other SoHO		**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
Platform;	entities, as available in the EU SoHO Platform;		
(iv) **where ~~available~~ applicable, clinical functionality** evidence generated as part of the process of certification, in accordance with Regulation (EU) 2017/745, of **a** certified medical device **that is critical to the specific processing** ~~used~~ for the SoHO preparation, where available;	(iv) **where ~~available~~ applicable, clinical functionality** evidence generated as part of the **conformity assessment procedure** ~~process of certification~~, in accordance with Regulation (EU) 2017/745, of **a** certified medical device **that is critical to the specific processing** ~~used~~ for the SoHO preparation, where available;	'Conformity assessment procedure' is the term used in the Regulation 2017/45.	**DE**
	where ~~available~~ applicable,clinical functionality evidence generated as part of the process of certification, in accordance with Regulation (EU) 2017/745, of **a** certified medical device **that is critical to the specific processing** ~~used~~ for the SoHO preparation~~, where available~~;	Minor text suggestion	**NL**
(v) documentation of a **standardised** ~~systematic~~ process of identification, quantification and evaluation of any risks to **a SoHO** ~~the~~ donor**s**, **a SoHO** ~~or the~~ recipient**s** **or the 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)**;			
(ba) an evaluation of the potential benefits for SoHO recipients weighed against the	~~**(ba) an evaluation of the potential benefits for SoHO recipients weighed against the risks**~~	Already asked in b)	**FR**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
risks identified in the assessment referred to in point (2)(b)(v).	~~**identified in the assessment referred to in point (2)(b)(v).**~~		
(c) in cases where the indicated risk is ~~other~~ **greater** than negligible, **or the expected clinical effectiveness is unknown,** a **proposed plan** ~~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 **benefit-**risk assessment **and pursuant to Article 22(4a)**;	(c) in cases **of uncertainties on the benefit-**risk ~~–~~a **proposed plan** ~~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 **benefit-**risk assessment **and pursuant to Article 22(4a)**;	As long as the benefit/risk ratio is positive, there is no need for a follow-up plan even if the risk is more than negligible. In such a case, there is a risk that there will be plans to monitor clinical outcomes for all SoHOs. A plan should only be drawn up when there is a need for confirmatory clinical data.	**FR**
(d) an indication of the data which should be regarded as proprietary accompanied by verifiable justification, where appropriate.			
3. ~~In the **proposed clinical outcome monitoring plan** proposal referred to in paragraph 2, point (c), the applicant shall **take into account the guidance from their SoHO competent authority as referred to in Article 21(1)**. propose a clinical outcome monitoring plan as follows:~~ **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 22a(4)~~as referred to paragraph 2 point (c)~~, the applicant shall request approval for the use of such registry to their SoHO competent authorities.**			
~~(a) in cases of low risk, clinical follow up~~			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~of a defined number of patients;~~			
~~(b) in cases of moderate risk, in addition to point (a), a clinical investigation study of a statistically significant number of patients assessing pre-defined clinical endpoints;~~			
~~(c) in cases of high risk, in addition to point (a), a clinical investigation study of a statistically significant number of patients assessing pre-defined clinical endpoints with a comparison to standard therapy.~~			
4. SoHO entities shall **prepare and distribute the SoHO preparation in question solely for the performance, and within the limitations of** ~~perform~~ the clinical outcome monitoring **after approval of the clinical outcome monitoring plan by the SoHO competent authority,** ~~**plan as approved**~~ ~~once a conditional authorisation has been granted~~ pursuant to Article 21(2), point (c), and submit the results **and their analysis** to their **SoHO** competent authorities **according to the timeline set in the approval**. ~~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~~.			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
5. SoHO entities shall not make any **significant** change **within ~~the~~** ~~to the chain of~~ **steps of the processing applied or in the** activities performed for **an authorized** SoHO preparation **subject to the authorisation**, without the prior written **authorisation** ~~approval~~ of their **SoHO** competent authorities.	SoHO entities shall not make any **change of significance for quality and safety** within the steps of the processing applied or in the activities performed for an authorized SoHO preparation subject to the authorisation, without the prior written authorisation approval of their SoHO competent authorities.	Denmark propose to add the text in bold for clarity.	**DK**
SoHO entities shall also **~~provide~~ inform, without unduer delay, ~~to~~** ~~inform~~ their **SoHO** competent authorities **of any** changes **that might affect the authorisation, including the changes related to** ~~in the SoHO preparation authorisation~~ **responsible's**~~holder's~~ details **of the SoHO entity previously authorised for the SoHO preparation**.	SoHO entities shall also inform, without undue delay, their SoHO competent authorities of any changes that might affect the authorisation, including the changes related to details of the SoHO entity previously authorised for the SoHO preparation.		**DK**
	SoHO entities shall also **~~provide~~ inform, without unduer delay, ~~to~~** ~~inform~~ their **SoHO** competent authorities **of any** changes **that might affect the authorisation, including the changes related to** ~~in the SoHO preparation authorisation~~ **responsible's**~~holder's~~ **contact?** details **of the SoHO entity previously authorised for the SoHO preparation**.	In the end it is not clear what kind of changes shall be reported (e.g., administrative, techical related to SoHO or process type or any of them).	**LV**
6. The **SoHO entity authorised for the** SoHO preparation ~~authorisation responsible holder~~ shall be based ~~in the Union~~ **in the Member State where the application is submitted**. ~~In cases where other SoHO entities~~			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~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~~.			
CHAPTER VI (SoHO Donor Protection): Definitions 8, 9a, 13, 13a, 14, 23, 59, 64, 65; Articles 52, 53, 54, 55, 56			
CHAPTER I			
GENERAL PROVISIONS			
Article 3			
Definitions			
(8) 'SoHO donor' means any**:**			
(a) living person who has presented themselves to a SoHO entity **or been presented by a person granting consent on th*ei*r behalf, in accordance with national legislation,** with a view to making a donation of SoHO**s, for the purpose of application to a person other than themselves, and other than situations of within couple use as defined in point (63)~~, for the purpose of application to a person other than themselves, and other than situations of~~**			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~within couple use as defined in point (63);~~ ~~or~~, ~~whetherthat donation is successful or not~~;			
(b) deceased person who has been referred to a SoHO entity, and ~~for~~from whom consent has been granted or from whom SoHO collection is permitted, in accordance with national legislation;			
(9a) 'consent', in the context of this Regulation, means the permission given by:	**~~'consent', in the context of this Regulation, means the permission given by:~~**	CZ in accordance with previously expressed CZ comments that the term "consent" is relevantly specified in the corresponding articles. Therefore, the definition no. 9a) is proposed to be deleted.	**CZ**
	~~(9a) 'consent', in the context of this Regulation, means the permission given by:~~	Deletion of the definition. Necessity for this definition is not seen. Consent is a well-known concept that is further developed in national law. The definition is also too vague. Consent must relate not only to the collection of SoHO, but also to the subsequent processing steps and application. This is also how it is regulated in Art. 55. As an alternative to the deletion, we are	**DE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		submitting a wording proposal for a possible concretisation of (9a) point a: **(a) a living SoHO donor for the collection of SoHO from the living SOHO donor for the purpose of application to a person other than themselves or a SoHO recipient for the purpose of application of SoHO, in the case of autlogous use consent includes the permission given by the SoHO recipient to collect SoHO from the same recipient~~or a SoHO recipient for an action affecting them to proceed, or~~**	
		The consent is also needed for reproductive SoHO preparation for within couple use in medically assisted reproduction	**SI**
(a) a living SoHO donor or a SoHO recipient for an action affecting them to proceed, or	~~**a living SoHO donor or a SoHO recipient for an action affecting them to proceed, or**~~	Please see comment above.	**CZ**
	~~**(a) a living SoHO donor or a SoHO recipient for an action affecting them to proceed, or**~~		**DE**
