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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 the compromise text prepared by the Presidency in preparation for obtaining a mandate for negotiations with the European Parliament on the above-mentioned proposal. This version will be presented to the Working Party on Public Health on 19 October 2023.

Changes compared to the latest versions of compromise text presented (made either on the Commission proposal or on the Presidency text) are in **bold and underlined** and in ~~strikethrough~~ and highlighted in light grey shading.

Text marked in **bold and underlined** and in ~~strikethrough~~ without grey shading reflects changes made to the Commission proposal which were already presented in previous versions of Presidency text.

ANNEX

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(4), point (a), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

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

[1] OJ C , , p. .
[2] OJ C , , p. .

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** the supply of SoHO~~s~~ that are critical for the health of patients.

(4) Directives 2002/98/EC[3] and 2004/23/EC[4] 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**ed** 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

[3] 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).

[4] 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).

framework for these substances, which achieves safety and quality **of** all **SoHO,** ~~parties involved,~~ enhances legal certainty **for ~~patients~~ stakeholders 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 **quality and** 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.

(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[5] of the European Parliament and of the Council. ~~Shortcomings have not been raised regarding the existing quality and~~

[5] 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).

~~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 purpose~~s~~ 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 the own ~~an~~ infant with one's own breast milk should not fall within the scope of this Regulation. This includes also ~~In~~ situations where one's own breast milk is stored in a communal facility, such as a childcare facility or workplace, since it would be disproportionate to apply the provisions of this Regulation to those entities. However, if one's own breast milk is processed, in particular pasteurized, the provisions of this Regulation should apply.

(8) Ensuring the quality and safety of SoHO~~s~~ 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 SoHO~~s~~ that are intended to be applied to humans fall within the scope of this Regulation. SoHO~~s~~ can be prepared and stored in a variety of ways, becoming SoHO preparations, which can be applied to **SoHO** recipients. In these circumstances, this Regulation should apply to all activities from **SoHO** donor ~~recruitment~~ **registration** to human application and **clinical** outcome monitoring **registration**. SoHO~~s~~ ~~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[6], on medicinal products, regulated by Directive 2001/83/EC of the European Parliament and of

[6] 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).

the Council[7]**,** ~~and by Regulation (EC) No 726/2004 of the European Parliament and of the Council[8], including~~ on advanced therapy medicinal products, regulated byRegulation (EC) No 1394/2007 of the European Parliament and of the Council[9] **~~and,~~ investigational medicinal products, as regulated by Regulation (EU) No 536/2014** ~~or on food, regulated by Regulation (EC) No 1925/2006 of the European Parliament and of the Council[10]~~. ~~The criteria that define when SoHOs or SOHO preparations become products regulated under other Union legislation are not defined in this Regulation but are defined in those other acts. In addition, t~~**T**his 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 SoHO living donors, recording the information needed to identify a match with ~~are registered and tested for the purposes of matching them with~~ prospective recipients in the same Member State, or internationally, should be considered as SoHO entities. The registering of individuals that indicate their consent to donate tissues after death, or from whom donation is permitted in accordance with national legislation, should not be considered as SoHO donor registration within this

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7 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).

~~8 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).~~

9 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).

~~10 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).~~

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~~ the quality and safety 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 So~~O~~HO activity. Hence, laboratories that carry out such testing should also be registered as SoHO entities. While such testing is generally for the purposes of protecting the SoHO recipient, infectious disease testing of individuals prior to the storage of SoHO collected from them, for the purposes of subsequent re-application to them, is important to prevent cross-contamination between such SoHO while in storage. Therefore, this testing should include 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 or, in the autologous context, prior to human application. Processing can have objectives such as preservation by, for example, cooling, freezing or freeze-drying; pathogen inactivation, by, for example, washing, antibiotic decontamination or sterilisation; or, physical separation or purification into selected elements by, for example, centrifugation of blood to prepare red cell concentrates, platelet concentrates and plasma as separate components. If not performed correctly and in a consistent manner, processing steps

carry risks of contamination or of changing the inherent properties of SoHO in a manner that might reduce their effectiveness. Therefore, they should be considered SoHO activities and any entity performing SoHO processing should be subject to appropriate oversight, including by being authorised for the corresponding SoHO preparation. In cases where a surgical team prepares distributed SoHO for human application, without removal from the surgical field and immediately prior to the application, such preparatory handling should not be considered processing for the purposes of this Regulation. Such preparatory handling might include rinsing or rehydration, in accordance with the instructions provided with the SoHO, or cutting and shaping to render the SoHO suitable for the intended use in the SoHO recipient, for allogenic or autologous use. In addition, in the autologous context, the preparation of SoHO during and for the purpose of application as part of the same surgical intervention in which they were collected and without removal from the surgical field ~~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 as processing for the purposes of this Regulation. Mixing of released human breast milk with medication before human application should also not be considered as processing.

