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From:	Presidency
To:	Delegations
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Subject:	Proposal for a Regulation on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC *- Examination of the Presidency compromise text*

Delegations will find in Annex a compromise text prepared by the Presidency on the above-mentioned subject to be examined in the Working Party on Public Health on 10 October 2023.

Regarding the section on recitals, text marked in **bold and underlined** and in ~~strikethrough~~ reflect changes made to the Commission proposal.

Regarding the section on delegated and implementing acts, the text presents relevant parts of the text as presented in 12955/23, 13231/23, 13503/23 +COR1 and 13586/23, including the colour coding used therein with the following exceptions:

- New text adaptations are highlighted in green (with the exception of comments from the Presidency).

- Text and references to delegated acts are highlighted blue, unless they present new text adaptations.
- Text and references to implementing acts are highlighted yellow, unless they present new text adaptations.

ANNEX

Section on Recitals

Whereas:

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

(2) Article 168(4), point (a), TFEU provides that the European Parliament and the Council should adopt measures setting high standards of quality and safety for organs and substances of human origin (SoHO~~s~~), blood and blood derivatives. At the same time, Member States cannot be prevented from maintaining or introducing more stringent protective measures. ~~Pursuant to Article 193 TFEU, Member States are to notify the Commission of any such measures.~~ According to Article 168(7) TFEU, **the Union should respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care, and** the measures adopted pursuant to Article 168(4), point (a) should not affect national provisions on the donation or medical use of organs and blood.

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

(4) Directives 2002/98/EC[1] and 2004/23/EC[2] of the European Parliament and of the Council constitute the Union's regulatory framework for blood and for tissues and cells, respectively. Although these Directives have harmonised to a certain degree the rules of Member States in the area of safety and quality of blood, tissues and cells, they include a significant number of options and possibilities for Member States to implement the rules they laid down. This **has** result**eds** in divergences between national rules, which ~~can~~ create obstacles to cross-border sharing of these substances. A fundamental revision of those Directives is needed for a robust, transparent, up-to-date and sustainable regulatory framework for these substances, which achieves safety and quality **offor** all **SoHO,** ~~parties involved,~~ enhances legal certainty **for patients involved** and supports continuous supply, whilst facilitating innovation for the benefit of public health. In order to achieve a coherent application of the legal framework, it is appropriate to repeal Directives 2002/98/EC and 2004/23/EC and to replace them by a Regulation.

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

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

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

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

(7) Solid organs are excluded from the definition of SoHO~~s~~ for the purposes of this Regulation and, thus, from its scope. Their donation and transplantation are significantly different**, determined, inter alia, by the effect of ischemia in the organs,** and are regulated in a dedicated legal framework, set out in Directive 2010/53/EU[3] of the European Parliament and of the Council. ~~Shortcomings have not been raised regarding the existing quality and safety provisions for organs.~~ **Composite vascular allografts such as hands or faces should be considered to meet the definition of organs, as indicated in that Directive.** Nonetheless, when organs are removed from a **SoHO** donor for the purposes of separating tissues or cells for human application, for example heart valves from a heart or pancreatic islets from a pancreas, this Regulation should apply.

(7a) While the donation and banking of human breast milk should be regulated to prevent disease transmission and ensure safety and quality, the feeding of an infant with one's own breast milk should not fall within the scope of this Regulation. In situations where one's own breast milk is stored in a communal facility, such as a childcare facility or workplace, it would be disproportionate to apply the provisions of this Regulation to those entities.

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3 Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14).

(8) Ensuring the quality and safety of SoHOs is crucial **when** ~~, especially where~~ such substances interact with the body of the **SoHO** recipient **or of recipients receiving products manufactured from SoHO regulated by other Union legislation**. Hence, this Regulation should not cover the placing of a substance on the body when it does not have any biological ~~or physiological~~ interaction with that body, such as in the case of wigs made from human hair.

(9) All SoHOs that are intended to be applied to humans fall within the scope of this Regulation. SoHOs can be prepared and stored in a variety of ways, becoming SoHO preparations, which can be applied to recipients. In these circumstances, this Regulation should apply to all activities from **SoHO** donor ~~recruitment~~ **registration** to human application and **clinical** outcome monitoring **registration**. SoHOs ~~or SoHO preparations~~ can also be used to manufacture products regulated by other Union legislation, ~~or as the starting and raw material thereof, in particular~~ on medical devices, regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council[4], on medicinal products, regulated by Directive 2001/83/EC of the European Parliament and of the Council[5] and ~~by Regulation (EC) No 726/2004 of the European Parliament and of the Council[6], including~~ on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007 of the European Parliament and of the Council[7] ~~, or on food, regulated by Regulation (EC) No 1925/2006 of the European Parliament and of the Council[8]~~. ~~The criteria that define when SoHOs or SOHO preparations become products regulated under other Union legislation are not defined in this Regulation but are defined in those other acts.~~

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

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

~~6 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).~~

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

~~8 Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).~~

In addition, this Regulation should apply without prejudice to Union legislation on genetically modified organisms.

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

(9b) Organisations that register individuals with a view to becoming SoHO donors in the future, or when prospective donors are registered and tested for the purposes of matching them with prospective recipients in the same Member State, or internationally, should be considered SoHO entities. The registering of individuals that indicate their consent to donate tissues after death should not be considered as SoHO donor registration within this Regulation and should not, therefore, require the organisation carrying out that activity to register as a SoHO entity.

(9c) The gathering of SoHO donor history and conduct of medical examinations to establish the eligibility of a prospective SoHO donor is an activity that can have an impact on safety and quality of SoHO and, as such, should be considered a SoHO activity.

(9d) Testing for infectious disease status, or for the purposes of matching a SoHO donor with a specific donor recipient is an activity with a high degree of impact on the safety of SoHO and, as such, it should be considered a SOHO activity. Hence, laboratories that carry out such testing should be registered as SoHO entities. While such testing is generally for the purposes of protecting the SoHO recipient, infectious disease testing of individuals prior to the storage of SoHO collected from them, for the purposes of subsequent re-application to them, is important to prevent cross-contamination between such SoHO while in storage. Therefore, testing in both the autologous and allogeneic contexts should be considered as SoHO activities.

(9e) Collection of SoHO involves risks both to SoHO donors and to individuals from whom SoHO are being collected for subsequent re-application to them or individuals or couples from whom SoHO are collected as part of their own current or future medically assisted reproduction treatment. As such, it should be considered as a SoHO activity. For the purposes of this Regulation and in the interest of ensuring comprehensive SoHO donor protection, the activity should be understood to include the pre-treatment of individuals with hormones, growth factors or other medicinal products, that is required to make the collection possible.

(9f) SoHO are frequently processed prior to distribution. Processing can have objectives such as preservation by, for example, cooling, freezing or freeze-drying; pathogen inactivation, by, for example, washing, antibiotic decontamination or sterilisation; or, physical separation or purification into selected elements by, for example, centrifugation of blood to prepare red cell concentrates, platelet concentrates and plasma as separate components. If not performed correctly and in a consistent manner, processing steps carry risks of contamination or of changing the inherent properties of SoHO in a manner that might reduce their effectiveness. Therefore, they should be considered SoHO activities and any entity performing SoHO processing should be subject to appropriate oversight. The necessary procedures to be carried out, in accordance with the instructions provided with the preparation, immediately prior to human application, of released and distributed SoHO should not be considered processing for the purposes of this Regulation.

(9g) Quality control is a key element of a quality management system that is critical for the safe release of SoHO for human application or for distribution or export. As the tests and checks performed as part of quality control are sometimes carried out in dedicated quality control laboratories or departments, the activity should be considered as a SoHO activity and to allow appropriate oversight, such laboratories or departments should be registered as SoHO entities.

(9h) SoHO are stored in SoHO establishments prior to their release. For the purposes of this Regulation, storage refers to maintaining particular environmental conditions, such as temperature, that were established during the preservation step of processing and that ensure that the quality of SoHO will be maintained. The storage of released and distributed SoHO in a hospital, for example, should be considered a SoHO activity.

(9i) As the activity of release is a critical step that allows SoHO to be moved from a 'quarantined' to an 'available for use' status, it should be considered a SoHO activity. Any SoHO entity carrying out release should be overseen by a SoHO competent authority as a SoHO establishment. SoHO that are distributed or exported should first have been subjected to a formal release step. In cases where the receiving entity carries out a further processing step on released and distributed SoHO, those SoHO should be subjected to a second release step prior to re-distribution. In the case of autologous, bedside or in-surgery, processing of SoHO without storage, it would be impractical to require a formal release step prior to the re-application of the SoHO preparation to the patient. In such cases, quality control steps and checks should instead be incorporated in the processing steps that have been authorised. This should allow consistent quality criteria to be achieved without the need for a release activity in these circumstances.

(9j) SoHO distributed for human application might be intended for an individual SoHO recipient and be distributed on the basis of a medical prescription. Alternatively, SoHO may be distributed in batches to be stored as a local stock to be used, as required, in a facility carrying out application. In such cases, the distributed SoHO should not be released a second time but their provision to individual SoHO recipients, in some cases involving a biological matching step, should be considered as another distribution step.

(9k) The import of SoHO should include a formal verification that the safety and quality of the imported SoHO are equivalent to the safety and quality of SoHO provided in the Union in accordance with this Regulation. As such, import should be considered a SoHO activity with a significant impact on safety and quality and entities performing import should be authorised as SoHO establishments. Following import, SoHO should be subject to release, prior to distribution within the Union. In certain cases, and in particular in the case of haematopoietic stem cells, national and international donor registries play a key role in the organisation of the import of matching stem cells for individual SoHO recipients in the Union. Such registries verify equivalence of safety and quality to the standards of this Regulation. As such, registries organising import of SoHO should be authorised as importing SoHO establishments. In those cases, it should be possible for the SoHO to be received by the transplanting centres and the steps of physical checking of the imported SoHO and their documentation to be delegated by the authorised registry to the SoHO entity receiving and applying the SoHO to the SoHO recipient.

9(l) All SoHO being exported from the Union will first require a release to confirm compliance with the safety and quality provisions of this Regulation. Such SoHO activity may have an impact on SoHO supply within the Union. Therefore, organisations exporting SoHO should be authorised as SoHO establishments and be subject to certain supervisory activities.

(9m) In the context of this Regulation, the term effectiveness should be interpreted as a systematic evaluation, in compliance with a previously approved clinical monitoring plan, involving one or more SoHO recipients, to assess the result expected, in response to the application of SoHO in a SoHO recipient, whatever the form of measurement of the result established in the pre-established.

(9n) Human application of SoHO is an activity that is within the scope of this Regulation with limited associated provisions. Organisations applying SoHO to SoHO recipients are subject to provisions concerning traceability, recording, reporting annual activity data and notifying adverse reactions or events, where relevant, and monitoring clinical outcomes when applying SoHO in the context of a plan for SoHO preparation authorisation. There are also obligations relating to not applying SoHO unnecessarily or in cases where effectiveness has not been demonstrated and to obtaining recipient consent. However, the clinical decisions relating to SoHO application and the clinical procedures for applying SoHO fall outside the scope of this Regulation and are governed rather by Member State healthcare systems.

(9o) Most aspects of the monitoring of SoHO recipients, following surgical and other interventions, are outside the scope of this Regulation and fall under healthcare responsibilities. However, certain obligations of this Regulation should apply to SoHO recipient outcome monitoring in the context of the application of SoHO to SoHO recipients as part of a plan to generate evidence for SoHO preparation authorisation. Clinical registries to record the clinical data generated during the clinical outcome monitoring are useful tools that allow for more efficient data collection from aggregated groups of SoHO recipients, applying standardised outcome measurements and reflecting outcomes in the 'real world' setting. Managing such registries should be considered a SoHO activity to ensure that data quality and data management procedures are robust and will allow the data to be used for the purposes of SoHO preparation authorisation. The transfer of such outcome data from local or national registries to international registries should be promoted as it facilitates the aggregation and analysis of significantly larger data cohorts of SoHO recipients and can contribute to earlier authorisations and access to SoHO therapies.

(-10) Individuals from whom SoHO are collected for subsequent application as part of their own treatment, or individuals or couples from whom SoHO are collected as part of their own current or future medically assisted reproduction treatment, should not be considered as SoHO donors in the context of this Regulation. The protection of the health of such individuals being treated in the autologous or in-couple settings is the responsibility of the national healthcare system and applying provisions targeted to the protection of SoHO donors, for example monitoring such individuals on SoHO donor registries, would be disproportionate. However, when the SoHO collected from such individuals are processed or stored, their quality and safety should be ensured. In particular, contamination from the environment or cross-contamination with infectious pathogens from other SoHO should be prevented and there should be full traceability to avoid mix-ups. Therefore, individuals from whom SoHO are collected in the autologous context or in their medically assisted reproduction context are not addressed in the SoHO donor protection provisions of this Regulation, but are deemed duly protected under the SoHO recipient provisions.

(10) When SoHO~~s~~ are used in the autologous setting without any manipulation, processing or storage, the application of this Regulation would not be proportionate to the limited quality and safety risks arising in such a setting. **The handling of autologous SoHO during and for the purpose of application as part of the same surgical intervention in which they were collected, and without removal from the surgical field, should not be considered as processing and should, therefore, be excluded from the scope of this Regulation. In certain cases, such as hemodialysis at the bedside, or at home, or red cell salvage during surgery, closed system medical devices are used in autologous context. Where such closed system medical device has been CE marked for the specific purpose, and have therefore been demonstrated to achieve the intended result, and where the process carried out within the device does not meet the criteria for classification under another regulatory framework, this should be seen as analogous to non-removal from the surgical field and should not be considered as falling within the scope of this Regulation.**

(10a) When autologous SoHO~~s~~ are collected and processed before being ~~re-used~~**applied again** in the same person **and without storage**, risks **associated with the processing** ~~appear that~~ should be mitigated. ~~Thus~~**Therefore**, there **should** ~~needs to~~ be an assessment and authorisation of the processes applied to ensure that they are demonstrated to be safe and effective for the ~~recipient. When autologous SoHOs~~**SoHO recipient. In such cases, the SoHO preparation authorisation should specify the required quality control checks to be performed during the process, and therefore, and no release step should be required before application to the SoHO recipient. Such situation would also apply to the specific case of intra-uterine insemination within couple use, when SoHOs are collected and processed from one of the partners before being applied to the other partner, without storage. When autologous SoHO~~s~~, or SOHO for use within couples,** are collected to be processed and also stored, risks of cross-contamination, loss of traceability or damage to the biological properties inherent to the substance, and necessary for ~~efficacy~~**effectiveness** in the **SoHO** recipient, also appear. Thus, the requirements for **SoHO release and for SoHO** establishment authorisation should apply.