(b) any person granting consent on their behalf, or the authorisation granted by the national law, for such an action to proceed in the case of living SoHO donors or SoHO recipients who have no capacity to consent, or	~~**any person granting consent on their behalf, or the authorisation granted by the national law, for such an action to proceed in the case of living SoHO donors or SoHO recipients who have no capacity to consent, or**~~	Please see comment above.	**CZ**
	~~**(b) any person granting consent on their behalf, or the authorisation granted by the national law, for such an action to proceed in**~~		**DE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	~~the case of living SoHO donors or SoHO recipients who have no capacity to consent, or~~		
	any person granting consent on their behalf, or the authorisation granted by the national law, for such an action to proceed in the case of living SoHO donors or SoHO recipients who have no capacity to consent in accordance with national legislation, or	9b It is proposed to add at the end of the point 'in accordance with national legislation' for consistency with the following point and to ensure compliance with current national regulations.	**IT**
	(b) any person granting consent on their behalf of the (intended) donor or recipient in accordance with national legislation**, or the authorisation granted by the national law, for such an action to proceed in the case of living SoHO donors or SoHO recipients who have no capacity to consent, , or**	If the definition for consent is kept, we would like to add also in (b), just like in (c), "in accordance with national legislation" for enhanced coherence and clarification. If this is added, the references throughout the text can be more effective as no reference to national legislation will be needed in the Articles. In the current version of this Chapter, such a reference seems to be made in some cases (Art 53(1)(b) and (h), 54(1)), but not in others (Article 55(1), (2), (3) and (3)(f).). This needs to be consistent in either one way or the other. The present wording with "on their behalf" can be misleading. It should be clear that "their" in "their behalf" refers to the intended donor or recipeint and not to the person granting consent. See proposal	**SE**
(c) any person granting consent, or the	~~any person granting consent, or the~~	Please see comment above.	**CZ**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
authorisation granted by national law, for such an action to proceed in the case of deceased SoHO donors in accordance with national legislation.	~~**authorisation granted by national law, for such an action to proceed in the case of deceased SoHO donors in accordance with national legislation.**~~		
	~~**(c) any person granting consent, or the authorisation granted by national law, for such an action to proceed in the case of deceased SoHO donors in accordance with national legislation.**~~		**DE**
	(c) any person granting consent in accordance with national legislation, or the authorisation granted by national law, for such an action to proceed in the case of deceased SoHO donors in accordance with national legislation.	Small editorial change for enhanced clarity.	**SE**
~~(13) '**SoHO** donor recruitment' means any activity aimed at encouraging persons to become SoHO donors;~~			
(13a) 'SoHO donor registration' means recording information ~~regarding a prospective~~ on SoHO donors, including the results of the donor health evaluation and~~,~~ the ~~biological~~ tests performed, ~~including~~and transferring such information to other registries, when applicable ~~for the purposes of matching that registered prospective~~	**'SoHO donor registration' means recording information ~~regarding a prospective~~ on SoHO donors, including the results of the donor introductory health evaluation and~~,~~ the ~~biological~~ tests performed, ~~including~~ and transferring such information to other registries, when applicable ~~for the purposes of matching that registered~~**	CZ is of the opinion that other SoHO health evaluation than introductory should be excluded. Therefore, "introductory" is proposed to be added. The aim is to distinguish introductory health evaluation from others repeated SoHO collections which should not be aligned to corresponding obligations related to	**CZ**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~SoHO donor to a prospective SoHO recipient.~~[3]	**~~prospective SoHO donor to a prospective SoHO recipient.~~**	registration process as well.	
	(13a) 'SoHO donor registration' means recording information ~~regarding a prospective~~ on SoHO donors~~,~~ if including the results of the donor health evaluation and~~,~~the ~~biological~~ tests performed, ~~including~~and, when applicable, transferring such information to other registries~~, when applicable for the purposes of matching that registered prospective SoHO donor to a prospective SoHO recipient.~~ [3]	Suggestion to add "if" in the sentence to clarify that the donor registries need to include donor health evaluations in order to make sure that post mortal donors are not included here, so registries in which solely the willingness to donate is registered. In addition a minor text suggestion to clarify that "when applicable" is only applicable to transferring such information.	**NL**
(14) 'collection' means a process by which SoHO~~s~~ are ~~removed, procured, excreted, secreted or~~ obtained **from a SoHO donor~~person~~** ~~by any other manner~~, including any preparatory steps **~~SoHO donor treatment~~**, such as ~~hormone~~ treatment~~,~~ needed to facilitate the process, **at or under the supervision of a SoHO entity ~~at or under the supervision of a SoHO entity~~**;	'collection' means a process by which SoHO~~s~~ are ~~removed, procured, excreted, secreted or~~ obtained **from a ~~SoHO donor~~ person** ~~by any other manner~~, including any preparatory steps **~~SoHO donor treatment~~**, such as ~~hormone~~ treatment~~,~~ needed to facilitate the process, **at or under the supervision of a SoHO entity ~~at or under the supervision of a SoHO entity~~**;	CZ points out that in the definition no. 8 on SoHO donor autologous use and couple MAR is excluded, which is supported by CZ. In this context, CZ proposes to not mention "SoHO donor" in the definition no. 14 on collection and suggests using initial term "person". Moreover, CZ supports current version of the definition no. 23 on autologous use.	**CZ**
	(14) 'collection' means a process by which SoHO~~s~~are ~~removed, procured, excreted, secreted or~~ obtained **from a person ~~SoHO donor~~ ~~person~~** ~~by any other manner~~, including any preparatory steps **~~SoHO donor treatment~~**, such as ~~hormone~~ treatment~~,~~ needed to facilitate the process, **at or under the supervision of a**	Suggestion to remove "SoHO donor" as the activity "collection" is also used in the context of collection for autologous use.	**NL**

[3] Changes highlighted in comparison to definition 13 as presented in 10846/23

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	SoHO entity ~~at or under the supervision of a SoHO entity~~;		
	‘collection’ means a process by which SoHO~~s~~ are ~~removed, procured, excreted, secreted or~~ obtained **from a SoHO donor or from person needed SoHOs for autologous use or from individuals involved in medically assisted reproduction ~~person~~**~~by any other manner~~, including any preparatory steps **~~SoHO donor treatment~~**, such as ~~hormone~~ treatment~~,~~ needed to facilitate the process, **at or under the supervision of a SoHO entity ~~at or under the supervision of a SoHO entity~~**;	Collection can not be limited only to SoHO donors	**SI**
	(14) ‘collection’ means a process by which SoHO~~s~~ are ~~removed, procured, excreted, secreted or~~ obtained **from a person SoHO donor~~person~~**~~by any other manner~~, including any preparatory steps **~~SoHO donor treatment~~**, such as ~~hormone~~ treatment~~,~~ needed to facilitate the process, **at or under the supervision of a SoHO entity ~~at or under the supervision of a SoHO entity~~**;	It would be more correct to refer to “person” here, since “collected” is used in the definition of autologous use, art 3(23) (unless there is a reason for not covering autologous situations by this definition? – in that case another term can be considered in art 3 (23) – obtained?)	**SE**
(23) ‘autologous use**~~application~~**’ means ~~collection~~**application~~use** of **a** SoHO **collected** from ~~one individual~~ **a person** ~~for subsequent application~~ to the same ~~individual~~ **person**~~, with or without further SoHO activities between collection and application~~;		This definition should be harmonised with the definition of collection, if “collected” is kept in the text here. See above.	**SE**
~~[(59) ‘EDQM SoHO monograph’ means a~~			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~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;]~~			
(64) 'compensation' means making good of any **~~quantifiable~~** losses associated with donation;	~~'compensation' means making good of any quantifiable losses associated with donation;~~	PL prefers to delete the definition of compensation.	**PL**
(65)			
CHAPTER VI			
SoHO DONOR PROTECTION			
Article 52			
Objectives regarding SoHO donor protection			
1. **~~SoHO competent authorities and~~** SoHO entities shall ensure ~~high levels of safety~~**respect for the dignity and integrity** of SoHO donors.			