(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 also 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~~authorised as a SoHO establishment. SoHO that are distributed or exported should first have been subjected to a formal release step. In cases where the receiving entity carries out a further processing step on released and distributed SoHO, those SoHO should be subjected to a second release step prior to re-distribution. In the case of autologous, bedside or in-surgery, processing of SoHO without storage, it would be impractical to require a formal release step prior to the re-application of the SoHO preparation to the ~~patient~~recipient. 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 an entity~~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 quality and safety ~~and quality~~ of the imported SoHO are equivalent to the quality and 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 safety and entities performing import should be authorised as SoHO establishments. Following import, SoHO should be subject to release, prior to distribution within the Union. In certain cases, and in particular in the case of haematopoietic stem cells, national and international donor registries play a key role in the organisation of the import of matching stem cells for individual SoHO recipients in the Union. Such registries verify equivalence of ~~safety and~~ quality and safety 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~~ should first require a release to confirm compliance with the ~~safety and~~ quality and safety provisions of this Regulation. Such SoHO activity may have an impact on SoHO supply within the Union. Therefore, organisations exporting SoHO should be authorised as SoHO establishments ~~and be subject to certain supervisory activities.~~

(9m) In the context of this Regulation, the term effectiveness should be considered to include an expected response in a SoHO recipient that is measurable in degree, such as an engraftment of bone marrow cells after transplant, or an expected result in a SoHO recipient that is successful or not, but cannot be measured in degree, such as cornea or bone transplant success or failure, and which is evaluated ~~interpreted as a systematic evaluation,~~ in ~~compliance~~ accordance 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 rules on the organisation of their 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, as it ~~to~~ ensures 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.

(9p ~~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 ~~ir~~ 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 a closed system medical device has been CE marked for the specific purpose, and hasve therefore been demonstrated to achieve the intended result, and where the process carried out within the device does not meet the criteria for classification under another regulatory framework, this should be seen as analogous to non-removal from the surgical field and should not be considered as falling within the scope of this Regulation. However, this Regulation should apply to the processing of SoHO at the bedside or in the same surgical field by using medical devices for which quality, safety and effectiveness have not been proven as part of the CE marking process for that specific purpose.

(10a) When autologous SoHOs 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~~ should also apply to the specific case of intra-uterine insemination within couple use, when SoHO are collected and processed from one of the partners before being applied to the other partner, without storage. When autologous SoHO, or SOHO for use within couples,** are collected to be processed and also stored, risks of cross-contamination, loss of traceability or damage to the biological properties inherent to the substance, and necessary for ~~efficacy~~**effectiveness** in the **SoHO** recipient, also appear. Thus, the requirements for **SoHO release and for SoHO** establishment authorisation should apply **in those circumstances**.

(11) When SoHOs are **distributed** ~~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 of recipients of those products manufactured using SoHOs** ~~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 **and (EU) No 536/2014**~~,~~ **rules laid down in** 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.

(11a~~b~~) 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, making public the locations and activities of these organisations ~~may~~ is likely to compromise the defence, national security or public security. Therefore, the reporting and oversight provisions of this Regulation should apply to these organisations, but the publication of associated information should not be obligatory.

(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 **living SoHO** donors as well as for recipients **and offspring from~~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 **living SoHO** donors. As different

types of **SoHO** donation imply different risks for **SoHO** donors, with varying levels of significance, the monitoring of **SoHO** donor**'s** health should be proportionate to those levels of risk. This is particularly important when donation involves some risk to the **SoHO** donor's health due to a need for pre-treatment with medicinal products, a medical intervention to collect the substance or a need for **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 **serious genetic disorder that might result in a life-threatening, disabling or incapacitating condition** ~~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****make** ~~-~~such measures **public**~~,~~ **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 SoHO~~s~~ 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[11], 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 the principles of altruism of the donor and solidarity between donor and recipient.

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11 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.

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.

Therefore, the reimbursement of SoHO donors for actual expenses incurred in connection with SoHO donation or the compensation of SoHO donors for losses related to donation are acceptable practices, as long as these measures ensure financial neutrality. For feasibility purposes, it is reasonable that compensation may be provided in the form of a fixed allowance, based on average estimates of losses and expenses. When Member States decide to reimburse or compensate SoHO donors, ~~T~~the conditions for~~of~~ such reimbursement or~~and~~ allowances, including the setting of an upper limit that ensures financial neutrality, 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, and as such ~~that would be~~ contrary to the principle of voluntary unpaid donation and should not be permitted. Additionally, any advertising of SoHO donations ~~linked~~ by means of a reference to a financial reward should be prohibited, and recruitment campaigns and promotion and publicity activities should not refer to any compensation.

(18b) In order to comply with the principle that the human body and its parts shall not, as such, give rise to financial gain and thus support a donation system that SoHO donors and SoHO recipients can trust, Member States should take measures to ensure that SoHO entities are transparent in the calculation of fees for their services and the financial management of their services. These services refer, among other things, to the cost of testing, processing, storage, distribution, personnel and transportation,

infrastructure and administration, and the need to invest in state-of-the-art processes and equipment to ensure the long-term sustainability of the services offered.