(11) When SoHO~~s~~ are used to manufacture products regulated by other Union legislation, ~~or as the starting and raw material thereof,~~ **the provisions laid down in this Regulation that aim to protect SoHO recipients should contribute, also, to the objectives of the legislative measures in those other frameworks** ~~in order~~ to ensure a high level of protection ~~and~~**of recipients, including recipients of those products manufactured using SoHOs~~and~~** ~~contribute to legal clarity and certainty, this Regulation should apply to the extent that the activities to which they are subjected are not regulated by the other Union legislative framework~~. **Thus,** ~~W~~without prejudice to ~~other Union legislation, and in particular to~~ Directive 2001/83/EC **and**~~,~~ Regulations ~~(EC) No 726/2004, (EC) No 1925/2006,~~ (EC) No 1394/2007 and (EU) 2017/745, this Regulation should ~~at least~~ apply to the ~~recruitment and selection~~**registration and evaluation** of **SoHO** donors, **SoHO donor testing,** ~~donation,~~ collection ~~and donor testing~~ as well as to **storage,** release, ~~distribution,~~ import and export **until the SoHO are distributed to a manufacturer** ~~when those activities concern SoHOs up to the point of their transfer to operators~~ regulated by other Union legislation. This means that close interaction between this regulatory framework and other related frameworks is essential to ensure ~~interplay and~~ coherence between relevant legal frameworks, without gaps or overlaps.

(11b) In many Member States, military organisations are active in carrying out the above mentioned SoHO activities, in particular in the collection, processing, storage, testing and distribution of blood and blood components. These organisations and their SoHO activities should be regulated by this framework to ensure equivalent levels of donor and recipient protection as that provided by civil services. However, make public the locations and activities of these organisations may compromise the defence, national security or public security. Therefore, the reporting and oversight provisions of this Regulation should apply to these organisations, but the publication of associated information should not be obligatory.

(12) SoHO~~s~~ can ~~also~~ be combined with other regulated products before human application. In these circumstances, close interaction between this regulatory framework and other related frameworks is also necessary to ensure a high level of human health protection for all cases where these substances are used.

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

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

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

(16) This Regulation should not interfere with national legislation in the health area with objectives other than quality and safety of SoHO~~s~~**,** that is compatible with Union law, in particular legislation concerning **health care organisation or** ethical aspects. Such aspects arise due to the human origin of the substances, which touches upon various sensitive and ethical concerns for Member States and citizens, such as access to **SoHO or** particular services that use SoHO~~s~~. This Regulation should also not interfere with decisions of an ethical nature made by Member States. Such ethical decisions might concern the use, or limitation of the use, of specific types of SoHO~~s or specific uses of SoHOs~~, including reproductive ~~cells~~ **SoHO** and embryonic stem cells. When a Member State allows the use of such cells, this Regulation should apply in full with a view to ensuring safety and quality and to protecting human health. **However, this Regulation does not require a specific use, or the import, of SoHO where prohibited under national legislation concerning ethical aspects.**

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

(18) ~~As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. Voluntary and unpaid SoHO donation is also a factor which can contribute to high safety standards for SoHOs and therefore to the protection of human health. It is also recognised, including by the Council of Europe Committee on Bioethics[9], that while financial gain should be avoided, it may also be necessary to ensure that donors are not financially disadvantaged by their donation. Thus, compensation to remove any such risk is acceptable but should never constitute an incentive that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives.~~

Article 3 of the Charter of Fundamental Rights of the European Union prohibits the making of the human body and its parts, as such, a source of financial gain. The use of financial incentives for SoHO donations can have an impact on the quality and safety of SoHO, posing risks to the health of both SoHO donors and recipients and therefore to the protection of human health. Without affecting national responsibilities on the definition of health policies, the organisation and delivery of health services and medical care, as well as provisions on donation of SoHO, such donation should, as a matter of principle, be voluntary and unpaid, and be founded on altruism of the donor and solidarity between donor and recipient. It is however recognised, including by the Council of Europe Committee on Bioethics , that while it is important to avoid financial gain, it may also be appropriate to take measures to ensure that donors are not financially disadvantaged.

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9 Council of Europe Committee on Bioethics (DH-BIO). Guide for the implementation of the principle of prohibition of financial gain with respect to the human body and its parts from living or deceased donors (March 2018). Available at https://rm.coe.int/guide-financial-gain/16807bfc9a.

Therefore, the reimbursement of SoHO donors for actual expenses incurred in connection with SoHO donation or the compensation of SoHO donors for losses related to donation are acceptable practices, as long as these measures ensure financial neutrality. For feasibility purposes, it is reasonable that compensation be provided in the form of a fixed allowance, based on average estimates of losses and expenses. The conditions of reimbursement and allowances, including the setting of an upper limit, should be defined at a Member State level. Member States may delegate the setting of such conditions to independent bodies.

(18a) SoHO entities should not offer inducements to potential SoHO donors or to those giving consent on their behalf as such an action would be contrary to the principle of voluntary and unpaid donation. Refreshments and small gifts, such as pens or badges, should not be considered as inducements and the practice of offering them to SoHO donors is acceptable as a recognition of their efforts. Rewards or benefits such as payment of funeral expenses, granting of time off work that is more than is needed for donation or payment of health insurance unrelated to the SoHO collection should be considered as inducements that would be contrary to the principle of voluntary unpaid donation and should not be permitted. Additionally, any advertising of SoHO donations linked to a financial reward should be prohibited, and recruitment campaigns and promotion and publicity activities should not refer to any compensation.

(19) In order to maintain public trust in SoHO donation and use programmes, information that is given to prospective **SoHO** donors, **SoHO** recipients or physicians regarding the likely use and benefits of particular SoHOs ~~or SoHO preparations~~ when applied to **SoHO** recipients should accurately reflect reliable scientific evidence. This should ensure that **SoHO** donors, or their families, are not coerced to donate by exaggerated descriptions of benefits and prospective ~~patients~~ **SoHO recipients** are not given false hopes when making decisions on their options for treatment.

(19a) The verification of compliance with this Regulation through **SoHO** supervisory activities is of fundamental importance to ensure that, across the Union, the objectives of the Regulation are effectively achieved. The responsibility to enforce this Regulation lies with the Member States, whose **SoHO** competent authorities should monitor and verify, through the organisation of **SoHO** supervisory activities, that relevant Union requirements are effectively complied with and enforced.

(20) **SoHO ~~C~~competent** authorities should be designated by the Member States for all the areas that fall within the scope of this Regulation. While Member States are best placed to identify the **SoHO** competent authority or authorities for each area, for example by geography, topic or substance, they should also be required to designate a single **SoHO N~~n~~**national **A~~a~~**uthority that ensures appropriately coordinated communication with other Member States' ~~competent~~ **SoHO National ~~a~~A**uthorities and with the Commission~~.~~**, as well as other tasks assigned in this Regulation.** The SoHO National Authority should be considered the same as the designated **SoHO** competent authority in Member States where only one **SoHO** competent authority is designated**. The designation of a single SoHO National Authority should not preclude Member States from assigning certain tasks to other SoHO competetent authorities of that Member State, in particular for the management of rapid alerts to ensure an efficient and agile communication when serious adverse events or reactions involve more than one Member State.**

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

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

(22a) In carrying out their SoHO supervisory activities, SoHO competent authorities should ensure transparency. Nonetheless, professional and commercial interests should be protected by ensuring confidentiality of the information discussed in the course of inspections and other supervisory activities. However, when a serious risk to human health is detected that results in the SoHO competent authorities taking enforcement action, they should give priority to transparency over confidentiality. Circumstances such as the detection of an entity offering services to the public without the required registration, and without complying with standards for SoHO recipient protection such as infectious disease testing, should be considered as posing a serious risk to human health and should be published.

(23) The correct application and enforcement of the rules falling within the scope of this Regulation require an appropriate knowledge of those rules. It is therefore important that the staff performing **SoHO** supervisory activities have an appropriate professional background and are regularly trained, in accordance with their area of competence, on the obligations resulting from this Regulation.

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

(25) **SoHO C**~~c~~competent authorities should perform **SoHO** supervisory activities regularly, on the basis of a risk assessment and with appropriate frequency, on **SoHO** entities and activities governed by this Regulation. The frequency of **SoHO** supervisory activities and the mode **inspections are carried out**, ~~whether on-site or by remote document review,~~ should be established by the **SoHO** competent authorities, having regard to the need to adjust the **degree of** control ~~effort~~ to the risk and to the level of compliance expected in the different situations, including the possible violations of this Regulation perpetrated through fraudulent or other illegal practices and previous compliance history. Accordingly, the likelihood of non-compliance with all the areas of this Regulation should be taken into account when scheduling **SoHO** supervisory activities.

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

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

(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~~ **plans** proportionate in extent and complexity to the identified level of risk of the SoHO preparation. In the case of low risk, in addition to the mandatory continuous vigilance reporting, the applicant should organise proactive clinical follow-up for a defined number of ~~patients~~**SoHO recipients.** For moderate and high risk, in addition to the mandatory vigilance reporting and the clinical follow-up, the applicant should propose clinical investigation studies with monitoring of pre-defined clinical end-points. In case of high risk, these should include a comparison with **a** standard ~~treatments~~**therapy**, ideally in a study with ~~subjects~~**SoHO recipients** 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.

(29) In the interests of efficiency, it should be permitted to conduct clinical outcome **monitoring** ~~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[10], when ~~operators~~ **SoHO entities** wish to do so. Whilst applicants can choose to record the clinical data generated during the clinical outcome monitoring themselves, they should also be permitted to use existing clinical ~~data~~ registries as a means of such recording when those registries have been verified by the **SoHO** competent authority, or are certified by an external institution, in terms of the reliability of their data **quality** management procedures.

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10 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).

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

(31) A broad range of public and private organisations influence the safety, quality and ~~efficacy~~**effectiveness** of SoHOs, even if they do not **store** ~~maintain banks of~~ those SoHOs. Many organisations carry out a single SoHO activity, such as collection or **SoHO** donor testing on behalf of one or many organisations that **store** ~~maintain banks of~~ SoHO~~s~~. The SoHO entity concept includes this broad range of organisations, from **SoHO** donor registries to **hospitals and clinics where SoHO are** ~~physicians that apply~~**ied** ~~SoHOs~~ to **SoHO** recipients or ~~use~~ SoHO processing devices **are used** at the recipient's bedside. The registration of all such SoHO entities should ensure that **SoHO** competent authorities have a clear overview of the field and its scale and can take enforcement action when deemed necessary. A SoHO entity registration should refer to the legal entity, regardless of the number of physical sites associated with the entity. **Activities performed in a personal context, such as breast feeding the infant of a friend or relative, and respecting the principles of voluntary and unpaid donation, should not be considered as SoHO activities. However, if such activities were to be carried out repeatedly as a service for multiple individuals, or for many families, they should be considered as SoHO activities and should fall under the scope of this Regulation.**

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

(32a) SoHO entities should keep a record of their activities, including the types and quantities of SoHO, as part of its working procedures and quality management systems, and report data relating to their SoHO activities; at least the data sets included in EU SoHO Platform. In cases where national or international registries collect activity data meeting the criteria defined in the SoHO Platform and such registries have been verified by SoHO competent authorities as having in place data quality management procedures that ensure accuracy and completeness of data, Member State should decide if SoHO entities may delegate the submission of the activity data to such registries.

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

(33a) When a couple uses their own sperm and oocytes for treatment by medically assisted reproduction, testing for genetic conditions should be regulated by national legislation as these are associated with particular ethical concerns that fall outside the scope of this Regulation.

(34) Where evidence demonstrates that specific processing steps reduce or eliminate the risk of transmission of specific infectious or non-infectious disease agents, the quality and safety standards for the verification of **SoHO** donor eligibility by means of **SoHO** donor health evaluations, including testing, and the related guidelines for their implementation, should take this evidence into account. ~~Thus, in the case of, for example, plasma for fractionation, that in a subsequent step in the manufacturing process of medicinal products undergoes sterilisation steps, certain donor eligibility criteria used for donation of plasma for transfusion might not be necessary nor appropriate.~~

(35) The EDQM is a structural part of the Council of Europe working under the European Pharmacopoeia Partial Agreement. The text of the Convention on the elaboration of a European Pharmacopoeia (ETS No. 050), accepted by Council Decision 94/358/EC[11], is considered to be the text of the European Pharmacopoeia Partial Agreement. Member States of the Council of Europe that have signed and ratified the European Pharmacopoeia Convention are the member States of the European Pharmacopoeia Partial Agreement and are therefore the members of the intergovernmental bodies functioning within the framework of this partial agreement, including among others: the European Pharmacopoeia Commission, the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH). The European Pharmacopoeia Convention has been signed and ratified by the European Union and all its Member States, all of whom are represented in their intergovernmental bodies. In this context, the work of the EDQM on developing and updating guidelines on safety and quality of blood, tissues and cells, should be considered an important contribution to the field of SoHO~~s~~ in the Union and should be reflected in this Regulation. The guidelines address issues of quality and safety beyond the risks of communicable disease transmission, such as **SoHO** donor eligibility criteria for the prevention of the transmission of cancer and other non-communicable diseases and the assurance of safety and quality during collection, processing, storage and distribution **or export**. ~~-~~It should therefore be possible to use those **technical** guidelines as one of the means to implement the ~~technical~~ standards provided for in this Regulation.