2. **~~SoHO competent authorities and~~** SoHO entities shall **ensure high levels of safety and** protect the health of living **SoHO** donors **from risks related to the donation. They shall do so by identifying and minimising such risks** before, during and after the **SoHO collection**~~donation~~.	**~~SoHO competent authorities and~~** SoHO entities shall **ensure high levels of safety and** protect the health of living **SoHO** donors **from risks related to the donation. They shall do so by identifying and minimising such risks** before, during and after the **SoHO collection**~~donation~~, **including by employing or having at their disposal medical professionals,**	*We cannot agree to drop the requirement that the donation of SoHO be carried out under the control of medical specialists. Interviewing a potential blood donor and allowing him or her to donate is a process of medical assessment given the possible health consequences for the donors. We are proposing a wording that allows those*	**BG**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	as appropriate.	*Member States, which do not consider appropriate, not to involve medical professionals.*	
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			
Standards concerning SoHO donor protection			
1. In case of collection of SoHO~~s~~ from ~~allogeneic~~**living** donors, regardless of whether or not the **SoHO** donor is ~~genetically~~ related to the intended recipient, SoHO entities shall:	In case of collection of SoHO~~s~~ from ~~allogeneic~~ **living SoHO** donors, regardless of whether or not the **SoHO** donor is ~~genetically~~ related to the intended **SoHO** recipient, SoHO entities shall:	Editorial change in order to clarify the text.	**CZ**
(a) meet all applicable consent or authorisation requirements in force in the Member State concerned;			
(b) provide **SoHO** donors or**, where applicable,** ~~their relatives or~~ any persons granting ~~authorisation~~**consent** on their behalf, in accordance with national legislation, with**:**	b) provide **SoHO** donors or**, where applicable,** ~~their relatives or~~ any persons granting ~~authorisation~~**consent** on their behalf of the donor, in accordance with national legislation, with**:**	See comments under art 3(9a)(b).	**SE**
(i) the information referred to in Article 55 and in a way that is adequate in view of their capacity to understand it;			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
ii) the contact details of the SoHO entity responsible for the collection 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;~~[4]			
(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;			
(e) ensure that donation is voluntary and unpaid, pursuant to Article 54;			
(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;	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;	CZ considers points f) and i) within para 1 duplication as marked in green. These points should be unified as they both are focused on the matter of risk minimising in SoHO collection and donation.	**CZ**
(g) document the results of the **SoHO** donor health evaluation ~~referred to in point (f)~~;			

[4] Elements of point c are reflected in point (b)(ii)

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
(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~~**consent** on ~~his/her~~**their** 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~~**consent** on ~~his/her~~**their** behalf, in accordance with national legislation;	See comment under art 3(9a)(b).	**SE**
(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~~**deleterious harmful to health**;	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~~ **deleterious harmful to health**~~;~~	Please see comment above. Moreover, part marked in yellow is considered redundant as the excessive detail may cause confusion. Therefore, this part is proposed to be deleted.	**CZ**
	(i) identify and minimise any risks to the health of the **SoHO** donor during the ~~donation~~**collection** procedure, including exposure to **medecine** reagents or solutions that might be ~~toxic~~**deleterious harmful to health**;		**FR**
(j) verify, by means of a registry, **as referred to in paragraph 3,** that **SoHO** donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article 56**(4)** and ~~demonstrate~~**make sure, by monitoring relevant health indicators to evaluate,** that their health is not compromised;			
(k) develop and implement a plan 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			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
referred to in paragraph **4**~~3~~;			
(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**s concerned** ~~and follows the expressed wishes of both parties~~.	in the case of an ~~allogeneic and~~ unrelated donation, refrain from revealing the **SoHO** donor's identity to the **SoHO** recipient **and vice versa or to the offspring from medically assisted reproduction**, apart from ~~exceptional~~ circumstances where such information exchange is permitted in the Member State**s concerned** ~~and follows the expressed wishes of both parties~~.	CZ recommends adding "and vice versa" as identity should be kept as secret not only of SoHO donor to SoHO recipient but as vice versa as well. Moreover, editorial change in order to clarify the text.	**CZ**
In the course of the **living SoHO** donor health evaluations referred to in paragraph 1, point (f), 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 **responsible** physician, ~~as~~ referred to in Article ~~51~~**49b**, shall approve the procedure and criteria for **SoHO** donor health evaluations.	2. In the course of the **living SoHO** donor health evaluations referred to in paragraph 1, point (f), **Medical professionals at** SoHO entities **as appropriate and in accordance with the requirements at national level,** 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 **responsible** physician, ~~as~~ referred to in Article ~~51~~**49b**, shall approve the procedure and criteria for **SoHO** donor health evaluations.	*In addition, in the field of blood and blood components, blood donation is an extremely important activity, which is related to access to personal data, medical information, medical decisions, donated blood safety through local control and what is particularly sensitive - access to the database of blood donors throughout the country. Access to this information should be given very carefully and to structures where only medical professionals have access to it, such as blood establishments(large or small). They are the only places authorized for blood donation (mobile places for blood donation are temporary and team is part of blood establishment in this area).*	**BG**
	2. In the course of the **living SoHO** donor health evaluations referred to in paragraph 1, point (f), SoHO entities shall conduct interviews	Responsible physician is located in establishments. All enitites are not establishmnents .	**SI**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	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 **responsible** physician, as referred to in Article 51~~**49b**~~, shall approve the procedure and criteria for **SoHO** donor health evaluations.~~	Who will approve procedure and criteria in enitites who are not establishmnents for SoHo donor health evaluation?	
3. SoHO entities that collect SoHOs 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 potential risk to the SoHO donor**, 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 registries, **as referred to in paragraph 1, point (j).**~~as referred **according to the standards issued by their SoHO competent authorities in this regard**paragraph 1, point (j). SoHO entities that manage such registries shall ensure interconnectivity between them~~. **SoHO entities that manage such registries shall ensure**		Denmark finds that this is a very important paragraph and we support keeping it as is.	**DK**
		We would like to point out that the obligation to create a system that interconnects all registries online could be a difficult task especially in deciding, who would be responsible for hosting and maintenance of this system.	**EE**
	SoHO entities that collect SoHOs from donors that are subjected to a surgical procedure in order to donate, that are treated with prescribed medication to facilitate donation, or that donate on a frequent and repeated basis with a potential risk to the SoHO donor, shall register such SoHO donors and the results of their donor health	We see article 53 as very challenging. Donor registries, which are meant to operate in cooperation between SoHO entities are very difficult to implement. We should take into account the different types of donations and donors. We see internal surveillance within a SoHO entity as an adequate surveillance method.	**FI**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
interconnectivity between them, in accordance with national legislation.	evaluations and relevant health indicators. . ~~in a cross-entity registry that allows interconnection with other such registries, as referred to in paragraph 1, point (j).as referred according to the standards issued by their SoHO competent authorities in this regard paragraph 1, point (j). SoHO entities that manage such registries shall ensure interconnectivity between them. SoHO entities that manage such registries shall ensure interconnectivity between them, in accordance with national legislation~~.	- Building a cross entity registry would be very expensive with limited benefits. - The type of registry described here is also vulnerable to cyberattacks and creates new risks to donors and their sensitive data. We should note the principles of the general data protection regulation, especially data minimization. - The benefits of such a registry system would fall on specific individuals in rare situations, but the risks are directed to all donors.	
	3. SoHO entities that collect SoHOs 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 potential risk to the SoHO donor**, 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 registries, **as referred to in paragraph 1, point (j).**~~as referred according to the standards issued by their SoHO competent authorities in this regard paragraph 1, point (j). SoHO entities that manage such registries shall ensure interconnectivity between them~~. **SoHO entities that manage such registries shall ensure interconnectivity**	Once again, it should be expressly noted that the establishment of a 'cross-entity' register in DE will cause significant implementation problems and also does not appear to be justified from the point of view of data protection law. Personal data may only be collected if this is necessary for a specific purpose. The collection of personal data to record multiple donors or for donor protection, on the other hand, is not considered necessary.	**DE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	between them, in accordance with national legislation.	Donor protection would only be ensured if it is assumed that donors do not provide truthful information when donating in order to go to donation more often than permitted. But due to the fact that donation is unpaid, there is no incentive to go to donation to an excessive extent. Talking to donors is therefore the milder remedy of obtaining this information. Also is it not necessary to monitor the health status of a donor with such registers. E.g. you can only give a stem cell donation two times in your life. The registration for these two donations is disproportionate. Also problems with inadmissible multiple donations in the EU are not known. Therefore, we do not consider the register to be necessary for the purpose of donor protection.	