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

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

(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 or, advanced therapy medicinal products**~~, medical devices, organs or food~~, with the aim of ensuring coherent procedures for the application of this Regulation. **SoHO 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**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~~ set out in this Regulation. Such verifications could be organised in different ways, such as audits,**

visits, surveys, and in collaboration with the Member States so as to limit the administrative burden. 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**, safety** 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 **and safety**. This should apply for well-established SoHO preparations that are introduced in a new SoHO entity but have been robustly demonstrated as safe and effective by their use in other entities.

(28) With regard to SoHO preparations that pose a ~~certain level of~~ risk **other than negligible**~~(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 **and a positive benefit-risk assessment**, 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 **a positive benefit-** ~~high~~ risk **assessment**, in

addition to the mandatory vigilance reporting and the clinical follow-up, the applicant should propose clinical investigation studies with monitoring of pre-defined clinical end-points. In case of high risk **and a positive benefit-risk assessment, and cases where risk or benefit are not evaluable due to a lack of scientific and clinical data or knowledge**, these should include a comparison with **a** standard ~~treatments~~**therapy**, ideally in a study with ~~subjects~~**SoHO recipients** allocated to test and control groups in a 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**, without changing the regulatory status of the SoHO concerrned,** 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[12], 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.

(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**, safety** 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

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12 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).

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**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**ompetent authorities should consider the impact on ~~safety,~~ quality**, safety** 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 certain~~their~~ SoHO activities; at least the data sets included in the EU SoHO Platform. In cases where national or international registries collect activity data meeting the criteria defined in the SoHO Platform and such registries have been verified by 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, **these**~~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, i~~**I**n 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**ppropriate** 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~~fall outside of the scope of this R~~r~~egulation as these are associated with particular ethical concerns that fall outside the scope of this Regulation.

(34) Where evidence demonstrates that specific ~~processing steps~~**procedures** reduce or eliminate the risk of transmission of specific infectious or non-infectious disease agents, the 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[13], 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 **and safety** 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 **and safety** during collection, processing, storage and distribution **or export**. ~~-~~It should therefore be possible to use those **technical** guidelines as one of the means to implement the ~~technical~~ standards provided for in this Regulation.

(36) The ECDC, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council[14], 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

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13 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).

14 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).

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.

(37a) In the development of national emergency plans, Member States should cooperate with involved stakeholders and should take into account the opinions of the Health Security Committee referred to in Article 4 of Regulation (EU) 2022/2371 and the Health Crisis Board referred to in Article 5 of Council Regulation (EU) 2022/2372, when applicable. Member States ~~will~~ should also benefit from ~~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. **The Commission should support the SCB in its cooperation with similar advisory bodies responsible for deciding on the regulatory status of products under other relevant Union legislation, in particular by organising meetings, at least annually. Such meetings should contribute to promote understanding and to ensure efficiency and scientific consistency with other relevant Union legislation and coherence with the different regulatory status mechanisms established under other Union legislation.** These measures should promote a coherent cross-sectoral approach and facilitate SoHO innovation.

(40) ~~The concept of a plasma master file (PMF) was established in Commission Directive 2003/63/EC[15]. 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~~ should contribute** ~~as well as~~ **to** improve~~d~~ transparency of ~~national~~ reporting and **SoHO** supervisory activities **and to the exchange of information between relevant parties**.

(42) The processing of personal data under this Regulation should be subject to strict guarantees of confidentiality and should comply with the rules on the protection of personal data**, including health data,** laid down in Regulation (EU) 2016/679 of the European Parliament and of the Council ~~-~~and in Regulation (EU) 2018/1725 of the European Parliament and of the Council~~-~~.

(43) As the EU SoHO Platform requires the processing of personal data, **including health data,** it will be designed respecting the principles of data protection. Any processing of personal data 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

~~[15] 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).~~

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 **limited to what is** 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[16]. 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

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

Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(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** authorisation~~s~~, 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 **into the EU SoHO Platform**, the SoHO preparation authorisation system and the authorisation of SoHO preparations, ~~the SoHO establishment authorisation system,~~ **common elements for the quality management system of SoHO entities and for** the inspections of SoHO establishments, the consultation and coordination related to vigilance, ~~the quality management system for SoHO establishments~~**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[17].

(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

[17] 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).

Regulation should be introduced to ensure legal certainty and clarity. In particular, there should be clarity for the establishments concerned as regards their registration and authorisation status as well as their tasks and responsibilities under this Regulation, whilst allowing **SoHO** competent authorities additional time to transfer the relevant information to the systems introduced by this Regulation. To allow for a smooth transition, it is also appropriate that those preparation processes already authorised and lawfully used under the former regimes are still valid, and that SoHOs 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][18],

[18] OJ C , , p. .