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

(36) The ECDC, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council[12], is a Union agency with the mission of strengthening Europe's defences against communicable diseases. The work of the ECDC on developing and updating guidelines on safety and quality of SoHO~~s~~ from a communicable disease threat perspective, should be considered an important contribution in the field of SoHOs in the Union and should be reflected in this Regulation. In addition, the ECDC established an expert network for the Microbial Safety of SoHO~~s~~, which ensures the implementation of the requirements on the ECDC's relations with the Union Member States and EEA Member States stated in Regulation (EC) No 851/2004, regarding strategic and operational collaboration on technical and scientific issues, surveillance, responses to health threats, scientific opinions, scientific and technical assistance, collection of data, identification of emerging health threats, and public information campaigns related to the safety of SoHO~~s~~. This SoHO expert network should provide information or advice in relation to relevant outbreaks of communicable diseases, in particular regarding the eligibility and testing of **SoHO** donors and the investigation of serious adverse **reactions and events** ~~occurrences~~ involving suspected transmission of a communicable disease.

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

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

(37a) In the development of national emergency plans, Member States should cooperate with involved stakeholders and should take into account the opinions of the Health Security Committee referred to in Article 4 of Regulation (EU) 2022/2371 and the Health Crisis Board referred to in Article 5 of Council Regulation (EU) 2022/2372. Member States will also count on the supportive role of the appropriate Commission services, such as the Health Emergency Response Authority, the risk assessments and recommendations of ECDC and the guidelines of EDQM in the establishment and operation of national SoHO emergency plans. National emergency plans might include, among preparedness and response measures, stock-piling of certain SoHO where possible and appropriate.

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

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

(40) ~~The concept of a plasma master file (PMF) was established in Commission Directive 2003/63/EC[13]. Since that Directive provided for a specific regulatory role for the European Medicines Agency (EMA) in relation to authorisation of plasma for fractionation, the SCB should also collaborate with the relevant EMA expert working groups to exchange experience and good practices so that criteria for the eligibility of donors of plasma for fractionation and of donors of blood for transfusion are implemented by Member States in a consistent and coherent way.~~

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

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[13] ~~Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 159, 27.6.2003, p. 46).~~

(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 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 ~~provided for~~**laid down** in this Regulation.

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

(45) SoHO~~s~~, by definition, relate to persons, and there are circumstances where the processing of personal data ~~relating to donors and recipients~~ may be necessary to achieve the objectives and requirements of this Regulation, especially provisions relating to vigilance and communication between **SoHO** competent authorities. This Regulation should provide a legal basis under Article 6 and, where relevant, fulfil the conditions under Article 9(2), point (i), of Regulation (EU) 2016/679 for processing of such personal data. With respect to personal data processed by the Commission, this Regulation should provide a legal basis under Article 5 and, where relevant, fulfil the conditions under Article 10(2), point (i), of Regulation (EU) 2018/1725. Data on safety and ~~efficacy~~**effectiveness** of new SoHO preparations ~~in recipients~~ should also be shared, with appropriate protective measures, to allow aggregation at Union level for more robust evidence gathering ~~on the clinical efficacy~~ of SoHO preparations. For all data processing, such processing should be necessary and appropriate with a view to ensuring compliance with this Regulation in order to protect human health. Data **collected** on **SoHO** donors, **SoHO** recipients and offspring **from medically assisted reproduction** should hence be limited to the minimum necessary and pseudonymised. **SoHO** donors, **SoHO** recipients and offspring **from medically assisted reproduction** should be informed of the processing of their personal data**, including health data,** in line with the requirements of Regulations (EU) 2016/679 and (EU) 2018/1725, and in particular as provided for under this Regulation, including the possibility of exceptional cases where circumstances require such processing.

(46) In order to enable better access to health data in the interests of public health, Member States should entrust **SoHO** competent authorities as data controllers within the meaning of Regulation (EU) 2016/679 with powers to take decisions on the access to ~~and re-use of~~ such data.

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

(48) In order to ~~be able to~~ supplement this Regulation where necessary with additional standards concerning the protection of **SoHO** donors, **SoHO** recipients and offspring from medically assisted reproduction**, and in order** to take into account **the** technical and scientific developments in the field of SoHO~~s~~, and ~~with~~ additional rules on the authorisation of importing SoHO entities, on obligations and procedures for importing SoHO ~~entities~~**establishments**, on the organisation of Union training and exchange programmes, on technical specifications concerning the EU SoHO Platform, and on data protection, the **Commission should** ~~power to~~ adopt **delegated** acts in accordance with Article 290 TFEU ~~should be delegated to the Commission~~. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[14]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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

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

(50) In order to ensure uniform conditions for the implementation of this Regulation, including the determination of the regulatory status of a substance, product or activity, rules and practical arrangements in respect of the consultation and cooperation with competent authorities of other regulatory sectors, the national registers of SoHO entities, the registration process of SoHO entities, the SoHO preparation authorisation system and the authorisation of SoHO preparations, the SoHO establishment authorisation system, the inspections of SoHO establishments, the consultation and coordination related to vigilance, the quality management system for SoHO ~~establishments~~**entities**, the implementation of the standards concerning the protection of **SoHO** donors, **SoHO** recipients and offspring from medically assisted reproduction, the national SoHO emergency plans, the tasks of the **SCB** ~~SoHO Coordination Board~~, and the transitional provisions concerning SoHO preparations, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[15].

[15] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(51) Transitional provisions should be laid down in order to ensure a smooth transition from the former regimes for tissues and cells and for blood and blood components to this new Regulation, in particular in order to adapt practices to the new requirements, the changes in SoHO entities, SoHO establishments and SoHO preparations, and to avoid that donated SoHO~~s~~ are discarded unnecessarily. A transitional regime for establishments already designated, authorised, accredited or licensed before the date of application of this Regulation should be introduced to ensure legal certainty and clarity. In particular, there should be clarity for the establishments concerned as regards their registration and authorisation status as well as their tasks and responsibilities under this Regulation, whilst allowing **SoHO** competent authorities additional time to transfer the relevant information to the systems introduced by this Regulation. To allow for a smooth transition, it is also appropriate that those preparation processes already authorised and lawfully used under the former regimes are still valid, and that SoHO~~s~~ already collected and stored before the date of application of this Regulation may be used for a certain period of time. The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 and delivered an opinion on … [date of the opinion][16],

[16] OJ C , , p. .

Section on DELEGATED ACTS AND IMPLEMENTING ACTS

- Chapter II – Art. 14.
- Chapter III, IV and V:
  - Section I – Art. 18, 19, 37b
  - Section II – Art. 25
  - Section III – Art. 26, 28, 42, 43
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  - Section V- Art. 33, 44
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CHAPTER II

Compromise Text (13231/23)

Article 14

~~Obligations to c~~Consultation and cooperatione with authorities of other regulatory sectors

-1a. Member States shall ensure that ~~communication channels are established within that Member State between~~ the SoHO National Authority has appropriate mechanisms to communicate~~, and~~ with the competent authorities for organs designated under Directive 2010/53/EU and ~~the~~ any competent authorities designated under other Union legislation referred to in Article 2(3) within that Member State.

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

2. In the course of the consultation referred to in paragraph 1, the **SoHO** competent authorities ~~**in the SoHO sector**~~ **involved in such consultation** may also**, via the SoHO National Authority,** submit a request to the SCB for ~~its~~ **an** opinion on the regulatory status of the substance, product or activity under this Regulation**. The SoHO competent authorities** ~~and~~ shall do so in all cases where ~~the competent authorities, after~~**following** the consultations referred to in paragraph 1, **have not lead to**~~**they**~~ ~~are not in a position to~~ ~~**where**~~ ~~take~~ a decision ~~in that respect~~ **on the regulatory status of such substance, product or activity** ~~**can be taken**~~ **in the Member State concerned**. **The SoHO competent authorities** ~~**in the SoHO sector**~~ **involved in the consultation shall take into account the opinion issued by the SCB following such a request.**

The **SoHO** competent authorities ~~**in the SoHO sector**~~ **involved in the consultations referred to in paragraph 1** may also**, via their SoHO National Authority,** indicate ~~that~~ **if** they consider **that** there is a need ~~that~~ **for** the SCB **to** consult~~s~~**, before issuing its opinion and** in accordance with Article 68(1), point (b), with the **relevant** equivalent advisory bodies established in other relevant Union legislation referred to in Article 2(3).

3. **When a consultation referred to in paragraph 1 leads to a ~~consensus~~ decision, ~~T~~t**he ~~competent~~ **SoHO National A~~a~~uthorit~~y~~ies~~** shall inform the SCB of the ~~subsequent~~ **regulatory status** decision taken in its Member State **and the reasons for it**~~, following the consultations referred to in paragraph 1 of this Article, regarding the regulatory status of the substance, product or activity concerned under this Regulation and on any consensus reached as a result of those consultations for~~ **with a view to the** publication thereof **by the SCB** in the **SoHO** compendium**, pursuant to Article 68(1) point (d)** ~~by the SCB~~.

4. The Commission ~~may~~**shall**, upon a duly substantiated request ~~of~~**from** a Member State following the consultation referred to in paragraph 1, or **may** ~~**may**~~ on its own initiative, by means of implementing acts, determine the regulatory status of a substance, product or activity under this Regulation, in case **this is needed to avoid risks to the safety of SoHO donors, recipients or offspring from medically assisted reproduction, or of a compromised access of recipients to safe and effective treatment.**

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

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

5. ~~For~~ **In the case of** SoHOs ~~that are intended to be subsequently used to manufacture products under other Union legislation, or as the starting and raw material thereof,~~ as referred to in Article 2(3)~~,~~ or ~~**for** SoHOs that are intended to be combined with medical devices, as referred to in~~ Article 2(4), the **SoHO** competent authority ~~**in the SoHO sector**~~ shall cooperate with the authorities responsible for the supervisory activities under **other**~~the~~ relevant Union legislation **as referred to in Article 2(3)**, with a view to ensuring coherent oversight. During th**at**~~e~~ process, the **SoHO** competent authorities may seek the assistance **and advice** of the SCB ~~**concerning, inter alia, good cooperation practices that ensure coherent oversight when SoHOs change regulatory status**~~.

6. The consultation and cooperation referred to in paragraphs 1, 2 and 5 may also be initiated on the basis of a request **from a SoHO entity** for ~~advice~~ **an opinion**Error! Bookmark not defined. ~~from a SoHO entity, as referred to in Article 40~~.

6a. In case a SoHO competent authority ~~in the SoHO sector~~ takes any enforcement decision concerning a SoHO entity that also performs activities regulated under other Union legislation as referred to in Article 2(3) and overseen by competent authorities as referred to in paragraph -1a, the SoHO competent authority ~~in the SoHO sector~~ shall, without undue delay, via the SoHO National Authority, inform the relevant competent authority designated under that other Union legislation, of its decision.

7. ~~The Commission may, by means of implementing acts, lay down rules concerning procedures for consultation referred to in paragraph 1 and cooperation referred to in paragraph 5 by the competent authorities when they consult the authorities established in other relevant Union legislation referred to in Article 2(3).~~

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).~~

SECTION I – REGISTRATION OF SoHO ENTITIES

Compromise Text (12955/23)

Article 18

Register of SoHO entities

1. SoHO National Authorities shall establish and maintain a register of SoHO entities on their territory. **In carrying out this task, SoHO National Authorities may make use of the EU SoHO Platform, in accordance with Article 74(1). In such case, SoHO National Authority shall instruct SoHO competent authorities, where necessary, and SoHO entities to register directly on the EU SoHO Platform.**

2. ~~Instead of establishing a register of SoHO entities, as referred to in paragraph 1,~~ **The** SoHO National Authorit**ies**~~y~~ may use the EU SoHO Platform as referred to in Chapter XI**in accordance with Article 74(1) for the requirement set out in the first paragraph**~~.~~ ~~In this case, the SoHO National Authority shall instruct~~ **SoHO** ~~competent authorities, where necessary, and SoHO entities to register directly on the EU SoHO Platform.~~

3. ~~Competent authorities shall verify that each registered SoHO entity has provided the following information:~~

   (a) ~~name or business name and address of the SoHO entity, and name and contact details of a contact person;~~

   (b) ~~a declaration that the SoHO entity complies with the obligations and requirements on SoHO entities set out in this Regulation, in particular Articles 44, 47, 56 and 59, as relevant;~~

   (c) ~~a statement from the SoHO entity that it accepts to be inspected as provided for in this Regulation;~~

   (d) ~~a list of the SoHO activities that the SoHO entity is carrying out;~~

   (e) ~~the name and curriculum vitae of the responsible person for release of SoHOs as referred to in Article 38, if the SoHO entity releases SoHOs or SoHO preparations.~~

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

5. The Commission may adopt implementing acts concerning the ~~compatibility and comparability~~ **procedures for the upload of data from** ~~of~~ the **national** registers of SoHO entities ~~for facilitating the submission~~ to the EU SoHO Platform.
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

Article 19

Registration of SoHO entities

1. ~~**In cases where SoHO National Authorities establish their own registries of SoHO entities,**~~ **SoHO C**~~c~~ompetent authorities shall have procedures in place for the registration of SoHO entities in accordance with Article 37.

1a. SoHO competent authorities shall verify that each registered SoHO entity on a national registry or the EU SoHO platform has provided the information pursuant to Article 37(1). In cases where national registries are in place and ~~F~~following such verification and where an authorisation is not required under Articles 21, 27 or 28, the SoHO competent a~~A~~uthority shall submit the information on the registration to the EU SoHO Platform. In cases where an authorisation is required, the SoHO competent auhority shall inform the SoHO entity on the procedure to request an authorisation for SoHO establishement pursuant to Article 49.