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	3. SoHO entities that collect SoHOs 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 potential risk to the SoHO donor's 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 registries, **as referred to in paragraph 1, point (j).**~~as referred~~ **according** ~~to~~ **the standards issued by their SoHO competent authorities** ~~in~~ **this regard**~~paragraph 1, point (j). SoHO entities that manage such registries shall ensure interconnectivity between them~~. **SoHO entities that manage such registries shall ensure interconnectivity between them, in accordance with national legislation.**	53. 3 It is being questioned whether SoHO entities should be responsible for ensuring interconnectivity between the registries.	**IT**
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 shall include in the plan the time period during which the monitoring shall continue.	The SoHO entities referred to in paragraph 3 shall ensure that the plan for monitoring **the SoHO** donor health after ~~**living**~~ donation **from a living SoHO donor**, as referred to in paragraph 1, point (k), is proportionate to the risks associated with the donation. They shall include in the plan the time period during which the monitoring shall continue.	Editorial change in order to clarify the text.	**CZ**
~~5. In case of collection of SoHOs for autologous use or in the context of individuals or couples from whom SoHOs are~~		Remark: We understand that the presidency has chosen to not include the individuals from whom SoHO is collected for	**NL**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~collected as part of their own current or future medically assisted reproduction treatment, the treating physician~~**~~SoHO entities~~** ~~shall ensure that any risks associated with the collection are explained to the individuals and are outweighed by the potential benefit for those individuals.~~ **~~In such cases, the paragraphs 1(a), (b), (d), (f), (g) (h) and (i) shall apply.~~**		autologous or within couple use in the definition of SoHO donor and therefore also not let this article apply to these individuals. We also understand that these individuals will be protected as SoHO recipient under this regulation. **We can agree to this**. We do however see a need for some minor changes in **article 58** (4, and 14b) to make sure that these paragraphs are also applicable to these individuals and give them the necessary protection. But we will mention them when we discuss that article.	
5a. In case of collection of SoHOs from deceased SoHO donors, in accordance with national legislation, the paragraphs 1(a), (b), (d), (e) and (l) shall apply~~, as well as 1(h), for those cases in which the results of the health evaluation may affect persons related to the SoHO donor.~~	**5a. In case of collection of SoHOs from deceased SoHO donors , , in accordance with national legislation, the paragraphs 1(a), (b), (d), (e), (f), (g) and (l) shall apply, ~~as well as 1(h), for those cases in which the results of the health evaluation may affect persons related to the SoHO donor.~~**	It seems that the qualification of deceased donors is not mentioned, although this seems necessary. It is therefore proposed that f) and g) be added to make them applicable.	**FR**
6. The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this Regulation in cases where additional standards are needed in order to ensure the protection of donors.			
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			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
adopted pursuant to this Article.			
Article 54			
Standards concerning voluntary and unpaid nature of SoHO donations		**The Commission's original proposal gives member states the most flexibility.**	**AT**
		To ensure the principles of the articles are upheld, we believe a periodic review of the application of the article would be useful.	**BE**
1. SoHO entities shall not provide financial incentives or inducements to **SoHO** donors or ~~their relatives or~~ any persons granting ~~authorisation~~**consent** on their behalf**, in accordance with national legislation**~~, in accordance with national legislation~~.	SoHO entities shall not provide financial incentives or inducements to **SoHO** donors or persons granting **consent** on their behalf.	The phrase "in accordance with national legislation" does not seem to make sense, as a complete exclusion of incentives is specified in the same paragraph.	**AT**
	SoHO entities shall not provide financial incentives or inducements to **SoHO** donors or ~~their relatives or~~ any persons granting ~~authorisation~~**consent** on their behalf of the SoHO donor**, in accordance with national legislation**~~, in accordance with national legislation~~.	See comment under Art 3(9a)(b).	**SE**
2. Member States may allow for the ~~compensation or~~ reimbursement **of SoHO donors for** ~~from~~**of actual expenses incurred in connection with SoHO donation or for** the **compensation of** SoHO ~~entities to~~ donors for losses related to their participation in **SoHO** donations through fixed rate allowances. In such case, Member States shall establish the conditions for such **reimbursement or**		It seems contradictory to mention the reimbursement of actual costs incurred on the one hand and to introduce maximum limits at the same time. Nevertheless, maximum limits are indispensable. In addition, it should be clarified that compensation can also be permitted nationally only for individual SoHOs or their products in order to be able to	**AT**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
allowances 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 **reimbursement or** allowances to independent bodies that are established in accordance with national legislation.		differentiate. We suggest to clarify this in the recitals.	
		In our opinion tshere should not be a financial reimbursement of any way. A donor can be reimbursed not money wise. It can be with parking tickets, sales on shops, deduction on taxes, etc. These are considered incentives and not reimbursements.	**CY**
	Member States may allow for the ~~compensation or~~ reimbursement **of SoHO donors for ~~from~~~~of~~ actual expenses incurred in connection with ~~SoHO~~ donation ~~of SoHO~~ or for the compensation of** SoHO ~~entities to~~ donors for losses related to their participation in ~~SoHO~~ donations **of SoHO** through fixed rate allowances. In such case, Member States shall establish the conditions for such **reimbursement or** ~~allowances~~ **compensation** 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 **reimbursement or** ~~allowances~~ **compensation** to independent bodies that are established in accordance with national legislation.	CZ in accordance with previously expressed CZ comments considers it important to use apart from term "reimbursement" the term "compensation" as well. This term should be used instead of the term "allowances" in order to maintain terminology used within definitions. Furthermore, this term is considered more complex in the context of voluntary unpaid donation. It is a red-line for CZ. Moreover, editorial change in order to clarify the text.	**CZ**
	Member States may allow for the ~~compensation or~~ reimbursement **of SoHO donors for ~~from~~~~of~~**	We want to reiterate our concerns regarding the requirement to establish an upper limit,	**EE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	actual expenses incurred in connection with SoHO donation or for the **compensation of** SoHO ~~entities to~~ donors for losses related to their participation in **SoHO** donations through fixed rate allowances. In such case, Member States shall establish the conditions for such **reimbursement or** allowances in national legislation, including the setting of an upper limit, if applicable*, 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 **reimbursement or** allowances to independent bodies that are established in accordance with national legislation. * if this change with the recital (see also the proposed wording for recital 18) does not convey the optional nature of setting an upper limit, we propose to rephrase the second sentence as follows: In such case, Member States shall establish the conditions for such reimbursement or allowances in national legislation, which may include the setting of an upper limit, that ensures financial neutrality consistent with the standards laid down in this Article. Or rephrasing it as follows: In such case, Member States shall establish the conditions for such reimbursement or allowances in national legislation, which may include the setting of an upper limit. The established conditions shall	which we have previously discussed in the working party as well. Although Member States do not have to allow reimbursement or compensation for the donation of SoHOs, then if they do, they are clearly obliged to set an upper limit for these payments as part of the conditions for such reimbursement or allowances. This reading is also very clear from the Estonian language version of the proposal. **We do not support this mandatory imposition of an upper limit and this is our red line.** Our perspective is that each Member State should have the flexibility to determine their own strategies for ensuring the financial neutrality of such compensations. The risk associated with setting an upper limit is that it may standardize payments at that specific amount, irrespective of whether it accurately reflects the costs incurred by the donors. Also, the current wording, even if it could be interpreted as not obligatory, creates pressure to the Member States to set such an upper limit. We therefore need a more flexible approach that grants Member States the autonomy to select the most suitable measures to attain financial neutrality, without the compulsory inclusion of an upper limit as part of the conditions for permitting SoHO donor compensations. It's worth noting that in the proposed text this	

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	ensure the financial neutrality consistent with the standards laid down in this Article. ** The upper limit itself might not ensure the financial neutrality of these reimbursements or allowances, therefore it is important to clarify that the conditions of reimbursement and allowances in general must ensure the financial neutrality, whatever these conditions set by the Member State are.	obligation is currently in place when allowing SoHO donor compensations.	