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation establishes measures setting high standards of quality and safety for all substances of human origin ('SoHO~~s~~') intended for human application and for activities related to those substances in order to ensure a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted reproduction. ~~This Regulation is without prejudice to national legislation which establishes rules relating to aspects of SoHOs other than their quality and safety and the safety of SoHO donors.~~

Article 2

Scope

1. This Regulation shall apply to:

(a) SoHO ~~intended for human application, to SoHO preparations~~**intended for human application**~~,~~ **and** ~~to~~ **SoHO used to manufacture** products **defined in other Union legislation as referred to in paragraph 3**~~manufactured from SoHOs and~~ **and** intended for human application;

(b) SoHO donors**.** ~~and~~**SoHO** recipients **and offspring from medically assisted reproduction;** ~~, and to the following SoHO activities;~~

(c) ~~—~~ **SoHO activities that have a direct impact on the safety, quality, or effectiveness of SoHO, as follows:**

(**i**~~a~~) ~~SoHO~~ donor ~~recruitment~~**registration**;

(**ii**~~b~~) ~~SoHO~~ donor history review **and medical examination** ~~and eligibility assessment~~;

(~~c~~**iii**) ~~SoHO~~ testing **of SoHO donors or of persons from whom SoHO are collected for autologous use** ~~of donors for eligibility or matching purposes,~~ ;

(~~d~~**iv**) collection ~~of SoHOs from donors or patients~~;

(~~e~~**v**) processing ~~of SoHOs~~;

(~~f~~**vi**) quality control ~~testing of SoHOs~~;

(~~g~~**vii**) storage ~~of SoHOs~~;

(~~h~~**viii**)~~SoHO~~ release;

(~~i~~**ix**) distribution ~~of SoHOs~~;

(~~j~~**x**) import ~~of SoHOs~~;

(**xi**~~k~~) export ~~of SoHOs~~;

(~~l~~**xii**) human application ~~of SoHOs~~;

(~~m~~**xiii**)~~SoHO~~ clinical outcome **~~monitoring~~ registration** ~~monitoring~~.

1a. This Regulation shall not apply to:

(i) organs intended for transplantation within the meaning of Article 3, points (h) and (q), of Directive 2010/53/EU;

(ii) breast milk when used exclusively for feeding the own child, without any processing.

1b. **This Regulation is without prejudice to national legislation which establishes rules relating to aspects of SoHO other than their quality and safety and other than the safety of SoHO donors~~other than their quality and safety and the safety of SoHO donors~~.**

1ba. By way of derogation, the provisions of this Regulation concerning the publication or communication of information, specifically ~~the publication~~ with regards to obligations in Articles 4(2), 8, 17, 21(3), 31, 33, 39, 44, 62, 63, 66, 77, 81(3b) may not apply when such publication or communication might imply a risk to public security or national security and defence.

2. In case~~s~~ of **SoHO intended for** autologous ~~use~~ **use,** ~~of SoHOs~~ where:

(a) SoHO~~s~~ ~~are processed and~~ **processed or** stored before application, this Regulation shall apply in **full**~~full~~;

~~(b) SoHOs are processed and not stored before application, only the provisions on vigilance referred to in Article 35, on SoHO rapid alerts referred to in Article 36, on SoHO entity registration referred to in Article 37, on SoHO preparation authorisation referred to in Article 40, and on activity data collection and reporting referred to in Article 44 shall apply;~~

(c) SoHO~~s~~ are ~~not~~ **neither** processed **nor**~~and not~~ stored before application, this Regulation shall not apply.

3. ~~For~~ **In case of** SoHO~~s~~ that are used to manufacture ~~products~~ **regulated by other** ~~in accordance with~~Union legislation**,**~~on medical devices, regulated by~~ **in particular, medical devices, as regulated by ~~defined in~~** Regulation (EU) 2017/745, ~~on medicinal products, regulated by~~ **medicinal products, regulated by ~~as defined in~~** ~~Regulation (EC) No 726/2004 and~~ Directive 2001/83/EC, ~~including on advanced therapy medicinal products, regulated by~~ **advanced therapy medicinal products, regulated by ~~as defined in~~** Regulation (EC) No 1394/2007 **or investigational medicinal products, as defined in Regulation (EU) No 536/2014** ~~or on food, regulated by Regulation (EC) No 1925/2006, or as the starting and raw material thereof~~, ~~the provisions of~~ , **the provisions of** this Regulation **applicable to the SoHO activities referred to in paragraph (1a) point (i), (ii), (iii) and (iv), shall apply in all cases. Insofar as the activities of SoHO referred to in paragraph (1a) point (vii), (viii), (x) and (xi) relate to SoHO ~~until their distribution~~distributed to a manufacturer regulated by other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.** ~~applicable to the activities of SoHO donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, and collection of SoHOs~~

~~from donors or patients shall apply. Insofar as the activities of SoHO release, distribution, import and export relate to SoHOs prior to their distribution to an operator regulated by the other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.~~

~~By way of derogation from the first subparagraph, in cases where SoHOs, SoHO preparations, or products manufactured from SoHO, as referred to in that subparagraph, are exclusively for autologous use, only those provisions of this Regulation that concern the collection of SoHOs from patients shall apply.~~

3a. By way of derogation from paragraph 3, when SoHO are used to manufacture products under other Union legislation for the exclusive therapeutic use on the person from whom SoHO are collected, the provisions of this Regulation relating to the SoHO activities referred to in Article 2(1c) point (iii) and (iv) shall apply.