~~**1b. By derogation from paragraph 1a, the registration of a SoHO entity carrying out SoHO activities for the purposes of public security, defense or military matters shall not be subject to publication requirements provided for in this Regulation.**~~

1c. **SoHO competent authorities shall identify whether the SoHO entity is a critical SoHO entity, according to the criteria agreed by the SCB, and taking into account the self-assesment done by the SoHO entity, as referred to in Article 37(1), ~~when relevant~~. SoHO competent authorities shall update the registration information accordingly.**

1d. **Where, ~~on the basis of the information submitted to the national registry or to the EU SoHO Platform, pursuant to Article 37,~~ the SoHO entity does not longer meet the definition of a SoHO entity, pursuant to Article 37, the SoHO competent authority shall remove the registration from the national registry or from the EU SoHO Platform and inform the entity without undue delay.**

2. **SoHO ~~C~~c**ompetent authorities shall:

(a) acknowledge receipt of the registration **without undue delay**~~within 14 working days of its submission~~;

(b) request the SoHO entity to provide supplementary information, **in accordance with article 37(1),** if needed;

(c) **provide instructions on the procedures to follow to apply for an authorisation, when relevant**~~inform the SoHO entity in cases where the registration indicates that an authorisation pursuant to Articles 21, 27 or 28 is required;~~

(d) **inform** ~~identify whether~~ the ~~entity is a critical~~**the** SoHO entity~~, and inform the entity~~ in cases where it is considered a critical SoHO entity **and the related obligations pursuant to Articles 63 and 66**;

(e) ~~submit any additional information on~~ **inform the SoHO entity that** ~~the~~ **its** registration **has been verified and published in the EU SoHO Platform**~~as necessary, including the requirement for an authorisation pursuant to point (c), and whether the SoHO entity is a critical SoHO entity to the EU SoHO Platform referred to in Chapter XI~~.

2a. **In case of changes in the registration submitted by the SoHO entity in accordance with Article 37(3), SoHO competent authorities shall verify those changes and publish the updated registration in the EU SoHO Platform without undue delay.**

~~3. The Commission may adopt implementing acts concerning the registration process to facilitate the compatibility of the registers of SoHO entities with the EU SoHO Platform.~~

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).~~

*Article **37b**~~50~~*[17]

Quality management system

1. SoHO e**ntities**~~stablishments~~ shall establish, maintain and update~~, as necessary,~~ a quality management system**, appropriate to ~~its~~ their activities,** achieving a high level of quality of SoHOs~~by following, in particular, the Good Practice Guidelines published by the EDQM and which are included in the technical guidelines referred to in Article 56(4), point (a), and Article 59(4), point (a)~~.

2. SoHO e**ntities**~~stablishments~~ shall design the quality management system to ensure that SoHO activities are carried out in a consistent manner, by personnel that **have documented and periodically assessed competence**~~are competent~~ to perform the tasks allocated to them and in facilities that are designed and maintained in a manner that prevents SoHO contamination, or cross-contamination **between SoHO**, ~~with infectious agents~~ or loss of traceability. **In so doing, SoHO entities shall take into account the technical guidelines for quality management published by the EDQM, together with the EDQM Good Practice Guidelines, as indicated in the EU SoHO Platform. Alternative approaches to the design of the quality management system may be applied where SoHO entities can demonstrate to their SoHO competent authorities, that they achieve an equivalent level of quality.**

[17] This Article is adapted based on Article 50, which should be moved here

3. SoHO e**ntities**~~stablishments~~ shall put in place procedures and specifications covering**, when applicable to their activities,** the following:

(a) documentation of roles**,** ~~and~~ responsibilities of personnel **and organization**;

(b) selection, training and competence assessment of personnel;

(c) **the procurement qualification, validation and monitoring of** premises**, materials** and equipment, ~~procurement, qualification and monitoring~~**including information technology systems**;

(ca) other documentation relevant for the quality management sytem put in place;

(d) quality control, ~~as applicable,~~ of SoHO activities;

(da) quarantine and release~~, if applicable;~~

(e) withdrawal of SoHOs from the inventory of released SoHOs and recall**s**~~of unused SoHOs following distribution~~;

(f) internal audits;

(g) management of contracted third parties;

(h) management of ~~identified~~ cases where **procedures have not been followed** ~~personnel have not followed procedures~~ or specifications have not been **met** ~~complied with~~

(ha) complaints;

(hb) management of traceability and vigilance, pursuant to Articles 45, 46 and 47;

(hc) continuity planning.

4. SoHO e**ntities**~~stablishments~~ shall review the quality management system at regular intervals to verify its effectiveness and introduce corrective **and preventive** measures if deemed necessary.

5. The Commission may adopt implementing acts regarding ~~further details on~~ **selected elements of** the procedures and specifications of the quality management system in order to ensure uniform quality management.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

Section II – Authorisation of SoHO Establishments

Compromise Text (13231/23)

Article 25

SoHO establishment authorisation system

1. **SoHO c**~~C~~ompetent authorities shall establish and maintain a system for receiving and processing requests for the authorisation of SoHO establishments **in their territory**. **The system shall allow for the suspension and**~~**or**~~ **withdrawal of authorisations.**

2. **SoHO c**~~C~~ompetent authorities shall authorise as SoHO establishments the SoHO entities that ~~both~~ process and store**, release, import or export** ~~**or process and release or store and release**~~ SoHOs**,** in accordance with Article 27.

2a. SoHO competent authorities shall include all SoHO activities carried out by a SoHO establishment in the authorisation granted, including those SoHO activities carried out outside of the premises of the SoHO establishments.

~~3. Competent authorities may decide that certain SoHO entities that do not process and store SoHO also need to be authorised as SoHO establishments, in particular SoHO entities that:~~

~~(a) have significant influence on the safety and quality of SoHOs due to the scale, criticality or complexity of the SoHO activities they perform; or~~

~~(b) carry out SoHO activities in connection with multiple SoHO establishments.~~

3. Competent authorities may decide that certain SoHO entities, that do not meet the SoHO establishment definition also need to be authorised as such, in particular SoHO entities that:

(a) have significant influence on the safety and quality of SoHOs due to the scale, criticality or complexity of the SoHO activities they perform; or

(b) carry out SoHO activities in connection with multiple SoHO establishments.

~~4. Paragraph 3 shall not apply to SoHO entities that import SoHO.~~

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

~~6. The Commission may adopt implementing acts to specify uniform procedures and working methods for establishing and maintaining a SoHO establishment authorisation system.~~

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).~~

Section III - Registration of SoHO Importers

Compromise Text (13231/23)

~~Article 26~~

~~**Importing SoHO entity authorisation system**~~

~~1. Competent authorities shall establish and maintain a system for receiving and processing requests for the authorisation of importing SoHO entities.~~

~~2. Competent authorities shall authorise as importing SoHO entities the SoHO entities that import SoHOs pursuant to Article 28.~~

~~3. Importing SoHO entity authorisations shall be valid throughout the Union for the period defined in the terms of the authorisation, when such a time period has been defined, or until a competent authority has suspended or withdrawn the authorisation or the entity has ceased to conduct SoHO activities. Where a Member State has adopted a more stringent measure, in accordance with Article 4, which relates to a specific importing SoHO entity authorisation, that Member State may decline to recognise the validity of the importing SoHO entity authorisation of another Member State pending verification that the more stringent measure has been met.~~

~~4. The Commission shall adopt implementing acts to specify uniform procedures and working methods for establishing and maintaining an importing SoHO entity authorisation system.~~

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).~~

Article 28

Authorisation of importing SoHO ~~entities~~ establishments

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

1a. Articles 25(1), 25(5), 25(6) and 27 shall apply, mutatis mutandis, to the authorisation of importing SoHO establishments.

1b. In cases of import of human plasma for the manufacture of medicinal products, the authorisation may be based on information provided as part of a plasma master file ~~(PMF)~~ as referred to in Directive 2003/63/EC.

2. Upon receipt of an application for **an** ~~the authorisation of an~~ importing SoHO ~~entity~~ **establishment authorisation**, **SoHO** competent authorities shall **act in accordance with** ~~perform the actions set out in~~ **Article 27(2). ~~In particular,~~ SoHO competent authorities shall also assess the procedures in place at the applicant importing SoHO establishment to ensure that the imported SoHOs are equivalent, in terms of safety, quality and effectiveness, to SoHOs ~~and SoHO preparations~~ authorised according to the provisions of this Regulation~~, before release~~.**

~~(a) acknowledge receipt of the application within 14 working days;~~

~~(b) assess the application;~~

~~(c) examine agreements between the applicant SoHO entity and any third parties contracted by that SoHO entity to perform SoHO activities;~~

~~(d) request that the applicant provides supplementary information, if needed;~~

~~(e) inform the applicant, without undue delay, of the outcome of the assessment and examinations referred to in points (b), (c) and (d) where relevant, and of the decision on the authorisation;~~

~~(f) grant or refuse the authorisation of the applicant as an importing SoHO entity, as appropriate, and indicate which SoHOs are covered by the authorisation and which conditions apply, if any;~~

~~(g) assess and, as appropriate, approve subsequent changes made by the SoHO importing entity and communicated to them as referred to in Article 43(3);~~

~~(h) submit information regarding the authorisation, by amending accordingly the status of the SoHO entity concerned, and including the name and contact details of the importing SoHO entity authorisation holder, in the EU SoHO Platform as referred to in Chapter XI, without undue delay.~~

2a. With regards to Article 27(2)(e), and in cases where the imported SoHO are not physically received by the importing SoHO establishment but are directly sent to the SoHO entity for application to a SoHO recipient or to an operator for manufacturing a product under other Union legislation, as referred to in Article 2(3), SoHO competent authorities may choose to carry out only a document review-based inspection. ~~As regards the on-site inspection of the applicant importing SoHO establishment, pursuant to Article 27(2)(e), SoHO competent authorities may choose to perform only a document review based inspection in cases where the imported SoHO are not physically received by the importing SoHO establishment but are sent directly to the SoHO entity where they will be applied to a SoHO recipient or to an operator that will manufacture a product under other Union legislation as referred to in Article 2(3).~~

~~3. In cases where the applicant intends to distribute the imported SoHOs to other Member States, competent authorities may perform the actions set out in paragraph 2, points (b), (c) and (d), in consultation with the SoHO National Authorities of the Member States concerned.~~

4. **~~The~~ SoHO** **~~C~~c**ompetent authorities may require to inspect any party in a third country supplying SoHOs to the applicant prior to granting or refusing the importing SoHO ~~entity~~**establishment** authorisation, in particular in cases where the application concerns regular and repeated import of SoHOs from the same party.

~~5. Competent authorities may suspend the authorisation of an importing SoHO entity if SoHO supervisory activities demonstrate or give reasonable grounds to suspect:~~

~~(a) that the SoHO entity in question does not comply with the conditions of the authorisation or the provisions of this Regulation; and~~

~~(b) that this non-compliance, or suspected non-compliance, implies a risk to the safety of recipients or offspring from medically assisted reproduction.~~

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

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

~~8. In cases of authorisation suspension or withdrawal, as referred to in paragraphs 5, 6 and 7, competent authorities shall amend accordingly the authorisation status of the SoHO entity concerned in the EU SoHO Platform as referred to in Chapter XI without undue delay.~~

9. By derogation from paragraph 1, **SoHO** ~~in case of emergency~~ competent authorities may authorise imports of **a** SoHO~~s~~ for immediate **human** application to a specific **SoHO** recipient, when **requested by the SoHO entity responsible for that application and when** justified by the clinical circumstances on a case-by-case basis.

SoHO competent authorities may also authorise imports of SoHOs in emergency situations for immediate human application to SoHO recipients whose health would be seriously endangered without such an import.

10. 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 specific criteria for the assessments~~, examinations and inspections~~ in the course of the authorisation **of importing SoHO establishments**.

11. Where, in the case of risk to quality and safety of imported SoHOs, imperative grounds of urgency so require, the procedure provided for in Article 78 shall apply to delegated acts adopted pursuant to this Article.

Article 42[18]

Importing SoHO ~~entity~~ establishment authorisation

1. SoHO ~~entities~~ **establishments** shall not import SoHOs without a prior importing SoHO ~~entity~~ **establishment** authorisation.

2. ~~In the case of importing SoHO entities that only import human plasma that is intended to be used for the manufacture of medicinal products regulated by other Union legislation and is included in a plasma master file (PMF) as referred to in Directive 2003/63/EC, paragraph 1 of this Article shall not apply.~~

[18] Articles 42 and 43 will be moved to the articles related to establishments in Chapter V as they are not entities anymore but establishments

SoHO entities responsible for immediate human application to a specific SoHO recipient may request to their SoHO competent authorities a derogation from the requirement for an importing SoHO establishment authorisation in the ~~exceptional~~ circumstances referred to in Article 28(9).

3. ~~The Commission shall adopt delegated acts in accordance with Article 77 supplementing this Regulation by laying down obligations and procedures for importing SoHO entities~~ **~~establishments~~** ~~regarding the import of SoHOs in order to verify equivalent standards of quality,~~ **~~and~~**~~and safety~~ **~~and effectiveness~~** ~~of such imports.~~*****

**** PRE considers that it is redundant with Art. 28.10 delegated act on the authorisation of importers***

Article 43[1]

Application for importing SoHO ~~entity~~ establishment authorisations

1. **Article 49 shall apply *mutatis mutandis* to the applications for importing SoHO establishments authorisation** ~~SoHO entities shall send applications for authorisation as importing SoHO entities to their competent authorities~~.

1a. Prior to applying for importing SoHO establishment authorisation, SoHO establishments shall put in place written agreements with one or more third country suppliers. Such agreements shall include the elements described in paragraph 2 of this Article.

2. The applicant SOHO **establishment** ~~entity~~ shall **also** provide**:**

~~the name and contact details of the prospective importing SoHO entity authorisation holder. This paragraph shall be without prejudice to Article 38(1).~~

(a) ~~details of third parties contracted included in the~~ a written agreements between the applicant SoHO establishment and any third country~~parties~~ supplier contracted to ~~perform~~ supply SoHO ~~activities~~. ~~This~~ Such written agreement shall include, at least:

(i) details of the third country supplier contracted;

(ii)~~(i)~~ the quality and safety requirements to be met to ensure the equivalency of the quality and safety standards of the SoHO to be imported~~.~~;

(iii)~~(ii)~~ the right of the SoHO competent authorities to inspect the activities, including the facilities, of any third country supplier ~~entities~~or organisation sub-contracted by that supplier~~third parties from a third country~~, contracted by the importing SoHO establishment.

(b) documentation proving that the procedures ~~they~~ the third country suppliers have in place will ensure that the imported SoHOs will be equivalent, in terms of safety, quality and effectiveness, to SoHOs authorised according to the provisions of this Regulation.