		DEU agrees with the current wording and the wording of recital 18. Donor can be compensated uniformly with a fixed compensation. Proof of the actual losses incurred must not be provided. Accordingly, compensation can also be paid for the time lost during the donation.	**DE**
2a. The conditions applied by each Member State shall be made available ~~to the public~~ on the EU SoHO P~~p~~latform and be updated without undue delay if modified.		We would like to see the upper limits published in the restricted part of the Eu SoHO platform	**BE**
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 an element of such activities.	**Member States shall take all necessary measures to ensure that any promotion and publicity activities in support of the donation of SoHO ~~does~~ do not include the compensation or reimbursement as an element of such activities.** **Corresponding Recital 18:** Thus, compensation to remove any such risk is acceptable but should never constitute an	CZ supports the current version without to mention the setting of an upper limit. CZ can accept not to refer to compensation in advertisement. At the same time, we have a sympathy for the DE proposal and could support changes proposed for Article 54 para 2b) and corresponding Recital 18 with an amendment to delete the reference to blood and blood plasma donation as we wish to include SoHO donors of reproductive	**CZ**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	incentive that would case 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 that of prospective recipients. **With respect to financial neutrality of the allowance, the donor does not have to prove to the SoHO entity any financial loss due to the participation in donation. The fixed rate allowance is also considered financially neutral ~~in the case of a blood or plasma donation~~ if it compensates for any loss, including losses of time due to the donation.** Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member States to reach such.	cells as well.	
	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 an advertising element of such activities.	The use of the compensation as an advertising measure should be prohibited, but the factual reference to the legal situation that the donor is compensated for the effort in making the donation cannot be prohibited. It mut be possible to inform the donors. Therefore it has to be clarified here and furthermore in detail in the recital (see comment on recital 18a) that the mere factual reference does not constitute advertising.	**DE**
	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	The proposed provision may be in conflict with the Swedish constitution. We have a very far-reaching and strong tradition and constitutional regulation on freedom of	**SE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	or reimbursement as an element of such activities.	speech and right to publication. We have two different constitutional regulations on this matter, with their own process order etc. It is important that the provisions of this regualtion are not in conflict, or possibly in conflict with our constitutional order. **We therefore propose a deletion of the paragraph**. An acceptable alternative for us would be to keep this intention by describing it, in a recital, as something to strive towards. If this paragraph is kept we may need to ask for a constitutional exception.	
3. SoHO entities may **reimburse or** compensate ~~or reimburse~~**SoHO** donors as provided for by their ~~competent authorities~~**Member States,** pursuant to paragraph 2.	SoHO entities or istituzioni incaricate a livello nazionale, in accordo con la legislazione nazionale vigente may **reimburse or** compensate ~~or reimburse~~**SoHO** donors as provided for by their ~~competent authorities~~**Member States,** pursuant to paragraph 2	54.3P For Italy, it is necessary to provide for the possibility of assigning this task to institutions appointed at the national level, in accordance with current national legislation.	**IT**
3a. ~~In order to ensure that voluntary unpaid SoHO donations do not, as such, lead to a profit from the human body, and for compliance with the Charter in this respect,~~ Member States shall take appropriate measures to ensure transparency in the fees for technical services required for making SoHOs and derived products available, and ~~in the pricing strategy applied to such~~	**~~In order to ensure that voluntary unpaid SoHO donations do not, as such, lead to a profit from the human body, and for compliance with the Charter in this respect,~~ Member States shall take appropriate measures to ensure transparency in the fees for technical services required for making SoHOs and derived products available, and ~~in the pricing strategy applied to such~~**	CZ is of the opinion that provision Article 54 para 3a) and part "to ensure transparency in the fees for technical services" as marked in green should be more specified.	**CZ**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~products.~~	~~products.~~		
		What does this mean? Technical services? In CY Blood products are provided for free to everyone by the Blood Establishment and Blood Banks. The clinics that trtansuse the products, charge for the transfusion service and the consumables (not the the blood product as such). 1) Are we talking about the fees from the clinics? Why should the services fees from the clinics be regulated in this regulation? 2) Are we talking about technical services and fees applied from the Blood Establishment? In Cyprus, since the Blood establishment is a public entity and the donation is volunteer/ unpaid, there is no fee on the products.	**CY**
		Denmark finds that this is a very important paragraph and we support keeping it as is.	**DK**
	3a. ~~In order to ensure that voluntary unpaid SoHO donations do not, as such, lead to a profit from the human body, and for compliance with the Charter in this respect, Member States shall take appropriate measures to ensure transparency in the fees for technical services required for making SoHOs and derived products available, and~~	It is still unclear what 'fees for technical services required for making SoHO available' should include and what requirements this places on the Member State. Connection with quality and safety of SoHO not comprehensible.	**DE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
	~~**in the pricing strategy applied to such products.**~~		
		We strongly argue that, at least, the transparency proposed in the compromise text on solely SoHO products will remain. To us it seems essential to be transparent on financial matters concerning voluntary donated material in order to protect the willingness to donate. Especially when it concerns commercially sold SoHO products**.**	**NL**
		Fees for technical services are not explained enough.	**SI**
		The paragraph has been improved, but we are still of the opinion that "fees for technical services" is not suffiently clearly explained.	**SE**
Article 55			
Standards concerning information to be provided prior to consent ~~or authorisation~~			
1. SoHO entities shall provide prospective SoHO donors~~, their relatives~~ or**, if applicable,** 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~~		It should be clarified that consent is also possible through opt-out systems. We suggest that this should at least be mentioned in the recitals.	**AT**
	1. SoHO entities shall provide prospective SoHO donors~~, their relatives~~ or**, if applicable,** any persons granting ~~authorisation~~**consent** on their behalf, ~~in accordance with national~~	Provisions in para. 1 and 2 are only applicable to living SoHO donors. SoHO entities can at	**DE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~uses and benefits of the donation~~.	~~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~~. **In the case of deceased donation of SoHOs Member States and SoHO entities shall provide access to appropriate information on deceased donation to the general public.**	best provide general information to the public on post-mortem donation. Who will once be a postmortem donor is completely unknown. Therefore, no information can be provided prior to consent to donation..	
	SoHO entities shall provide prospective SoHO donors~~, their relatives~~ or**, if applicable,** any persons granting ~~authorisation~~**consent** on their behalf of the SoHO donor, ~~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~~.	See comment under Art 3(9a)(b) – if that change is not made, "on behalf of the SoHO donor, according to national legislation" should be added here.	**SE**
2. SoHO entities shall provide the information referred to in paragraph 1 before the consent ~~is given or authorisation~~**to ~~donation~~ donate** is granted ~~for the donation~~. SoHO entities shall provide the information in an accurate and clear manner, using terms that are easily understood by the prospective **SoHO** donors~~,~~ or**, if applicable,** ~~the~~**any** persons ~~to~~ **granting** consent ~~or authorise the donation. It shall not mislead the prospective donors or persons granting authorisation~~ on their behalf~~,~~**. The information shall not be misleading,** in particular, as to the benefits of	SoHO entities shall provide the information referred to in paragraph 1 before the consent ~~is given or authorisation~~**to ~~donation~~ donate SoHO** is granted ~~for the donation~~. SoHO entities shall provide the information in an accurate and clear manner, using terms that are easily understood by the prospective **SoHO** donors~~,~~ or**, if applicable,** ~~the~~**any** persons ~~to~~ **granting** consent ~~or authorise the donation. It shall not mislead the prospective donors or persons granting authorisation~~ on their behalf~~,~~**. The information shall not be misleading,** in particular, as to the benefits of the donation to	Editorial change in order to clarify the text.	**CZ**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
the donation to future recipients of the SoHO concerned. ~~This provision shall also apply to persons from whom SoHO are to be collected for autologous use or as part of a current or future medically assisted reproduction treatment in the context of individuals or couples.~~	future SoHO recipients ~~of the SoHO~~ concerned. ~~This provision shall also apply to persons from whom SoHO are to be collected for autologous use or as part of a current or future medically assisted reproduction treatment in the context of individuals or couples.~~		
		It is not clear why the final sentence has been removed. Neverthless we would like to keep the last sentence: "This provision shall also apply to persons from whom SoHO are to be collected for autologous use or as part of a current or future medically assisted reproduction treatment in the context of individuals or couples."	**LV**
		See comment under Art 3(9a)(b) – if that change is not made, "on behalf of the SoHO donor, according to national legislation" should be added here.	**SE**
3. In case of living **SoHO** donors **or, if applicable, persons granting consent on their behalf**, SoHO entities shall provide information regarding:		See comment under Art 3(9a)(b) – if that change is not made, "on their behalf, according to national legislation" should be added here.	**SE**
(a) the purpose and nature of the donation;			
(aa) the intended use of the donated SoHO, specifically covering proven benefits for the future SoHO recipients and for patients treated with products manufactured from SoHO ~~any possible research or commercial uses, in particular for~~	**(aa) the intended use of the donated SoHO, specifically covering proven benefits for the future SoHO recipients and for patients treated with products manufactured from SoHO** **any possible research or commercial uses**, ~~in particular for manufacturing~~	A donor should be well-informed about the intended use of donated SoHO. Specially also when it is used for possible research or commercial uses. To us it seems essential to be transparent on possible commercial benefits in order to protect the willingness to	**NL**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~**manufacturing productsand regulated by other Union legislation, as provided for in Article 2.3, to which specific consent shall be grantedthe SoHO donor or any persons acting on their behalf shall consent;**~~[5]	~~**productsandregulated by other Union legislation, as provided for in Article 2.3, to which specific consent shall be grantedthe SoHO donor or any persons acting on their behalf shall consent;**~~[5]	donate. **We strongly argue** to keep this part or otherwise mention somewhere else in the regulation the necessity to inform the donor and SoHO recipient and be transparent about possible commercial benefits.	