4. Where non-viable SoHO~~s~~ or their derivatives, as defined in Article 2, point **(16) and** (17), of Regulation (EU) 2017/745, incorporate, as an integral part, a medical device, and where the action of the non-viable SoHO~~s~~ or their derivatives is principal ~~and not ancillary~~ to that of the device, **this Regulation shall apply in full on** the non-viable SoHO~~s~~ or their derivatives **and the final combination shall be subject to the provisions of this Regulation** ~~shall be governed by this Regulation~~. If the action of the non-viable SoHO~~s~~ or their derivatives is ancillary to that of the device ~~and not principal~~, **this Regulation shall apply for all SoHO activities to which the non-viable SoHO or their derivatives are subjected until distributed for integration into the medical device, and the final combination shall be subject to the provisions of ~~this Regulation applicable to the SoHO activities referred to in paragraph (1a) point (i), (ii), (iii) and (iv), shall apply in all cases. Insofar as the activities of SoHO referred in parragraph (1a) point (vii), (viii), (x) and (xi) relate to SoHO until their distribution to the manufacturer regulated by~~ Regulation (EU) 2017/745~~, the provisions of this Regulation shall also apply.~~** ~~the provisions of this Regulation, insofar as they concern donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, collection of SoHOs from donors or patients, shall apply~~.

~~**4a. By way of derogation from paragraphs 3 and 4, when SoHO are used to manufacture products under other Union legislation for the exclusive therapeutic use on the person**~~

~~**from whom SoHO are collected, only the provisions of this Regulation relating to the SoHO activities referred to in Article 2(1) (c) (iii and iv) shall apply.**~~

Article 3

Definitions

For the purpose of this Regulation the following definitions shall apply:

~~[(1) 'blood' means the liquid that circulates in arteries and veins carrying oxygen to and carbon dioxide from the tissues of the body;]~~

~~[(2) 'blood component' means a constituent of blood such as red cells, white cells, platelets and plasma, that can be separated from it;]~~

~~[(3) 'cell' means a mass of cytoplasm with or without a nucleus, that is bound externally by a cell membrane. Usually microscopic in size, cells are the smallest structural and functional unit of an organism;]~~

~~[(4) 'tissue' means a group of cells that function together as a unit;]~~

(5) 'substance of human origin' (SoHO) means any substance collected from the human body ~~in whatever manner~~, whether it contains cells or not and whether those cells are living or not**, including SoHO preparations resulting from the processing of that substance;**~~. For the purposes of this Regulation, SoHO does not include organs in the sense of Article 3, point (h), of Directive 2010/53/EU;~~

(6) 'human application' means inserted, implanted, injected, infused, transfused, transplanted, ingested, transferred ~~(as in transfer to the uterus or fallopian tube of a woman)~~**,** inseminated or otherwise added to the human body in order to create a biological~~, mechanical~~ [~~or physiological~~] interaction with that body;

~~(7) 'SoHO activity' means an action, or series of actions, that has a direct impact on the safety, quality or efficacy~~ **effectiveness** ~~of SoHOs, as listed in Article 2(1~~**c**~~);~~

(7a) **'~~E~~effectiveness of SoHO' means the extent to which the use of SoHO reaches~~quality ensures that~~ the intended biological or clinical outcome ~~is achieved~~ in the SoHO recipient;**

(8) 'SoHO donor' means any**:**

(a) living person who has **volunteered** ~~presented themselves~~ to a SoHO entity **or been presented by a person granting consent on their behalf, in accordance with national legislation,** with a view to making a donation of SoHO**s, for the purpose of** ~~application to~~**use in a person other than themselves, and other than situations of within couple use as defined in point (63)**~~, whetherthat donation is successful or not~~**;or**

(b) deceased person who has been referred to a SoHO entity, and from whom consent has been granted or from whom SoHO collection is permitted, in accordance with national legislation;

(9) 'SoHO recipient' means the person to whom SoHO~~s~~ are applied **or their application is envisaged, whether by allogeneic or autologous use**;

(9a) 'recipient' means a SoHO recipient or any person receiving a product manufactured from SoHO, regulated under other Union legislation, as provided for in Article 2(3);

(9b~~a~~) 'consent'~~, in the context of this Regulation,~~ means the permission given by:

(a) a living SoHO donor or a SoHO recipient for an action affecting them to proceed, or

(b) any person granting consent on ~~their~~ behalf of the living SoHO donor or the SoHO recipient who has no capacity to consent, or the authorisation granted by the national law, for ~~such~~ an action to proceed in the ~~case of~~ living SoHO donor~~s~~ or the SoHO recipient~~s who have no capacity to consent~~, or

(c) any person granting consent, or the authorisation granted by national law, for ~~such~~ an action to proceed in the case of the deceased SoHO donor~~s~~ in accordance with national legislation.