3. ~~The importing SoHO entity shall not make any substantial changes to the importing SoHO activities subject to the authorisation without the prior written approval of its competent authority. The same shall apply in case of changes in the importing SoHO entity authorisation holder's details.~~

4. The importing SoHO **establishment** ~~entity authorisation holder~~ shall ~~be based in the Union, and~~ be responsible for the physical reception and visual examination and verification of imported SoHOs prior to their release. The importing SoHO **establishment** ~~entity~~ shall verify coherence between the SoHO received and the associated documentation and conduct an examination of the integrity of packaging, ~~and the compliance of~~ labelling and transport conditions ~~with~~ **taking into account** the relevant standards and technical guidelines as referred to in Articles 57, 58 and 59.

5. An authorised importing **SoHO establishment** ~~entity~~ may delegate the physical reception, visual examination and verification referred to in paragraph 4 to the **SoHO** entity that will apply the SoHO to the **SoHO** recipient in cases where imports are organised for individual named **SoHO** recipients.

5a. The releasing officer of an importing SoHO establishment shall release imported SoHOs for distribution in the Union or for human application only when they have verified compliance with the quality and safety requirements specified in the agreement referred to in paragraph 2 of this Article and when the physical and documentation controls referred to in paragraph 4 are satisfactory. In the case of national or international donor registries that are authorised as importing SoHO establishments, the physical and documentation controls referred to in this paragraph may be delegated to the SoHO entity that receives the imported SoHO for human application and the release step may be completed remotely.

~~6. The Commission shall adopt implementing acts specifying the information to be provided in an application for an authorisation for importing SoHOs or SoHO preparations to ensure compatibility and comparability of such data.~~

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).~~ ***

**** PRE considers that it is redundant with Art. 28.10 delegated act on the authorisation of importers***

Section IV – Inspections

Compromise Text (13231/23)

Article 29

Inspections of SoHO establishments

1. **SoHO c**~~C~~ompetent authorities **of the Member States where SoHO establishments are located** shall carry out ~~the following~~ inspections ~~**for the verifications of the compliance with this Regulation by those**~~ ~~on~~ **of those** SoHO establishments, **and where applicable, by of SoHO entities or third parties** ~~**performing SoHO activities for such contracted by SoHO establishments.**~~, ~~as appropriate:~~

~~**Inspections shall be carried out on-site,at the premises of the SoHO establishments, or remotely, by fully virtual or hybrid means, when justified pursuant to paragraph 5 of this Article.**~~

1.a **SoHO competent authorities shall carry out the following inspections on SoHO establishments, as appropriate:**

(a) announced routine system inspections;

(b) announced or unannounced inspections, **in particular** ~~in particular in the case of~~ **for the** investigation~~s~~ of fraudulent or other illegal activities, or on the basis of **information that might indicate** ~~information that might indicate~~non-compliance with ~~the rules of~~ this Regulation;

(c) **announced or unannounced** inspections **targeted at a specific activity or topic** as provided for in Article**s** 22(6), ~~Article 27(2), point (e~~**d**~~),~~ ~~Article~~ 28(4), ~~**30(1),**~~ ~~Article~~ 31 and ~~Article~~ 35(5).

2. **SoHO c**~~C~~ompetent authorities that during inspections identify non-compliances with the rules of this Regulation may include follow-up inspections, where necessary and proportionate, to verify **that SoHO establishments have undertaken appropriate** ~~that SoHO establishments have undertaken effective~~ **compliance with the** corrective and preventive **actions.** ~~actions~~**measures laid down in the report**.

~~3. Competent authorities of the Member State in which the SoHO establishment is located shall carry out the inspections~~.

~~4. Competent authorities shall carry out on-site inspections of SoHO establishments and, where applicable, of any third parties contracted by the SoHO establishment to perform SoHO activities.~~

5. ~~By derogation from paragraph 4,~~**SoHO** competent authorities **shall carry out on-site inspections referred to in this Article. Exceptionally, SoHO competent authorities** may conduct inspections, in full or in part, by **virtual ~~or hybrid~~** means**, or by remote document review** ~~of a remote document review~~, provided that:

(a) such inspection mode does not **pose** ~~pose~~**overlook** a risk to the safety and quality of SoHO~~s~~;

(b) ~~such~~ **~~the type of~~** ~~inspection~~ **~~carried out~~ such inspection mode** does not prejudice the effectiveness of inspections; ~~and~~

ba) ~~confidentiality, professional secrecy and~~ protection of SoHO donors, SoHO recipients or offspring of medically assisted reproduction ~~are~~ is respected~~;~~; and

(c) the maximum interval between two on-site inspections pursuant to paragraph ~~11~~ **10** is not exceeded.

6. **SoHO c**~~C~~ompetent authorities shall ensure that inspections are carried out by inspectors meeting the requirements set out in Article 32.

7. **The i**~~I~~nspectors shall verify that SoHO establishments **comply with the requirements applicable under this Regulation, in particular with the standards concerning SoHO donor protection, laid down in Article 53, the voluntary and unpaid nature of SoHO donations, laid down in Article 54, the information to be provided prior to consent or authorisation, laid down in Article 55, and SoHO recipient and offspring protection, laid down in Article 58, as applicable.** ~~meet the general standards concerning SoHO donor protection laid down in Article 53, the standards concerning the voluntary and unpaid nature of SoHO donations laid down in Article 54, the standards concerning information to be provided prior to consent or authorisation laid down in Article 55 and the general standards concerning recipient and offspring protection laid down in Article 58, as applicable.~~

7a. The inspections shall include the verification that SoHO establishments comply with the standards or elements thereof set by the Regulation. In cases where the SoHO establishments follow:

(a) The technical guidelines published by the ECDC and by the EDQM referred to in Articles 56(4), point (a), and 59(4), point (a), as applicable, the inspectors shall consider the standards or elements thereof, to be met, insofar as they are addressed by the guidelines;

(b) other guidelines as referred to in Articles 56(4), point (b), and 59(4), point (b), **adopted by the Member State, according to paragraph 8,** the inspectors **shall consider the standards or elements thereof, to be met, insofar as they are addressed by the guidelines**~~shall assess on a case-by-case basis such guidelines in terms of level of safety, quality and efficacy achieved, as applicable, and accept or decline whether that level is equivalent to the level set by the technical guidelines referred to in Articles 56(4), point (a), and 59(4), point (a)~~;

(c) other technical methods **applied in specific circumstances,** as referred to in Articles 56(4), point (c), and 59(4), point (c), the inspectors shall evaluate **and verify that these methods guarantee** ~~the risk assessment and record provided, assess~~ the adequacy **with the guidelines and the achievement of equivalent levels of quality and safety.** ~~of the technical methods applied.~~ **For this assessment, the SoHO establishments shall provide the inspectors with all the necessary information, pursuant to Articles 56(7) and 59(7).**

8. In cases **referred to in** ~~of~~ paragraph 7**a**, second subparagraph, point (b)**, the** ~~where SoHO~~ **Member State** ~~competent authorities~~, prior to the inspection, **shall** have ~~accepted~~ **adopted** the level **of** safety **and**~~,~~ quality ~~and efficacy~~ achieved by those other guidelines, as equivalent to the level set by the technical guidelines referred to in paragraph 7, second subparagraph, point (a), **and shall have made them available at the EU SoHO Platform**~~the inspectors shall consider the standards or elements thereof, to be met, insofar as they are addressed by the guidelines~~.

9. Inspectors ~~may~~ **shall** carry out ~~**at least**~~ one **or more** ~~or more~~ of the following activities**:** ~~**in the SoHO establishment or their contracted SoHO entities or third parties**~~:

(a) inspect **premises** ~~SoHO establishment facilities and, where applicable, the facilities of any third parties contracted by the SoHO establishment concerning SoHO activities~~;

(b) evaluate and verify the procedures and the SoHO activities performed ~~in SoHO establishments and, where applicable, in facilities of third parties~~ that are relevant to the requirements of this Regulation;

(c) examine any documents or other records ~~kept by SoHO establishments and, where applicable, third parties~~ relating to the requirements of this Regulation ~~and in particular Chapter V thereof~~;

(d) **if applicable,** evaluate the design and implementation of the quality management system in place pursuant to Article 50*;*

(e) take samples for analysis**,** ~~and~~ copies of documents**, and photographic or video recording,** if required;

(f) evaluate the emergency plan in place in accordance with Article 66, where applicable;

(g) order the suspension or cessation of any procedure or activity where necessary and proportionate to the risk detected. **In such case, the inspector shall take all the necessary steps without undue delay~~inform the SoHO competent authorityimmediately~~.**

10. **Subsequent to the inspection referred to in Article 27(2) point (e), SoHO c**~~C~~ompetent authorities shall carry out **periodic** inspections pursuant to paragraph 1**a**, point (a), ~~regularly~~**, so that the interval between two on-site inspections shall not exceed, in any event, 4 years.**~~,~~ ~~on a risk basis and with~~ **an** ~~appropriate frequency~~**, according to the risk.**~~,~~ **The frequency of inspections shall** tak**e**~~ing~~ account of:

(a) identified risks associated with~~: (i)~~ the **type of** SoHO**s that are subject to the authorisation** ~~processed and stored;~~ **and** ~~(ii)~~ the **SoHO** activities ~~of the SoHO establishments, in particular the processes~~ carried out;

(b) the **SoHO** ~~establishments'~~ past record as regards the outcome of previous inspections ~~carried out on them~~ and their compliance with the rules of this Regulation;

(c) ~~results from~~ certification or accreditation by international bodies, ~~where those bodies verify provisions that are equivalent to those in this Regulation; and~~**where relevant;**

(d) the reliability and effectiveness of the quality management systems referred to in Article 50.

~~11. The interval between two on-site inspections shall not exceed 4 years~~.

~~12. Competent authorities shall consider on-site inspections carried out in the course of the authorisation of an establishment in accordance with Article 27(2), point (d), as the first on-site inspection in the sense of this Article~~.

~~13. **SoHO** Competent authorities shall provide immediate preliminary feedback on their findings at the request of the SoHO establishment concerned.~~

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

~~15. Where more than one authority is competent to perform SoHO supervisory activities in a Member State pursuant to Article 5(2), on a reasoned request from another competent authority in their Member State, the competent authority shall forthwith communicate the report referred to in paragraph 14 of this Article to the requesting competent authority.~~

16. For the purpose of ~~standardised~~ inspections referred to in paragraph 1 of this Article, **SoHO** competent authorities shall ~~consult~~ **take into account** the relevant best practices **on inspections** agreed and documented by the SCB as referred to in Article 68(1), point (c).

17. The Commission may adopt implementing acts concerning **common elements of national** ~~the~~ procedures to be followed for inspections of SoHO establishments.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

Section V – Activity Data

Compromise Text (12955/23)

Article 33

Activity data extraction, submission and publication

1. **SoHO** ~~C~~**c**ompetent authorities shall verify that SoHO entities that have activity data collection and reporting obligations pursuant to Article 44 **shall keep a record of their SoHO activities and** submit **to their SoHO competent authorities**~~em~~**, via the EU SoHO Platform,** ~~complete and accurate~~ **an** annual report~~s~~ of those activities ~~**and a confirmation that it complies with the obligations set out in Article 44.**~~ **The EU SoHO Platform shall allow the compilation of**~~aggregates~~ **the annual reports submitted by the SoHO entities and provides the SoHO competent authorities with an aggregated annual** ~~**summary**~~**report with the activity data from their SoHO entities.** ~~to the EU SoHO Platform referred to in Chapter XI.~~

1a. By derogation from paragraph 1, in cases where national or international registries collect activity data matching the data sets defined in the EU SoHO Platform, Member States shall decide if SoHO entities may delegate the submission of the activity data referred to in Article 44(1)~~**where SoHO competent authorities require SoHO entities to report activity data**~~ **to such registries. In this case**~~**platforms provided by them, and the reported data sets match the data sets required by the EU SoHO Platform**~~**, the SoHO competent authorities shall submit an annual aggregated report to the EU SoHO platform.**

2. **SoHO** Competent authorities shall **ensure** ~~extract~~ **that the**~~an~~ ~~aggregated~~ annual **aggregated** report of SoHO activity data for their SoHO entities **is made** ~~from the EU SoHO Platform. They shall make that report~~ available to the public **in their Member States**, including on the internet. **The annual aggregated report of SoHO activity data may also be published on the EU SoHO Platform after review and approval by SoHO National Authorities.**

~~**By derogation from paragraph 2, SoHO competent authorities shall not include in their annual report, activity data concerning SoHO entities carrying out SoHO activities for the purpose of public security, defence or military matters.**~~

3. **The Commission shall compile~~aggregate~~ the annual aggregated reports from~~national summaries of~~ the SoHO competent authorities, prepare and, after having shared the report with the SoHO National Authorities for review and approval, publish an Annual SoHO Activity Report ~~after having shared the report with the SoHO National Authorities for review and approval~~.**

~~**4. The Commission shall adopt implementing acts laying down the data sets to be reported to ensure uniformity and compatibility and comparability on the reports of SoHO Activity submitted to the EU SoHO Platform by competent authorities.**~~

~~**Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).****~~

***** PRE considers that implementing acts in Art. 33.4 is included in 44.3 on data activity.***

Article 44

Activity data collection and reporting

1. SoHO entities shall collect **and report** data relating to **any of the following** ~~their~~ **SoHO** activities ~~in cases where those activities include~~:

   (a) SoHO donor ~~recruitement~~ **registration**;

   (b) collection;

   (c) distribution;

   (d) import;

   (e) export;

   (f) human application.

2. The data collected pursuant to paragraph 1 shall comprise the ~~elements set out~~ **data set indicated** in the EU SoHO Platform ~~as referred to in Chapter XI~~.

3. The Commission shall adopt implementing acts laying down technical procedures **for setting and updating the list of data sets to be reported** to ensure uniformity and compatibility and comparability **on the activity data report, extraction, submission and publication**~~for the implementation of this Article~~.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2). **

***** PRE considers that implementing acts in Art. 33.4 is included in 44.3 on data activity.***

4. SoHO entities shall submit to the EU SoHO Platform an annual **report**~~summary~~ of the data collected pursuant to this Article **before 30 June of the subsequent year**. ~~In cases where national or international registries collect activity data meeting the **data sets** criteria defined in the **EU** SoHO platform and such registries have been verified by competent authorities as having in place data quality management procedures that ensure accuracy and completeness of data, **Member State shall decide if** SoHO entities may delegate the submission of the activity data referred to in this Article to such registries. The Commission shall aggregate the annual summaries of the SoHO entities, prepare and publish an Annual SoHO Activity Report.~~

4a. By derogation from paragraph 4, where SoHO competent authorities require SoHO entities to report activity data ~~to platforms provided by them~~ as referred to in Article 33(1a), SoHO entities shall submit their annual report~~summary~~ of activity data to the indicated registries~~platform~~.