(b) the consequences and risks of the donation;			
(ba) the obligation for consent, ~~as applicable in the Member Statein~~ accordance with national legislation, in order for SoHOs collection to be carried out.		**It should be clarified that consent is also possible through opt-out systems. We suggest that this should at least be mentioned in the recitals.**	**AT**
(c) the right to ~~withdraw~~**revoke** consent and any restrictions on ~~the~~**that** right **after the collection**~~to withdraw consent following donation;~~		Denmark finds that this is an important paragraph and we support keeping it as is.	**DK**
	the right to ~~withdraw~~**revoke** consent and any restrictions on ~~the~~**that** right ~~**after**~~ **before the collection**~~to withdraw consent following donation;~~	55 3c) It is essential that the option to withdraw consent is ensured until prior to collection. For Italy, it is not acceptable to provide for the possibility of revocation after the collection of SoHOs, as this could seriously jeopardize the health of certain types of recipients (e.g., HSC). This is a red line	**IT**
~~(d) the intended use of the donated SoHO, in particular covering proven benefits for the future recipients and any possible research or~~			

~~[5] This section captures elements of the deleted point (d)~~

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~commercial uses to which the donor should consent;~~			
(e) the **purpose of the** ~~analytical~~ tests that will be performed in course of the donor health evaluation**, in accordance with Article 53(2)**;			
(f) the right of the ~~donor~~**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,** ~~when relevant for their health~~ **in accordance with national legislation**;		See comment under Art 3(9a)(b) – if that change is not made, "on their behalf, according to national legislation" should be added here.	**SE**
(g) the recording and protection of ~~donor~~**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**;			
(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;	**the possibility that the SoHO donor identity may be revealed to offspring born from their ~~SoHO~~ donation of SoHO in cases where national legislations grants this right to such offspring;**	CZ recommends adding plural in the term "national legislation" to which it is referred in order to clarify that both Member States should have the possibility to reveal the SoHO donor's identity within their national legislation. Moreover, editorial change in order to clarify the text.	**CZ**
(h) ~~the~~**other** applicable safeguards ~~intended~~			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
to protect the **SoHO donor.**			
~~(i) the obligation for consent and authorisation, as applicable in the Member State, in order for SoHOs collection to be carried out.~~			
3a. In case of deceased SoHO donors, SoHO entities shall provide any persons granting consent to donation, according to the national law, with the information referred to in paragraphs 3(a), (aa), (ba), (c), (e), and (g), as well as 3(f) for those cases in which the results of the health evaluation may affect persons related to the SoHO donor ~~and their personal data;~~**.**	**The text defining the obligation should be deleted, or left up to the member states to decide.**	- We see the obligations set in section 3a as problematic. Nationally there is no information shared to the family members of deceased donors of SoHO´s or organs. This obligation would create a confusing situation that wouldn't be consistent with the purpose of the regulation. We propose that this obligation would be removed from the regulation or changed to leave room for national legislation. - The obligation seems to aim to protect the family members of donors, not the donors or recipients. - It is difficult to define the group of people that may be affected by the data. The affected people might differ vastly based on the type of results – infectious diseases, sexually transmitted diseases, genetic condition affect different people. This might be difficult to define, and even harder to locate. - It remains unclear, what would be done with the results shared with family members without a clear contact to a	**FI**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		healthcare provider. The path for the family member from receiving clinically significant information to getting the correct guidance and care from the correct, responsible entity remains unclear here. The goal of providing relevant information to family members does little to better their health or prevent further spread of disease is very limited if there is no clear contact to healthcare. Defining these types of obligations is not within the scope or purpose of this regulation. - **For these reasons, we propose that this obligation should be removed, or left up to the member states to decide.**	
		Clarification in the recital needed that clarifies that 'in accordance with national legislation' is also to be understood as meaning that information does not have to be disclosed if medical confidentiality after death prevents this. For a proposal on recital 16 see wording in compromise text 13655/23	**DE**
		If cases with opt-out type of consent to donate SoHO after death are not included here, this is not equal for persons related to such donors, moreover, we have provisions in national legislation to inform the family	**LV**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
		doctor regarding confirmed results of the donor tests when relevant for health.	
Article 56			
Implementation of the standards concerning SoHO donor protection			
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 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.			
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).			
2. On duly justified imperative grounds of urgency relating to a risk to **SoHO** donor health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 79(3).			
3. ~~In order to apply the standards concerning donor protection or elements thereof, referred to in Articles 53, 54 and 55,~~			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~SoHO entities shall follow the procedures laid down in any~~**The** implementing ~~act~~**acts** adopted in accordance with paragraphs 1 and 2 of this Article **shall also apply to SoHO entities when they apply the standards or elements concerning SoHO donors protection as refered to in Articles 53, 54 and 55**.			
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, SoHO entities shall ~~follow:~~ **take into account, in this order of priority:**	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, SoHO entities shall ~~follow:~~ ~~**take into account, in this order of priority:**~~	Deletion of priorisation. No prioritisation should be foreseen. The national guidelines can be applied if equivalence has been determined by the competent national authority. Therefore, they should be applied equally to the EDQM Guidelines. If a Member State does not have national guidelines, then automatically EDQM and ECDC guidelines has to be followed. **Red Line DE!**	**DE**
(a) the most recent technical guidelines, as indicated on the EU SoHO Platform ~~referred to in Chapter XI~~, as follows:			
(i) published by the ECDC concerning the prevention of communicable disease transmission ~~through SoHO donation~~;			
(ii) published by the EDQM concerning			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
SoHO donor protection other than from transmission of communicable diseases ~~through donation~~;			
(b) ~~other guidelines accepted by competent authorities, as achieving an equivalent level of donor safety as set by the~~**national or international** ~~technical~~ **other** guidelines**, as** referred to in **article 29(7a)** point (~~a~~**b**);	(b) **if existing,** ~~other guidelines accepted by competent authorities, as achieving an equivalent level of donor safety as set by the~~**national or international** ~~technical~~ **other** guidelines**, as** referred to in **article 29(7a)** point (~~a~~**b**);	Clarification that only the national guidelines have to be taken into account, as far as they exist.	**DE**
(c) ~~where the guidelines referred to in points (a) or (b) do not address a particular~~**other** technical methods**, applied in specific circumstances, as referred to in article 29 (7a) point (c)** ~~other technical methods in line with relevant international guidelines and~~**the** ~~scientific evidence in peer-reviewed scientific publications, where available~~.	(c) **where the guidelines referred to in points (a) or (b) do not address a particular** ~~other~~ technical methods~~, applied in specific circumstances,~~ **as referred to in article 29 (7a) point (c) other technical methods in line with** ~~relevant international guidelines and~~**the scientific evidence** ~~in peer-reviewed scientific publications,~~ **where available.**	On this point a priorisation is required. Therefore, the previous wording should be retained. It must be clearly shown that other technical methods may only be taken into account if there are no suitable specifications in the EDQM and ECDC guidelines or national guidelines.	**DE**
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 follow the **technical** guidelines referred to in paragraph 4, point (a).			