(10) 'medically assisted reproduction' means ~~the facilitation of conception by intra-uterine insemination of sperm, in vitro fertilisation or any other~~ **any** laboratory or medical intervention ~~that promotes conception~~**, including any preparatory steps, that involves the handling of reproductive SoHO for the purpose of the facilitation of pregnancy or~~**~~and~~** **for preservation of fertility**;

(10a) **'~~P~~p**reservation of fertility'~~:~~ **means ~~T~~t**he process of saving or protecting a person's reproductive SoHO intended to be used ~~for the purpose of medically assisted reproduction~~ later in **that person's** life.

(11) 'offspring from medically assisted reproduction' means ~~fetuses~~ **developed ~~f~~rom ~~third party donation,~~** ~~and~~ children ~~that are~~ born following medically assisted reproduction;

(12) 'SoHO preparation' means a ~~particular~~ type of SoHO**,** that:

(a) has been subjected to one or more SoHO activities, **as listed in Article 2(1c), ~~point c, at least,~~** ~~including~~**one of them being** processing**;**~~;~~ ~~in accordance with defined quality, and safety~~ **and effectiveness** ~~parameters~~ **in this Regulation**; **and**

~~(b) meets a pre-defined specification; and~~ **(b) has a specific clinical indication; and**

(c) is intended for application to a **SoHO** recipient ~~for a specific clinical indication~~ or is intended for distribution ~~for manufacture of a product regulated by other Union legislation,~~ **as referred to in Article 2(3)** ~~or as the starting and raw material thereof~~;

~~(13) 'donor recruitment' means any activity aimed at encouraging persons to become SoHO donors;~~

(13a) 'SoHO donor registration' means recording in a registry, and transferring to other registries where appropriate, the information on a SoHO donor~~s~~, that is essential for identifying a match with a prospective SoHO recipient~~including the results of the donor health evaluation and the tests performed, and transferring such information to other registries, when applicable .~~[19]~~;

(14) 'collection' means a process by which SoHO~~s~~ are ~~removed, procured, excreted, secreted or~~ obtained **from a person~~SoHO donor~~** ~~by any other manner~~, including any preparatory steps

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

, such as **hormone** ~~hormone~~ treatment~~,~~ needed to facilitate the process~~,~~ **at, or under the supervision of, a SoHO entity**;

(15) 'processing' means any operation involved in the handling of SoHO~~s~~, including**, but not limited to,** washing, shaping, separation, ~~fertilisation,~~ decontamination, sterilisation, preservation and packaging**,** ~~,except for the handling of SoHO for immediate application during a surgical intervention, without the SoHO being removed from the surgical field before they are applied~~

(16) 'quality control' means ~~several~~ **a pre-defined test, set of** tests or checks to confirm that ~~a SoHO activity or SoHO preparation meets~~ pre-defined quality criteria **are met**;

(17) 'storage' means the maintenance of SoHO~~s~~ under appropriate controlled conditions ~~until they are transferred to another SoHO entity~~ until distribution;

(18) 'release' means a process through which it is verified that a SoHO ~~or a SoHO preparation~~ meets defined safety and quality criteria and the conditions of any applicable authorisation, ~~as provided in this Regulation,~~ before distribution **or export** ;

(19) 'distribution' means ~~transportation and delivery~~**providing**~~, within the Union, of~~**,within the Union,** released SoHO~~s~~**:**

(a) ~~or SoHO preparations~~ intended for human application **to a specific SoHO recipient in the same or another SoHO entity;**

(b) intended for human applications in general, without the prior identification of a specific recipient, in the same or another SoHO entity;

(c) ~~or~~ **intended** for the manufacture of products regulated under **other** ~~other~~ Union legislation, **as ~~referred to~~provided for in Article 2(3),** ~~or as the starting and raw material thereof, including within the same organisation when SoHOs are delivered from a SoHO entity to a unit responsible for human~~ **to a manufacturer of such products;**

(20) 'import' means activities carried out to bring SoHO~~s or SoHO preparations~~ into the Union from a third country~~, including the organisation of such activities and physical verification of coherence with associated documentation, the appropriateness of transport conditions,~~

~~the integrity of packaging and the adequacy of labelling~~ **before their release**~~before release~~;

(20a) **'**third country supplier**'** means an organisation, ~~established in a third country~~**located** outside ~~of~~ the Union, which is **contracted to supply SoHOs or to perform ~~SoHO~~ activities that might influence the quality and safety of the SoHOs imported;~~.~~**

(21) 'export' means ~~distribution of~~ **activities carried out to send** SoHO**~~s~~ from the Union**~~or SoHO preparations~~ to **a** third countr**~~ies~~**.