Section VI –Traceability

Compromise Text (12955/23)

Article 46

European coding systems

1. SoHO entities shall apply a Single European Code ('SEC') to ~~all donated~~ SoHOs ~~preparations~~ distributed for human application. In cases where SoHOs ~~or SoHO preparations~~ are transferred for further processing in another SoHO **entities** ~~establishment entity~~ or released for manufacture of products regulated by other Union legislation **as provided for in Article 2(3)** ~~, or as the starting and raw material thereof,~~ **or exported to third countries,** SoHO **entities** ~~establishments entities~~ shall, at least, apply **the elements of the SEC that allow the identification of** ~~the part of the SEC that allows identification of~~ the donation[19] ~~identification sequence of the SEC~~. The SEC shall **also** appear ~~also~~ on the **primary** packaging or on a label attached thereto, or on the documents referring to the SoHO where it can be ~~guaranteed~~ **ensured** that such documents accompany the SoHO concerned.

2. Paragraph 1 shall not apply to:
   (a) reproductive ~~cells~~ **SoHO** for within couple use;
   (b) blood or blood components for transfusion or for the manufacture of medicinal products~~, within each Member State~~;
   (c) SoHOs applied to a **SoHO** recipient without being stored**, when donation and application of their own SoHO are carried out in the same ~~surgical~~ procedure, without any processing. However, in the case where these SoHOs are finally stored, paragraph 1 shall apply;~~**.
   (d) **SoHOs imported into the Union by derogation and authorised directly by SoHO competent authorities pursuant to Article 28(9);** ~~SoHOs imported into the Union in case of emergency authorised directly by competent authorities pursuant to Article 28(9);~~

[19] 'Donation identification sequence' in Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells Directive.

(e) **SoHOs other than those intended for medically assisted reproduction, within couple use, that are imported to or donated in the same SoHO entity where they are applied, unless the traceability system is used by that Member State for the verification of the limit of the offspring from the same donor.** ~~SoHOs that are imported to or donated in the same SoHO entity where they are applied.~~

3. The Commission shall adopt implementing acts concerning the format of the Single European Code and the requirements related to its application to SoHO establishments and to SoHOs at the point of distribution ~~or point of transport and delivery for further processing~~. ***

*** ***PRE proposes to simplify based on the new definition on distribution.***

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

Section VII – SoHO Preparation Authorisation

Compromise Text (13503/23)

Article 20

SoHO preparation authorisation system

1. **SoHO** ~~C~~**c**ompetent 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 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.

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 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

Authorisation of SoHO preparations

1. **SoHO** ~~C~~**c**ompetent authorities shall ~~have procedures in place to allow that applications for the authorisation of SoHO preparations are submitted in accordance with Article 41. They shall~~ provide guidelines and templates for the submission of applications for 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:

(a) acknowledge receipt of the application **without undue delay** ~~within 14 working days;~~

(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;

(ba) request ~~to~~ the applicant ~~SoHO entity~~ to provide supplementary information, if needed;

(c) grant **or refuse the approval for** ~~a conditional authorisation for the use of the 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~~**.

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 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.~~

4. **SoHO** ~~C~~**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 this time limit for**:**

(a) the duration of the consultation processes referred to in Article 14(1)~~and~~**,** (2) **and (3),**

(b) ~~**and in case of**~~ **a request for additional information to the SoHO entity,**

(c) the time needed to perform clinical outcome monitoring, or

(d) the performance of additional validation or the generation of additional quality and safety data as requested by the SoHO competent authority.

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 device has been certified by the competent body.

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:**

(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~~

(c) that non-compliance**, or suspected non-compliance,** impl**y**~~ies~~ **or might imply** a risk to the safety of SoHO donors, recipients or offspring from medically assisted reproduction **or** ~~unnecessary~~ **wastage of SoHO preparations.**

SoHO ~~C~~**c**ompetent 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, **SoHO** competent authorities shall, in accordance with national legislation, withdraw the authorisation of the SoHO preparation **from the SoHO entities** concerned.

8. **SoHO** ~~C~~**c**ompetent 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.**

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 Platform ~~as referred to in Chapter XI.~~

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:

(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;

(b) the safety and effectiveness of the 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

(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.

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 inform the SoHO National Authority of ~~the~~ that authorisation.

10. ~~Competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (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).

Section VIII – Authorisation of SoHO Establishments

Compromise Text (12955/23)

Article 35

Vigilance

1. **SoHO c**~~C~~ompetent authorities shall be responsible for the ~~management~~ **supervision** of vigilance associated with SoHO activities.

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

2. Upon receipt of a **SAR or SAE** ~~SAO~~ notification **pursuant to Article 47(3)**, **SoHO** competent authorities shall:

(a) ~~acknowledge receipt of the SAO notification;~~

(b) verify that the ~~SAO~~ notification includes the information referred to in Article 47(3**a**);

~~(c) assess the adequacy of the investigation planned to establish imputability and root cause;~~

(d) respond to the submitting SoHO entity ~~without undue delay~~ **if additional documentation or corrections are required.**

3. **Upon receipt of a SAR or SAE notification pursuant to Article 47(3), SoHO** ~~C~~**c**ompetent authorities may**:**

(a) provide advice on the investigation planned by the SoHO entity**;**~~.~~

(b) ~~In preparing such advice, competent authorities may~~ request contributing advice from the SCB pursuant to Article 68(1).

In case the **SAE or SAR notification** ~~SAO~~ concerns a**n outbreak** ~~suspected transmission~~ of a communicable disease, **Member States** ~~competent authorities~~ shall inform the ECDC and take into account any advice or information provided by the ECDC or its SoHO expert network.

4. Upon receipt of a ~~SAO~~**SAE or SAR** investigation report, **SoHO** competent authorities shall:

(a) ~~acknowledge receipt of the SAO investigation report~~;

(b) verify that the ~~SAO~~ investigation report includes the information pursuant to Article 47(5);

(c) assess the results of the investigation and of the corrective and preventive actions described;

(ca) request to the submitting SoHO entity additional documentation, if required

(d) inform the submitting SoHO entity of the conclusion of the ~~SAO~~ assessment**, if** ~~additional documentation or~~ **corrections are required**.

5. **SoHO** ~~C~~**c**ompetent authorities may carry out inspections, pursuant to Articles 29 or 30, as appropriate, when the **SAE or SAR** ~~SAO~~ notification or **the** ~~SAO~~ investigation report received indicates, or gives reasonable grounds for suspecting, that requirements of this Regulation have not been complied with, or to verify an accurate implementation of corrective and preventive actions planned **or when they consider that a particular SAR or SAE might comprise** ~~in case of~~**a public health threat**.

6. Upon receipt of a **SAE or SAR** ~~SAO~~ notification with implications for safety, quality or supply of a **SoHO-derived** product manufactured under other Union legislation ~~from a~~ that SoHO ~~or SoHO preparation~~, **SoHO** competent authorities shall inform, without undue delay **and**~~,~~ **via their SoHO National Authority,** the relevant authorities competent for that product, pursuant to Article 14(5).

6a. Upon receipt of information regarding a serious incident within the meaning of ~~according to~~ **Regulation (EU) 2017/745, or information regarding a serious adverse reaction** ~~according to~~ **within the meaning of Directive 2001/83/EC, associated with a product manufactured from or with a SoHO and indicating a possible association with the quality or safety of the SoHO used to manufacture that product, the SoHO competent authorities shall communicate the information to the SoHO establishment that supplied the SoHO without undue delay to facilitate possible actions to prevent further distribution of the SoHO implicated in the serious incident or serious adverse reaction.**

7. Upon receipt of information regarding a serious incident and field safety corrective action ~~according to~~**within the meaning of** Regulation (EU) 2017/745~~,~~ **and Regulation (EU) 2017/746** ~~**concerning a medical device or in-vitro diagnostic device,**~~ the **SoHO** competent authorities receiving such information shall **communicate it to** ~~inform~~ the SoHO entities **that may be using the device concerned when carrying out their SoHO activities**~~**affected** concerned~~. The **SoHO** competent authorities shall **also** submit that information to their ~~National~~ SoHO **National** Authority, provided that the incident meets the definition of a SA**E or SAR**~~O~~.

8. ~~Competent authorities shall provide a channel for self-reporting of SAOs by SoHO recipients and donors. Upon receipt of such notifications, competent authorities shall inform, as appropriate, the relevant SoHO entities or SoHO establishments thereof, and ensure that an adequate investigation of the occurrence is initiated by the SoHO entities or establishments concerned and that adequate corrective and preventive action have been taken by the SoHO entities or establishments concerned when necessary, and respond to the recipient or donor concerned.~~

9. **SoHO c**~~C~~ompetent authorities **or Member States,** shall ensure that the procedures referred to in paragraphs 1 to 5 provide for an adequate interconnection between the ~~SAO~~ notifications pursuant to this Article and the reporting system established in accordance with Article 11 of Directive 2010/53/EU, for instances where ~~SAO~~ **SAE or SAR** notifications relate to SoHO donations ~~after death,~~ by donors that also donated organs.

10. **SoHO c**~~C~~ompetent authorities shall submit to their SoHO National Authorities an annual summary of the **SAE and SAR** ~~SAO~~ notifications and **the** ~~SAO~~ investigation reports ~~o~~**of confirmed SAR or SAE** ~~received~~. **This report shall include recommendations, arising from an analysis of the SAE and SAR reported, where necessary.**

10a. ~~The~~ SoHO National Authorities shall submit an annual summary of **confirmed SAR or SAE** ~~those~~ ~~SAO~~ notifications and investigation reports ~~**of confirmed SAR or SAE**~~ to the EU SoHO Platform ~~referred to in Chapter XI~~ before 3**0 June** ~~1 May~~ of the subsequent year and shall make an aggregated version of that summary available to the public in their Member State, including on the internet. They shall include ~~in the annual summary~~ the numbers and types of **SAR or SAE** ~~those~~**notifications**~~SAO~~ reported to them that meet thresholds of seriousness and imputability that are agreed ~~at Union level within the SCB.~~ **and documented as best practices by the SCB, as referred to in Article 68(1), point (c).**

11. The Commission shall aggregate the annual summaries of the SoHO National Authorities, prepare and publish an annual **Union** SoHO vigilance report**,** after having shared **it**~~the report~~ with the SoHO National Authorities for review and approval. **The**~~is~~ **report should include overall pattern analysis and recommendations.**

12. ~~For the development of the guidance and templates referred to in paragraph 1 of this Article, and for the submission of the annual summaries referred to in paragraph 10 of this Article, competent authorities shall consult the best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).~~

13. The Commission may adopt implementing acts concerning the procedures to be followed for consultation and coordination between competent authorities and the ECDC concerning relevant **SAR or SAE**~~SAO~~ notifications and investigations.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

CHAPTER VI - SoHO donor protection

Compromise Text (13503/23)

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:

(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**:**

(i) the information referred to in Article 55 and in a way that is adequate in view of their capacity to understand it;

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;~~[20]

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

(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;

(g) document the results of the **SoHO** donor health evaluation ~~referred to in point (f)~~;

(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;

(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**;

(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 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~~.

2. 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.

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 between them, in accordance with national legislation.**

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.

~~5. In case of collection of SoHOs for autologous use or in the context of individuals or couples from whom SoHOs are collected as part of their own current or future medically assisted reproduction treatment, the treating physician~~**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.**

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~~.

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 adopted pursuant to this Article.

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, 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:**

(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 **SoHO** donor protection other than from transmission of communicable disease**s** ~~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**);

(c) ~~where the guidelines referred to in points (a) or (b) do not address a particular~~**other** technical method**s**, **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~~.

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 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~~).

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 VII - SoHO recipient and offspring protection

Compromise Text (13586/23)

Article 58

Standards concerning SoHO recipient and offspring protection

1. SoHO entities shall establish procedures ~~with measures, and, where necessary, combinations of measures,~~ that ensure high levels of safety and quality **of SoHO** and ~~demonstrate~~**that the** benefits for SoHO recipients and offspring from medically assisted reproduction ~~that~~ outweigh ~~any~~ **residual** risks. They shall, in particular, achieve a high level of assurance that pathogens, toxins or **serious** genetic conditions are not transmitted to **SoHO** recipients or offspring from medically assisted reproduction~~.~~**, to the extent that national legislation allows for genetic testing, as well as assurance that SoHO recipients or offspring from medically assisted reproduction do not develop potentially life-threatening, disabling or incapacitating conditions attributable to the SoHO~~s~~ applied.**

2. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks of communicable disease transmission from SoHO donors to **SoHO** recipients by combining, at least, the following measures:

   (a) reviewing and evaluating ~~the~~**SoHO** donors' current and past health, travel and relevant behavioural histories **and, where relevant, their family history,** to allow the application of temporary or permanent deferrals when risks cannot be ~~fully eliminated~~**minimised** by **SoHO** donor testing;

(b) testing of **SoHO** donors for communicable diseases **in laboratories duly accredited, certified or authorised, by** using certified and validated testing methods **or, when not feasible, by using other methods validated by those laboratories**;

(c) when feasible, **other measures are taken** ~~using processing technologies~~ that reduce or eliminate any potential communicable pathogens.

3. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks of non-communicable disease transmission, **when they apply to the SoHOs concerned,** including **serious** genetic conditions and cancer, from **SoHO** donors to the **SoHO** recipients or to offspring from medically assisted reproduction by combining, at least, the following measures:

(a) reviewing the **SoHO** donors' current and past health **and, where relevant, their family history,** to allow temporary or permanent deferral of **SoHO** donors that carry a risk of transmitting cancerous cells**, serious genetic conditions** or other non-communicable diseases that might be passed to a **SoHO** recipient by SoHO application;

(b) where the transmission of **serious** genetic conditions is an identified risk, and in particular in the case of medically assisted reproduction with third party donation**, and insofar as national legislation allows for those testing**:

(i) **routinely** testing **SoHO** donors for ~~those~~ **potentially life-threatening, disabling or incapacitating genetic** conditions~~, as indicated by~~ **with a significant** prevalence ~~or severity as presenting the highest risk~~ **in the SoHO donor population~~, insofar as national legislation allows for such testing~~**; or

(ii) testing prospective **SoHO** recipients to identify ~~any relevant~~ genetic risk **for potentially life-threatening, disabling or incapacitating conditions, according to family history**, combined with testing **third party SoHO** donors for such identified **serious** genetic conditions to ensure matching that will prevent the concerned condition in the offspring.

4. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks of communicable or non-communicable disease transmission to the **SoHO** recipients ~~through~~ **resulting from** cross-contamination ~~of donations~~ **between SoHOs** during collection, processing, storage and distribution ~~by~~**. Such** measures ~~that~~**shall** ensure that physical contact between SoHO~~s~~ from different **SoHO** donors is avoided or, in cases where ~~combining donations~~**pooling SoHOs** is necessary for ~~efficacy~~**effectiveness or feasibility** of the SoHO preparation, is ~~minimised~~**limited to the necessary level**.

5. In the procedures referred to in paragraph 1, SoHO entities shall mitigate risks arising from microbial contamination of SoHO~~s~~ from the environment, the personnel, the equipment~~,~~ **and the** materials ~~or solutions~~ coming into contact with SoHO~~s~~ during collection, processing, storage or distribution. SoHO entities shall mitigate such risks by, at least, the following measures:

   (a) specifying and verifying the cleanliness of collection areas~~;~~**, taking into account the degree of exposure of SoHOs to the environment during collection, and of storage areas;**

   (b) **in cases where SoHOs are exposed to the environment during processing,** specifying, based on a structured and documented risk assessment for each SoHO preparation, validating and maintaining a defined air quality in processing areas;

   (c) specifying, procuring and decontaminating equipment~~,~~ **and** materials ~~and solutions~~**that come into contact with SoHOs during collection, processing, storage or distribution,** such that their sterility**, where necessary,** is ensured.

   (ca) testing of SoHO for bacterial contamination, when feasible.

6. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks that any reagents and solutions added to SoHO~~s~~ or coming ~~in~~**into** contact with SoHO~~s~~ during collection, processing, storage and distribution might be ~~transmitted~~**transferred** to **SoHO** recipients and have a ~~toxic~~ **deleterious**~~, or other, detrimental~~ effect on their health by combining, at least, the following measures:

   (a) specifying such reagents and solutions prior to their purchase;

(b) verifying any required certifications of such reagents and solutions;

(c) demonstrating the removal of such reagents and solutions, when necessary, prior to distribution.

7. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks that inherent properties of ~~SoHOs~~**SoHO**, necessary for clinical ~~efficacy~~**effectiveness**, have been changed by any SoHO activity performed, in a manner that renders ~~SoHO preparations~~**the SoHOs** ineffective or less effective when applied to **SoHO** recipients by combining, at least, the following measures:

(a) conducting comprehensive process validation and equipment qualification as referred to in Article 41(2), point (a)(vii);

(b) gathering evidence of ~~efficacy~~**effectiveness** as referred to in Article 41(4), when needed.

8. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks that SoHO~~s~~ cause an **unexpected**~~**intended**~~ immune reaction in **SoHO** recipients by combining, at least, the following measures:

(a) accurately typing and matching of ~~patients~~**SoHO recipients** to **SoHO** donors~~, when such matching is necessary;~~

(aa) **using processing technologies to reduce those elements of SoHOs that stimulate an unintended immune response, as applicable;**

(b) correctly distributing **and applying** SoHO~~s~~ to the correct **SoHO** recipients pursuant to Article 45.

9. In the procedures referred to in paragraph 1, SoHO entities shall mitigate any other **avoidable** risk to the health of SoHO recipients or of offspring from medically assisted reproduction arising from ~~the application of~~ SoHO~~s~~ ~~or SoHO preparations~~ **applied** and not addressed in paragraphs 2 to 8**,** by applying procedures that they have validated as safely and effectively mitigating the risk concerned or that are demonstrated as mitigating the risk by published scientific evidence.

9a. SoHO entities distributing reproductive SoHOs from third party donation shall comply with rules established in national legislation regarding the limits of offspring or applications ~~on the maximum number of children born~~ with reproductive SoHOs from a single SoHO donor. SoHO entities shall monitor compliance with such limits via registries for gamete donors, in accordance with the national legislation ~~according to the standards issued by their SoHO competent authorities in this regard~~. Without prejudice of the former, when reproductive SoHOs are distributed to another Member State, the applicable limits ~~to offspring from the same donor~~ shall be that of the Member State that sets the most stringent rules, being either the Member State where the reproductive SoHO is donated or where ~~reproductive SoHOs~~ is are applied.

9b When carrying out SoHO activities, SoHO entities shall, to the extent possible, make use of technologies that reduce the risk of human error.

10. SoHO entities shall not:

(a) apply SoHO preparations to **SoHO** recipients without proven benefit, except in the context of ~~a clinical investigation~~**an** approved ~~in the context~~**clinical outcome monitoring plan** of a ~~conditional authorisation of the~~ SoHO preparation by their **SoHO** competent authority pursuant to Article 41(4). **Further exceptions are in the context of use pursuant to Article 21(9a), an individual treatment attempt with respect to the freedom of therapy and in health emergency situations pursuant to Article 64**;

(b) apply SoHO preparations to **SoHO** recipients unnecessarily;

(c) advertise or promote particular SoHO ~~preparations~~ to potential **SoHO** recipients**, or to any persons granting ~~authorisation~~ consent on their behalf,** or to healthcare professionals using information that is misleading, in particular, as to the potential use and benefits to **SoHO** recipients**, or minimising the associated risks** of the SoHO concerned.

~~(ca) distribute or apply SoHOs for purposes other than therapeutic.~~

11. For the measures referred to in paragraphs 2 and 3, SoHO entities shall verify the eligibility of a **SoHO** donor by means of**:**

(a) an interview with **them**~~him/her, his/her legal guardian or~~, in case of ~~a~~**living** donation ~~after death,~~**or, if applicable, with any persons granting consent on their behalf; or**

(b) in case of collection of SoHOs from deceased SoHO donors, an interview with a relevant individual that is informed regarding the **SoHO** donor's health and lifestyle history.

In case of living donation, t~~T~~he interview may **also include**~~be combined with~~ any **part of the** interview conducted as part of the evaluation referred to in Article 53(1), point (f).

For **living SoHO** donors that donate repeatedly, the interviews referred to in the ~~first subparagraph~~**paragraph 11(a)** may be limited to aspects that might have changed and may be replaced with questionnaires. **Interviews shall be added in cases where responses provided in questionnaire indicate changes in relevant information. This shall be without prejudice to 53(1), points (e) and (f) and Article 53(2).**

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

13. SoHO entities shall document the results of **SoHO** donor eligibility verification referred to in paragraphs 2 and 3, and shall communicate and clearly explain the results of **SoHO** donor eligibility verification to **SoHO** donors or, where relevant, ~~their relatives or~~ any persons granting ~~authorisation~~ **consent** on their behalf, in accordance with national legislation.

In case of **collection of SoHOs from deceased SoHO donors** ~~donations after death~~, SoHO entities shall communicate and explain the results **of the SoHO donor eligibility verification, notably any condition identified in the donor that might imply a risk for** the **health of SoHO donors relatives or close contacts,** to the relevant persons**,** in accordance with national legislation.

14. SoHO entities applying SoHO~~s~~ to **SoHO** recipients shall obtain their consent **or, where relevant, that of any person granting consent on their behalf, in accordance with national legislation,** for the application of SoHO~~s~~.

SoHO entities shall inform the **SoHO** recipients **or any person granting consent on their behalf,** of, at least, the following:

(a) the safeguards intended to protect the~~ir~~ **personal** data ~~and the~~**, including health** data**, of the SoHO recipients, and where relevant** of the offspring ~~in the case of~~ **from** medically assisted reproduction;

(b) the need **for SoHO recipients** to report back any unintended reactions following the application of SoHO~~s~~ or any genetic conditions in offspring ~~in the case of~~ **from** medically assisted reproduction with third party donation, **as referred to** in ~~line with~~ Article 47(2).

15. The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this Regulation in cases where additional standards are deemed necessary to ensure the protection of SoHO recipients or offspring **from medically assisted reproduction** from risks **associated with SoHOs** ~~posed by the application of SoHO preparations~~.

16. Where, in the case of risk to SoHO recipients and offspring from medically assisted reproduction arising from inadequate levels of safety and quality of SoHO~~s~~, imperative grounds of urgency so require, the procedure provided for in Article 78 shall apply to delegated acts adopted pursuant to this Article.

Article 59

Implementation of the standards concerning SoHO recipient and offspring 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 Article 58, in order to ensure convergent and high levels of ~~the~~ protection of SoHO recipients and offspring from medically assisted reproduction, the Commission may adopt implementing acts describing particular procedures to be applied and followed to meet such standard or element thereof.

   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 ~~a~~ **SoHO** recipient or offspring health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 79(3).

3. **The implementing acts adopted in accordance with paragraphs 1 and 2 of this Article shall also apply to SoHO entities when they** ~~In order to~~apply the standards or elements ~~thereof,~~ concerning **SoHO** recipient and offspring protection as referred to in Article 58~~,~~ ~~SoHO entities shall follow the procedures laid down in any implementing act adopted in accordance with paragraphs 1 and 2 of this Article.~~**.**

4. For those standards or elements of standards concerning **SoHO** recipient and offspring protection for which no implementing act has been adopted, in order to apply such standards or elements thereof, SoHO entities shall ~~follow:~~**take into account, in this order of priority:**

   (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 human application of SoHOs~~;

      (ii) published by the EDQM concerning **SoHO** recipient and offspring protection other than from transmission of communicable disease ~~through human application of SoHOs~~.

(b) ~~other guidelines accepted by competent authorities as achieving an equivalent level of safety and quality of SoHOs as set by the~~ **~~national or international~~ other** technical guidelines**, as** referred to in **Article 29(7a)** point (a**b**);

(c) ~~where the guidelines referred to in points (a) or (b) do not address a particular~~ **other** technical method**s**, **applied in specific circumstances, as referred to in Article 29(7a) point (c)** ~~other technical methods in line with relevant international standards and scientific evidence in peer-reviewed scientific publications, where available.~~

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 shall demonstrate to their **SoHO** competent authorities, for each of the standards or elements thereof, **which and to what extent they follow** ~~the equivalence~~**~~, in terms of SoHO recipient and offspring protection,~~** ~~of the other guidelines applied in terms of the level safety, quality and efficacy to the level set by~~ the technical guidelines referred to in paragraph 4, point (**~~a~~b**).

7. In those cases referred to in paragraph 4, point (c), for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall perform a risk assessment to demonstrate that the technical methods applied achieve a high level of protection of **SoHO** recipients and offspring from medically assisted reproduction and record the practice followed to establish the technical methods. They shall make the assessment and record available for review by their **SoHO** competent authorities during inspection or on specific request of **the SoHO** competent authorities.

CHAPTER VIII - Supply Continuity

Compromise Text (13586/23)

Article 62

Establishment of National SoHO emergency plans

1. Member States, in collaboration with **SoHO** National ~~SoHO~~ Authorities, shall draw up national SoHO emergency plans setting out measures to be applied without undue delay when **the demand or** the supply situation for critical SoHO~~s~~ presents~~s~~ or **are**~~is~~ likely to present a serious risk to human health.

In developing national SoHO emergency plans, Member States shall ensure cooperation and consultation, as appropriate, with their health surveillance bodies, military medical services, civil protection services and other services routinely involved in emergency responses. Member States shall implement national SoHO emergency plans in coordination with other response actions at national or Union level, if adopted, and, where relevant, in a manner consistent with the national prevention, preparedness and response plans developed in accordance with Article 6 of Regulation (EU) 2022/2371 and Directive (EU) 2022/2557.

~~2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of SoHO with a strong public and non-profit sector involvement.~~

3. Member States shall **draw up the plans referred to in paragraph 1 laying down the following elements**~~specify the following in the plans referred to in paragraph 1~~:

   (a) potential risks to the supply of critical SoHO~~s~~;

   (b) the **designation of** critical SoHO entities **and any other relevant third party to be involved in the supply of critical SoHOs** ~~to be involved~~;

(c) the powers and responsibilities of **SoHO** competent authorities **in cases of emergency as referred to in paragraph 1**;

(d) ~~channels and procedures for sharing~~ **the** information **exchanged** between **SoHO National** ~~competent a~~**A**uthorities ~~including competent authorities~~ of other Member States and other parties concerned, as appropriate**, via the EU SoHO Platform**;

(e) ~~a procedure for the development of~~ preparedness **and response measures**~~plans~~ for specific identified risks, in particular those concerning communicable disease outbreaks**, war or terrorist attacks and enviromental disasters**~~;~~

(f) a procedure for the assessment and authorisation **in the context of an emergency situation and in accordance with paragraph 4**, ~~when justified,~~ of requests from SoHO entities for derogations to the standards defined in Chapters VI and VII.

(fa) a mechanism to ensure that in case of emergency, critical SoHOs are prioritised according to the specific medical needs.

4. Member States shall ensure that any derogation granted in accordance with paragraph 3, point (f), is time-limited and is justified insofar as it implies risks that are lower than the risk of shortage of the **critical** ~~specific~~ SoHO.

5. Member States shall take into account the guidance of the ECDC, for emergencies related to epidemiological outbreaks, and of the guidelines published by the EDQM, for emergency planning in general.

6. Member States shall **inform the critical SoHO entities of their national SoHO emergency plans and shall** review **at least every 4 years such** ~~regularly their national SoHO emergency~~ plans **in order** to take into account changes in **the designation of critical SoHOs entities,** the organisation of **SoHO** competent authorities and **the** experience gained from implementing the plans and simulation exercises.

6a. The SCB~~Commission~~, in cooperation with the Commission~~SCB~~, shall support a coordinated approach to the implementation of emergency plans in cases where an emergency affects more than one Member States and, in the case of emergencies with an effect beyond the Union, to communicate and collaborate with relevant international organisations and authorities.