6. In those cases referred to in paragraph 4, point (b), for the purpose of Article 30 in conjunction with Article 29, SoHO entities	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	The rewording is essentially welcomed. But the deletion of 'for each of the standards or elements thereof' is needed. Addition is	**DE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
shall demonstrate to their **SoHO** competent authorities, for each of the standards or elements thereof, ~~the equivalence~~**~~, in terms of SoHO donor protection,~~** ~~of the other guidelines applied in terms of the level of safety, quality and efficacy~~ **which and to what extent they follow** ~~to the level set by~~ the technical guidelines referred to in paragraph 4, point (**b**~~a~~).	demonstrate to their **SoHO** competent authorities, ~~**for each of the standards or elements thereof,** the equivalence**, in terms of SoHO donor protection,** of the other guidelines applied in terms of the level of safety, quality and efficacy~~ **which and to what extent they follow** ~~to the level set by~~ the technical guidelines referred to in paragraph 4, point (**b**~~a~~).	not necessary, as SoHO entities have to specify 'which and to what extent they follow the technical guidelines' anyway.	
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** donor**s** ~~safety~~, and record the practice followed to 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 X (Union Activities): Articles 69, 69a, 70, 71, 72			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
CHAPTER X			
UNION ACTIVITIES			
Article 69			
Union training and exchange of <u>SoHO</u> competent authorities' personnel			
1. The Commission shall**<u>, in cooperation with SoHO National Authorities,</u>** organise Union training **<u>on the implementation of this Regulation.</u>** ~~in cooperation with the Member States concerned.~~		The wording of the paragraph is agreed upon, provided that the proposal to amend Article 5 regarding the recognition of a broad delegation system to SCAs is accepted.	**IT**
~~In the Union training organised, the Commission shall cover at least, the following topics, as appropriate:~~			
~~(a) the implementation of this Regulation;~~			
~~(b) procedures relevant for the SoHO supervisory activities of the competent authorities;~~			
~~(c) the functionality and use of the EU SoHO Platform;~~			
~~(d) other knowledge and skills relevant to facilitate SoHO supervisory activities.~~			
2. The Commission may provide Union			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
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 aspects of the training in collaboration with international organisations and regulators working in the field of SoHOs.			
3. **SoHO** ~~C~~**c**ompetent 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**.			
4. The Commission may support, in cooperation with the **SoHO National Authorities** ~~Member States~~, 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.		Please, refer to the comment at paragraph 1	**IT**
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 7**0**~~1~~. The	5. The Commission shall maintain a list of the **SoHO** competent authority **whose** 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 7**0**~~1~~. The	Further rejection that a list of personenel who have completed the EU training be drawn up. The list should include the competent authorities and the number of participants from this authority instead. Due to the high fluctuation of employees, it	**DE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
Commission shall make this list available to the **SoHO National Authorities** ~~Member States~~.	Commission shall make this list available to the **SoHO National Authorities** ~~Member States~~.	makes more sense to have the authority as contact point. In addition, experience has shown that employees do not like to be listed. This could reduce their willingness to participate in EU trainings.	
		Please, refer to the comment at paragraph 1	**IT**
6. ~~The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this 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 69a~~			
~~Information exchange~~			
~~The Commission shall hold regular meetings with the SoHO National Authorities designated by the Member States, delegations of experts designated by the Member States and other relevant parties to exchange information on the experience acquired.~~			
Article 70			
Commission verifications~~controls in Member States~~			
1. The Commission shall perform	1. The Commission **may** ~~**shall**~~ perform	Verifications should be carried out at most	**DE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
verifications to confirm whether ~~controls, including audits, in the~~ Member States **effectively apply** ~~to verify the effective application of~~ the requirements relating to:	**verifications to confirm whether** ~~controls, including audits, in the~~ Member States **effectively apply** ~~to verify the effective application of~~ the requirements relating to:	on a random basis.	
	1. The Commission ~~shall~~ **may, in duly justified circumstances** perform **verifications to confirm whether** ~~controls, including audits, in the~~ Member States ~~effectively~~ **apply** ~~to verify the effective application of~~ the requirements relating to	PL proposes replacing "shall" with "may, in duly justified circumstances". We continue to believe that such verifications should be conducted only in justified cases. The term is too vague – what would constitute or how would be measured the effectiveness of application?	**PL**
(a) **SoHO** competent authorities and delegated bodies provided for in Chapter II;			
(b) the SoHO supervisory activities ~~provided for in Chapter III as~~ carried out by **SoHO** competent authorities and delegated bodies;			
(c) the notification and reporting requirements of this Regulation.			
2. The Commission shall organise the ~~controls~~ **verifications** referred to in paragraph 1 in cooperation with the **SoHO National Authorities** ~~Member States~~, and shall carry them out in a manner that avoids unnecessary administrative burden.			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
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 ~~inspection, vigilance and any other~~ SoHO supervisory activities ~~as needed.~~			
4. ~~Experts from the Member States may assist~~ **T**~~t~~he Commission experts**,** in carrying out the ~~controls~~ **verifications** referred to in paragraph 1, **may be supported by experts from the SoHO competent authorities**~~. The Commission shall~~ select**ed**~~the experts from the Member States~~, whenever possible**,** from the list referred to in Article 69(5)~~,and~~**. Experts from the SoHO competent authorities** shall **be** give**n** the~~m~~ same rights of access as the Commission experts.			
5. Following each **verification**~~control~~, the Commission shall:			
(a) prepare a draft report on the findings and, where appropriate, include recommendations **addressing** ~~on how best to address~~ the shortcomings **identified**;			
(b) send a copy of the draft report referred to in point (a) to the concerned **SoHO National Authority**~~Member State~~ for its comments;			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
(c) take the comments ~~of the Member State~~ referred to in point (b) into account in preparing the final report; and			
(d) make publicly available **a summary of** the final report **on the EU SoHO P~~p~~latform** ~~referred to in point (c) and the comments of the Member State referred to in point (b).~~			
Article 71			
Cooperation with the EDQM			
The Commission shall establish and maintain cooperation with the EDQM**, in the form of a cooperation agreement,** in relation to the guidelines published by the EDQM.	~~The Commission shall establish and maintain cooperation with the EDQM~~**~~, in the form of a cooperation agreement,~~** ~~in relation to the guidelines published by the EDQM.~~	It is still unclear what the cooperation agreement should contain. This applies in particular against the background that the role of the EDQM guidelines will not be fundamentally changed by the regulation. They are already regularly updated. The Regulation now only stipulates that they must be taken into account by the Member States. We propose to hightlight the importance of cooperation with EDQM in a recital instead.	**DE**
		We support the clear reference on cooperation agreement with EDQM here. We object to the deletion of text in the bold: “in the form of a cooperation agreement”.	**LV**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
Article 72			
Assistance by the Union			
1. To facilitate the fulfilment of the requirements provided for in this Regulation, the Commission shall support implementation by:			
(a) providing secretariat and technical, scientific and logistic support to the SCB and its working groups;	providing secretariat and technical, ~~scientific~~ and logistic support to the SCB and its working groups;	CZ points out that it is not clear how EC could ensure scientific support. Therefore, the term "scientific" is proposed to be deleted.	**CZ**
(b) funding Commission **verifications**~~controls~~ in Member States, including the costs of Member State experts assisting the Commission ~~in such controls~~;			
(c) providing funding from the relevant Union programme**s** in support of public health to:			
(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 article 69(1) and programmes for the exchange of SoHO competent authorities' personnel referred to in article**			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
69(4);			
(ii) co-finance a cooperation agreement with the EDQM to support the development and updating of technical guidelines ~~supporting~~ **in order to support** the ~~coherent~~ **consistent** implementation of this Regulation.			
(ca) establishing, managing and maintaining the EU SoHO Platform;		CZ in general considers it crucial to ensure sufficient functioning of SoHO EU Platform, including all functionalities and noticies, before the Regulation entries into force. Communication between all stakeholders and access to which part of the platform for which representatives should be clarified.	**CZ**
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 meetings with SoHO National Authorities,**~~ 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 meetings with SoHO National Authorities,**~~ the travel of ~~**members**~~ **participants of such meetings** ~~of the SCB~~, reimbursement and special allowances for ~~scientific~~ experts that participate in those meetings~~, and ensure the appropriate follow-up~~.	Editorial.	**LV**
3. Upon request from Member States, technical support may be provided, through the Technical Support Instrument established by			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
Regulation (EU) 2021/240 of the European Parliament and of the Council[6], for the reform of national or regional SoHO supply supervision, provided those reforms aim to achieve compliance with this Regulation.			