(22) 'clinical outcome **registration** ~~**monitoring** monitoring **registration**~~' means **the management of a registry where information on the clinical outcome monitoring, as referred to in Article 41, including transferring such information to other registries, is recorded**~~evaluation of the health of a SoHO recipient for the purpose of~~ **following-up**~~monitoring the results of a SoHO preparation application, maintaining care and demonstrating safety and efficacy~~;

(22a) clinical outcome monitoring plan' means a programme for evaluating ~~monitoring, including the lasting of monitoring~~the safety~~, and~~ effectiveness ~~and indicators~~ of a SoHO preparation ~~effectiveness~~;

(23) 'autologous use' means ~~collection~~**application** of **a** SoHO **collected** from ~~one individual~~ **a person** ~~for subsequent application~~ to the same ~~individual~~ **person**~~, with or without further SoHO activities between collection and application~~;

(24) 'SoHO entity' means an organisation legally established in the Union that carries out one or more of the SoHO activities set out in Article 2(1**ca**);

~~(25) 'SoHO preparation authorisation' means the formal approval by a competent authority of a SoHO preparation, including the approval of the chain of activities carried out to obtain the SoHO preparation;~~

(26) **'**vigilance' means a set of organised surveillance and reporting procedures relating to adverse ~~occurences~~ **reactions and adverse events;**

(27) 'adverse **reaction**~~occurrence~~' means any incident **which could be reasonably associated with the quality or safety of SoHO, or its collection or application to a SoHO**

recipient, that caused harm to a living SoHO donor, ~~harm~~ to a SoHO recipient or to offspring from medically assisted reproduction ~~or that implied a risk of such harm~~.

(27a) 'adverse event' means any incident or error associated with SoHO activities that may affect the quality or safety of SoHO in such a way that implies a risk of harm to a living SoHO donor, to a SoHO recipient or to offspring from medically assisted reproduction.

(28) 'serious adverse **reaction**~~occurrence~~' (SA**R**~~O~~) means an adverse **reaction** ~~occurrence~~ that result**s**~~ed~~ in~~, or implied a risk of,~~ any of the following**:**

~~/~~(a) death;~~/~~

~~/~~(b) life-threatening, disabling or incapacitating condition, including transmission of a pathogen**, or a toxic substance** that might cause such condition;~~/~~

~~/~~(c) transmission of a genetic **disorder** ~~condition~~ **that, in the case of medically assisted reproduction with third party donation, resulted in pregnancy loss or that might result in a life-threatening, disabling or incapacitating condition** to offspring from medically assisted reproduction with third party donation**, or, within couple use, as a result of a pre-implantation genetic test error,**~~/~~

~~/~~(d) hospitalisation or prolongation of hospitalisation;~~/~~

~~/~~(e) the need for a **major** clinical intervention to prevent **or reduce the effects of** any of the above;~~/~~

~~/(f) loss of a quantity of SoHOs that causes human applications to be postponed or cancelled;/~~

~~/(g) loss of highly matched or autologous SoHOs;/~~

~~/(h) a mix-up of reproductive cells in such a way that an oocyte is fertilised with sperm from an individual other than the intended individual or reproductive cells are inseminated or transferred to the uterus or fallopian tube of a woman other than the intended recipient;/~~

~~[~~(i) prolonged sub-optimal health of a SoHO donor following single or multiple donations;~~]~~

(28a) 'serious adverse event' (SAE) means an adverse event that implies a risk in any of the following:

(a) inappropriate SoHO distribution;

(b) a defect implying risk to SoHO recipients or SoHO donors is detected in one SoHO entity that would have implications for other SoHO recipients or SoHO donors because of shared practices, services, supplies or critical equipment;

(c) loss of a quantity of SoHOs that causes human applications to be postponed or cancelled;

(d) loss of highly matched or autologous SoHOs;

(e) a mix-up of reproductive SoHO in such a way that an oocyte is fertilised with sperm from an individual other than the intended individual or reproductive SoHO are applied to a recipient other than the intended recipient;

(f) event resulting in loss of the traceability of ~~reproductive~~ SoHO

~~[(29) 'SoHO rapid alert' means a communication regarding a SAO, a communicable disease outbreak or other information that might be of relevance to the safety and quality of SoHOs in more than one Member State and is to be transmitted rapidly between competent authorities and the Commission to facilitate the implementation of mitigating measures;]~~

~~[(30) 'non-viable' means having no potential for metabolism or multiplication.]~~

~~(31) 'EU SoHO Platform' means the digital platform established by the Commission to exchange information concerning SoHO activities;~~

~~(32) 'SoHO supervisory activity' means any activity as provided for in Chapter III performed by a competent authority or by a delegated body in order to verify and enforce compliance with this Regulation, ;~~

(33) 'the **SoHO** compendium' means a list kept up-to-date by the SoHO Coordination Board **(SCB)** of decisions, taken at Member State level, and opinions, issued by **SoHO** competent

authorities and by the SCB, on the regulatory status of specific substances, products or activities and published on the EU SoHO platform.