~~7. The Commission may adopt implementing acts describing:~~

~~(a) rules for the establishment of the national SoHO emergency plans provided for in paragraph 1 to the extent necessary to ensure the consistent and effective management of supply interruptions;~~

~~(b) the role of stakeholders and the supportive role of the ECDC in the establishment and operation of national SoHO emergency plans.~~

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).~~

CHAPTER IX - SoHO Coordination Board

Compromise Text (13586/23)

Article 67

SoHO Coordination Board

1. The SoHO Coordination Board **(SCB)** is hereby established in order to promote coordination between Member States concerning the implementation of this Regulation and the delegated and implementing acts adopted pursuant to it, and to support them in that coordination, as well as to facilitate cooperation with stakeholders in that regard.

2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health **or other relevant ~~bodies~~authorities**. The SoHO National Authority may nominate members from other **SoHO** competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The **SCB** ~~Board~~ may ~~also~~ invite experts and observers to attend its meetings, and may cooperate with other external experts**,** as appropriate.

The ~~board~~SCB may also invite, where relevant, ~~O~~other Union institutions, bodies, offices and agencies**. In such cases, they** shall have an observer ~~role~~**status**.

3. Member States shall submit the names and affiliation of their nominated members **and alternates, together with ~~one~~the corresponding declaration of interest for any member and alternate, stating the absence of any financial or other interest,** to the Commission~~, who~~**. The Commission** shall publish **in the EU SoHO Platform** the membership list**, the name, the institution of origin and the declaration of interest of each nominated member and alternate** ~~in the EU SoHO Platform~~.

4. The Commission shall **co-**chair the meetings of the SCB **together with the SoHO National Authority of a Member State, rotating in turn**. ~~The chair shall not take part in votes of the SCB.~~

5. The Commission shall provide the secretariat for the SCB in accordance with Article 72.

5a. The **SCB shall deliberate by consensus as far as possible. If consensus cannot be achieved, the SCB shall deliberate and adopt an opinion or other positions by, at least, a majority of two thirds of the votes of all the Member States~~, rounded up to the following integer number when the result is not an integer number~~. The representative of the Commission co-chairing the SCB shall not take part in votes of the SCB. Each Member State shall have one vote.**

6. **When establishing the SCB, the** rules of procedure of the SCB **shall be** put forward by the Commission**, and shall be approved by the SCB within the first semester of functioning. They** shall, in particular, lay down procedures for the following:

(a) meeting scheduling;

(ab) the election of the SoHO National Authority co-chairing the meetings of the SCB and the duration of this mandate;

(b) ~~reaching consensus~~**deliberating deliberation** and voting**, as well as timeframes for issuing opinions, taking into account the complexity of the file, the available evidence or other factors**;

(c) the adoption of opinions or other positions, including in cases of urgency;

(d) **submission of** request~~ing~~ **for** advice to the SCB, ~~including eligibility criteria for requests for advice to the SCB,~~ and for other communications ~~with~~ **to** the SCB;

(e) consultation **procedures** with advisory bodies established under other relevant Union legislation;

(f) the delegation of ~~routine~~ tasks to working groups, including on vigilance, inspection, traceability, and on the applicability of the provisions of this Regulation;

(g) the delegation of ad-hoc tasks to SCB members or technical experts to explore and report to the SCB on specific technical topics, as required;

(h) invitation of experts to take part in the work of the SCB working groups and or to contribute to ad-hoc tasks, on the basis of their personal experience and expertise or on behalf of recognised Union level or global professional associations;

(i) invitation of individuals, organisations, or public entities in the capacity of observers;

(j) the rules for declarations regarding conflict of interests of invited experts;

(k) the composition and rules of procedure for the working groups and the delegation of ad-hoc tasks.

7. The Commission shall, by means of implementing acts, adopt the necessary measures for the establishment~~,~~ **and** management ~~and functioning~~ of the SCB.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

Article 68

Tasks of the SoHO Coordination Board

1. The SCB shall assist ~~the Member States'~~**SoHO** competent authorities regarding ~~any issue related to~~ the coordinat~~ion of~~**ed** implementation of this Regulation and the implementing and delegated acts adopted pursuant to it, by:

(a) preparing opinions**,** at the request of **SoHO** competent authorities**, via their SoHO National authorities,** in accordance with Article 14(2) first sub-paragraph, on the regulatory status under this Regulation of a substance, product or activity and ~~transmitting its~~**including such** opinions ~~to~~ **in** the **SoHO** compendium**~~. By [… years after the data of publication of this Regulation] the SCB shall draw up a list for the existing products, substances, or activities for which an opinion on the regulatory status under this Regulation has not been prepared.~~**;

(aa) By [one year after the datea of entry into force publication of this Regulation], the SCB shall draw up a list of the existing products, substances, or activities for which an opinion on the regulatory status under this Regulation is not available and is needed to avoid risks to the safety of SoHO donors, SoHO recipients or offspring from medically assisted reproduction, or of a compromised access of recipients to safe and effective treatments;

(b) when preparing the opinions referred to in point (a) of this paragraph, initiating, at Union level, a consultation with equivalent advisory bodies established in other relevant Union legislation in accordance with Article 14(2) second sub-paragraph, and including in the compendium the opinions concerning the Union legislation to be applied in cases where there is agreement with the equivalent advisory bodies;

(c) ~~exchanging and documenting best practices on the implementation of the SoHO supervisory activities, and~~ **documenting and** publishing ~~agreed and documented~~ best practices on the **implementation of SoHO supervisory activities on the** EU SoHO Platform;

(d) recording information notified in accordance with Article 14(3), and including such information in the **SoHO** compendium;

(da) defininge criteria of 'critical SoHO' and the criteria to be qualified as a critical SoHO entity, providing and updating a list of 'critical SoHO', and ~~review and update those criteria~~making such information available on the EU SoHO Platform;

(db) documenting practices among Member States for establishing the conditions for reimbursement and compensation as referred to in article 54(2);

(dc) providing assistance and advice for the cooperation between SoHO competent authorities and other competent authorities, with a view to ensuring coherent oversight when SoHOs change regulatory status, as provided for in article 14(5);

(dd) providing advice on the minimum necessary evidence for the authorisation of a particular SoHO preparation, as referred to in article 22(4);

(e) liaising for the exchange of experience and good practices, as relevant, with the EDQM and the ECDC regarding technical standards, and with the EMA on authorisations and supervisory activities concerning the implementation of the PMF certification pursuant to Directive 2003/63/EC, to support the harmonised implementation of standards and technical guidelines;

(f) collaborating for the effective organisation of joint inspections and joint SoHO preparation ~~authorisations~~**assessment** involving more than one Member State;

(fa) providing advice to the Commission on the functional specifications of the EU SoHO P~~p~~latform;

(fb) in cooperation with the Commission, supporting a coordinated approach to the implementation of emergency plans in cases where an emergency affects more than one Member States and in the case of emergencies with an effect beyond the Union, in accordance with Article 62 (6);

(g) providing assistance in other matters related to the coordination **or the implementation of this Regulation** ~~as referred to above~~.

2. The Commission may adopt implementing acts describing criteria and procedures for the consultation of advisory **bodies**~~groups~~ established under other relevant Union legislation **in the performance of the SCB tasks**. ****

******* PRE propose to merge implementing acts in Art. 67.7 and Art. 68.2 on the SCB.***

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

CHAPTER X – Union Activities

Compromise Text (13503/23)

Article 69

Union training and exchange of SoHO competent authorities' personnel

1. The Commission shall**, in cooperation with SoHO National Authorities,** organise Union training **on the implementation of this Regulation.** ~~in cooperation with the Member States concerned.~~

~~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 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.

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 Commission shall make this list available to the **SoHO National Authorities** ~~Member States~~.

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.~~

CHAPTER XI - EU SoHO PLATFORM

Compromise Text (13503/23)

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").**

2. ~~The Commission shall make a summary of data of public interest and make it accessible to the public on the EU SoHO Platform in aggregated and anonymised formats. The EU SoHO Platform shall provide a channel for restricted exchange of information and data between competent authorities, and between SoHO entities and their respective competent authorities.~~

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~~.

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~~, 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.**

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 environment for the~~ exchange of information **and data, 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;**

(d) between SoHO National Authorities and the SCB; and

(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;

(e) technical guidelines for quality management published by the EDQM;

(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;

(~~g~~f) the name, the institution of origin and the declaration of interest of each SCB member and alternate;

(h~~g~~) 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 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).

CHAPTER XII- PROCEDURAL PROVISIONS

Compromise Text (13586/23)

Article 76

Data protection

~~**-1. Member States shall apply Regulation (EU) 2016/679 to the processing of personal data, including health data, carried out in the Member States pursuant to this Regulation.**~~

~~**-1a. Regulation (EU) 2018/1725 shall apply to the processing of personal data, including health data, carried out by the Commission pursuant to this Regulation.**~~

1. Personal data required for the application of Articles 5(5) and ~~6~~**10**(2**a**), ~~Article 18(3), point (a), Articles 19(2) and 21(3), Article 27(2), Article 28(2),~~ Articles 35 and 36**, Article 37 (1a), (b), Article 37a, Article 38, Article 41(2)(-a), Article 49(2),** ~~Article 53(1), points (f) and (g), Article 53(3), Article 58(11),~~ and Article**s**~~s~~ 63 **and 67(3)** shall be collected for the purpose of identifying the relevant contact persons within the relevant SoHO entities, **SoHO** competent authorities or delegated bodies, and shall only be processed further for the purpose of ensuring the administration and transparency of the **SoHO** supervisory activities and SoHO activities concerned.

2. Personal data, including data concerning health, **exchanged through the EU SoHO Platform and** required for the application of Articles ~~74~~ **73** and ~~75~~ **74** shall**, where absolutely necessary,** be processed in the interest of public health and for the following **purposes**:

(a) to help to identify and evaluate risks associated with a particular SoHO donation or SoHO donor**, where SoHO collected from that SoHO donor have been distributed in more than one Member State**;

(b) to process relevant information on clinical outcome monitoring**, in the context of SoHO preparation authorisation, where such information may increase the protection of SoHO recipients in more than one Member State.**

~~**2a. Personal data at an individual level shall not be exchanged with regulatory authorities nor entities of third countries.**~~

3. Personal data, including data concerning health, required for the application of Articles 35, 36, 41**, 45** and 47, Article 53(1), points (f) and (g), Article 53(3), and Article 58(11), (13) and (14), shall only be processed for the purpose of ensuring safety and quality of SoHOs and protecting the concerned SoHO donors, SoHO recipients and offspring from medically assisted reproduction. Those data shall be directly related to the performance of the supervisory activities and SoHO activities concerned and be limited to the extent necessary and proportionate for that purpose.

4. All information shall be processed by the Commission, Member States, **SoHO** competent authorities, including SoHO National Authorities, delegated bodies**,** ~~and~~ SoHO entities **and**~~, including~~ any third party contracted by a SoHO entity, as applicable, in such a way that the personal data of the subjects remain protected in accordance with the applicable legislation on personal data protection. **They** ~~The Commission, Member States, competent authorities, including SoHO National Authorities, delegated bodies and SoHO entities, including any third party contracted by a SoHO entity,~~ shall, in particular, minimise the risk that subjects can be identified and shall limit the information processed to elements necessary and appropriate for carrying out their tasks and fulfilling their obligations under this Regulation.

5. The Commission, Member States, **SoHO** competent authorities, including SoHO National Authorities, delegated bodies**,** ~~and~~ SoHO entities **and**~~, including~~ any third party contracted by a SoHO entity, shall implement appropriate technical and organisational measures to protect information and personal data processed**, including health data,** against unauthorised or unlawful access, disclosure, dissemination, alteration, destruction or accidental loss, in particular where the processing involves transmission over a network.

6. In relation to their responsibilities to process personal data to comply with the obligations of this Regulation, ~~the~~ SoHO entities and ~~the~~ **SoHO** competent authorities of the Member States shall be regarded as controllers as defined in Article 4, point (7), of Regulation (EU) 2016/679 ~~and they are bound by the rules of that Regulation~~.

7. In relation to its responsibility to establish and manage the EU SoHO Platform, as referred to in Article 73 and the processing of personal data**, including health data,** that might result from that activity, the Commission shall be regarded as controller as defined in Article 3, point (8), of Regulation (EU) 2018/1725 ~~and it is bound by the rules of that Regulation~~.

8. For the purposes of this Article, the Commission is empowered to adopt delegated acts in accordance with Article 77 supplementing this Regulation by laying down the retention periods for personal data**, including health data,** as appropriate to their purpose and specific criteria that would allow identification of data relevant for public health protection as referred to in paragraph 2.

CHAPTER XIII - TRANSITIONAL PROVISIONS

Compromise Text (13586/23)

Article 82

Transitional provisions concerning SoHO preparations

1. The preparations resulting from tissue and cell preparation processes designated, authorised, accredited or licensed on the basis of Article 6(2) of Directive 2004/23/EC before the date of application of this Regulation shall be deemed to be authorised as the corresponding SoHO preparations in accordance with this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.

2. Blood components that were verified by **SoHO** competent authorities as complying with applicable quality and safety requirements for blood components on the basis of Article 5(3) and Article 23 of Directive 2002/98/EC or with the blood component monographs included in the edition of the Guide to the preparation, use and quality assurance of blood components of the EDQM indicated on the EU SoHO Platform on … [OP please insert the date = two years after the date of entry into force of this Regulation], or that were otherwise designated, authorised, accredited or licensed under national legislation before the date of application of this Regulation, shall be deemed to be authorised as the corresponding SoHO preparations in accordance with this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.

3. **SoHO c**~~C~~ompetent authorities shall submit the information referred to in paragraphs 1 and 2 to the EU SoHO Platform, and link those ~~entries~~ **SoHO preparations, authorised pursuant to transitional provisions,** to the respective SoHO entities.

4. The Commission may adopt implementing acts in order to establish uniform procedures for ensuring that SoHO preparations deemed to be authorised pursuant to paragraphs 1 and 2 are fully documented in line with the requirements for SoHO preparation authorisation in this Regulation.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).