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 **and verifications**~~, audit, and control~~, as well as to support expenditure, the Commission shall have recourse to the technical and administrative assistance it might need.			
CHAPTER XI (EU SoHO Platform): Recitals 41, 42, 43 ; Articles 3(31), 73, 74			
Recitals			
(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.			

6 Regulation (EU) 2021/240 of the European Parliament and of the Council of 10 February 2021 establishing a Technical Support Instrument (OJ L 57, 18.2.2021, p. 1).

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
The EU SoHO Platform will contribute to ~~as well as~~ improve~~d~~ transparency of ~~national~~ reporting and **SoHO** supervisory activities **and to the exchange of information between relevant parties.**			
(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 Parliament and of the Council and in Regulation (EU) 2018/1725 of the European Parliament and of the Council.			
(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, **including health 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 competent authorities, Member States or the Commission**, should be limited to the extent necessary to **perform SoHO related** ~~carry out supervisory~~activities **laid down**~~provided for~~ in this Regulation.			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
CHAPTER I			
GENERAL PROVISIONS			
Article 3			
Definitions			
~~(31) 'EU SoHO Platform' means the digital platform established by the Commission~~**~~,~~ referred to in Chapter XI** ~~to exchange information concerning SoHO activities;~~			
CHAPTER XI			
EU SoHO PLATFORM			
Article 73			
Establishment, management and maintenance of the EU SoHO Platform			
1. The Commission shall establish, manage and maintain ~~the~~ a **digital platform** ~~EU SoHO Platform~~ to facilitate effective and efficient exchange of information concerning SoHO activities in the Union, as provided for in this Regulation **("EU SoHO Platform").**	The Commission shall establish, manage and maintain the a digital platform EU SoHO Platform to facilitate effective and efficient exchange of information and ensure **data tracking** concerning SoHO activities in the Union, as provided for in this Regulation ("EU SoHO Platform")	Denmark finds that data tracking (historical record of data) on the SoHO platform is very important so one is able to detect changes and seek out previous/historical recordings. Thus, we propose to add the text in bold.	**DK**
2. ~~The Commission shall make a summary of data of public interest and make it accessible to the public on the EU SoHO Platform in aggregated and anonymised formats. The EU~~			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~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.~~			
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 components~~ shall only be carried out **in cases where it is necessary for the 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 shall be carried out in accordance with the applicable Union data protection legislation for the purpose of performing SoHOs related activities in accordance with this Regulation and in compliance with the applicable data protection legislation**~~for the purpose of performing SoHOs related activities in accordance with this Regulation and in compliance with the applicable data protection legislation~~.	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 components~~ shall only be carried out **in cases where it is necessary for the 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 shall be carried out in accordance with the applicable Union data protection legislation for the purpose of performing SoHOs related activities in accordance with this Regulation and in compliance with the applicable data protection legislation**~~for the purpose of performing SoHOs related activities in accordance with this Regulation and in compliance with the applicable data protection legislation~~.	Deletion. Relationship to Art. 76 (2) unclear, which also contains a legal basis for data collection under the SoHO platform. Legal basis for data collection should be bundled in Art. 76 for reasons of legal clarity.	**DE**
4. The Commission, **after having consulted the SCB,** shall adopt delegated acts in accordance with Article 77 supplementing this Regulation by laying down technical specifications regarding the ~~establishment~~,			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
management and maintenance of the EU SoHO Platform.			
5. The Commission shall provide instructions**, materials and training on the correct use of the EU SoHO Platform** for SoHO ~~entities and~~ 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 availabe on EU SoHo Platform.**	The Commission shall provide instructions**, materials and training on the correct use of the EU SoHO Platform** for SoHO ~~entities and~~ 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 availabe on EU SoHo Platform.**	It is requested to remove the reference to 'via their SoHO National Authority' in order to streamline the process.	**IT**
Article 74			
General functionalities of the EU SoHO Platform			
1. The EU SoHO Platform shall enable SoHO entities, **SoHO** competent authorities, Member States and the Commission to process information, data and documents concerning SoHO~~s~~, **and SoHO activities**, including the submission, retrieval, storage, management, handling, exchange, analysis, publication and deletion of such data and documents as provided for in this Regulation.			
2. The EU SoHO **P**platform shall ~~also~~ provide **a channel for restricted** ~~a secure~~	2. The EU SoHO **P**platform shall ~~also~~ provide **a channel for secure** ~~**restricted**~~ ~~a~~	Clarification that it should be a secure communication channel, but does not have	**DE**

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~environment for the~~ exchange of information **and data, in particular:**	~~secure environment for the~~ exchange of information **and data, in particular:**	to be restricted to the participants named. The wording 'restricted' is misleading and seems in contradiction to 'in particular'	
(a) between **Member States' SoHO National Authorities;**			
(b) between two SoHO competent authorities within the Member State or between a SoHO competent authority and its SoHO National Authority;			
(c) between SoHO National competent 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,** ~~SAO~~ **SoHO** ~~and~~ rapid alerts **and SoHO supply alerts;**		2c Please refer to the comment on Article 5 regarding the request for a broad delegation system to SCAs.	**IT**
		This point seems to reflect Art 33.3 on activity data (review and approval), Art 35.10a concerning the annual summaries of SAR or SAE, Art 36.1 on rapid alerts and Art 63.3 on supply alerts. Art 36(1) is not reflected in the proposal for Art 9(1a). Are all these activities supposed to be possible to delegate, in line with the added paragraph in Chapter II? If such delegation is made, the PF needs to make communication possible also between the COM and the SCA to which such activities are delegated.	**SE**
(d) between SoHO National Authorities and the SCB; and			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
(e) between SoHO National Authorities and the ECDC ~~for SoHO rapid~~ alerts related to communicable diseases~~, according to article 36(3)~~.			
(f) ~~T~~the EU SoHO Pplatform shall also provide a secure communication channel for the exchange of information between SoHO entities and their respective SoHO competent authorities, when the SoHO competent authorities choose to use the EU SoHO Platform for such exchanges.			
2a. The EU SoHO Platform shall ~~It shall also~~ provide public access to information regarding**:**			
(a) the registration and authorisation status of SoHO entities **and their identification code** and **the SoHO establishment identification code;**			
(b) authorised SoHO preparations ~~authorised~~;			
(c) annual SoHO Activity Report and annual SoHO vigilance report, in aggregated and anonymised formats, after their approval by SoHO National Authorities;			
(d) relevant best practices agreed and documented by the SCB;			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
(e) technical guidelines for quality management published by the EDQM;		France would like it to be added that this includes the monographs mentioned in Article 41.2 (b), as the expression "for quality management" suggests that this concerns good practice and not monographs.	**FR**
	(e) technical guidelines for quality management, Good practice guidelines and SoHO monographs published by the EDQM;	As there is a reference to quality management, we suggest adding "Good practice guidelines and SoHO monographs".	**LV**
(f) technical guidelines concerning the prevention of communicable disease published by the ECDC and concerning SoHO donor, SoHO recipient and offspring protection other than from transmission of communicable diseases published by the EDQM;			
(gf) the name, the institution of origin and the declaration of interest of each SCB member and alternate;			
(hg) the SoHO compendium;			
~~(ih) the conditions established in national legislation for reimbursement or allowances, including the setting of an upper limit to SoHO donors for losses related to their participation in SoHO donations~~.			
~~The EU SoHO Platform~~ ~~shall~~ **~~also~~** ~~indicate the applicable guidelines to be followed to meet the technical standards laid down in~~			

Compromise Text (13503/23 + COR 1)	Suggested adaptations to the text	Comments	MS
~~Articles 56 and 59.~~			
3. The Commission shall adopt implementing acts laying down technical specifications for the EU SoHO Platform, including its functions, the roles and responsibilities of each of the parties listed in paragraph 1, the retention periods for personal data and the technical and organisational measures to ensure the safety and security of personal data processed, **including health data**.			
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).			