~~[~~(34) 'quality management system' means a formalised system that documents processes, procedures, and responsibilities to support achieving defined quality standards in a consistent manner;~~]~~

~~[~~(35) ~~'delegated body' means a legal body to which the competent authority has delegated certain SoHO supervisory activities in accordance with Article 6;]~~

~~(36) 'audit' means a systematic and independent examination to determine whether activities and the related results of such activities comply with legislation and planned arrangements and whether these arrangements are applied effectively and are suitable to achieve the objectives;~~

(37) 'inspection' means a formal and objective control by a **SoHO** competent authority or delegated body to assess compliance with **the requirements of** this Regulation and other relevant Union or national legislation ~~and to identify~~ the need for corrective or preventive ~~action to achieve compliance~~;

~~(38) 'Union training' means activities for the personnel of competent authorities amd, where appropriate, for personnel of delegated bodies performing SoHO supervisory activities;~~

~~[(39) 'assessors' means personnel performing the assessment of SoHO preparations as referred to in Article 22;]~~

(40) 'SoHO establishment' means a SoHO entity that **carries out any of the following SoHO activities:**

(a) both processing and storage;

(b) release;

(c) import;

(d) export;

~~carries out both~~ processing ~~**and**~~and storage~~**, release, import or export**~~ of SoHOs ~~;~~

(41) 'critical ~~essential~~ SoHO' means a SoHO for which an insufficient supply will result in serious harm or risk of harm to ~~patients~~**recipients' health or to a serious interruption in the manufacture of products defined in other Union legislation, as referred to in Article 2(3), where an insufficient supply of such products will result in serious harm or risk of harm to human health.**

(42) **'**critical ~~essential~~ SoHO entity'means a SoHO entity that carries out activities contributing to the supply of critical SoHO~~s~~ and the scale of those activities is such that a failure to carry them out cannot be compensated by activities of other entities or alternative substances or products for ~~patients~~ **recipients**;

~~[(43) 'conditional authorisation' means the granting of permission by a competent authority to a SoHO entity to perform certain SoHO activities under specific conditions defined by that competent authority;]~~

~~(44) 'on-site inspection' means an inspection carried out at the premises of the SoHO establishment, or other SoHO entity, concerned;~~

~~[(45) 'technical guidelines' means a description of a series of methodological procedures and parameters that, if followed, achieve a level of quality and safety of a SoHO activity or a SoHO preparation that is considered to be acceptable as a means to comply with regulatory standards;]~~

~~(46) 'joint inspection' means an inspection carried out by inspectors from more than one Member State;~~

(47) 'traceability' means the ability to locate and identify SoHO~~s during any step~~ from collection ~~through processing and storage~~ to ~~distribution~~ **human application, disposal or distribution for the manufacture of products regulated by other Union legislation, as provided for in Article 2(3),** ~~or disposal, including the ability to:~~

~~(a) identify the SoHO donor~~ **~~or the person from whom SoHO are collected~~** ~~and the SoHO entity processing or storing~~**~~establishment releasing~~** ~~the SoHOs;~~

~~(b) identify the~~ **~~SoHO~~** ~~recipient at the SoHO entity applying the SoHOs to the~~ **~~SoHO~~** ~~recipient~~**~~, or the manufacturer of products regulated by other Union legislation~~**~~;~~

~~(c)locate and identify all relevant data relating to the safety and quality of the SoHOs and any materials~~ **~~or equipments [*or devices*]~~** ~~coming into contact with those SoHOs~~ **~~that pose a presumable risk to safety or quality~~**;

~~[~~(48) 'Single European Code' (SEC) means the unique identifier applied to certain SoHOs distributed in the Union;~~]~~

~~[(49) 'SAO notification' means the communication from a SoHO entity, a SoHO establishment or a SoHO donor or recipient to a competent authority, of a serious adverse occurrence or a suspected serious adverse occurrence associated with a SoHO donation or human application;]~~

~~[(50) 'SAO investigation report' means the report from a SoHO entity or a SoHO establishment to a competent authority on a specific SAO, describing the outcome and including an assessment of the seriousness and the level of imputability, the likely cause and any corrective action taken;]~~

(51) 'imputability' means the likelihood that a**n** ~~serious~~ adverse **reaction** ~~occurrence~~, in a SoHO donor, is **associated with** ~~related to~~ the ~~donation~~ **collection** process or, in a **SoHO** recipient~~,~~ **or offspring from medically assisted reproduction,** ~~to~~ **with** the application of the SoHOs;

(52) 'seriousness' means the degree of severity of an adverse **reaction** ~~occurrence~~, involving harm to a **living** SoHO donor, **a SoHO** recipient or offspring from medically assisted reproduction **or for public health in general**, **or an adverse event involving a risk of such harm** ~~at and above which the occurrence shall be notified to a competent authority~~;

~~[(53) 'self-reporting' means the notification of a SAO by a SoHO recipient or a SoHO donor directly to the competent authorities;]~~

~~[(54) 'Annual SoHO Vigilance Report' means the annual report published by the Commission aggregating the summaries from the SoHO National Authorities on SAO notifications and SAO investigation reports received;]~~

~~(55) 'deferral' means temporary or permanent suspension of the eligibility of an individual to donate SoHO;~~

~~*[*(56) 'responsible person' means the nominated individual in a SoHO entity that has responsibility for SoHO release;*]*~~

(56a) 'responsible person' means a nominated individual in a SoHO entity that has the responsibility of ensuring compliance with the Regulation;

~~[(57) 'process validation' means establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce results meeting predetermined specifications and quality attributes;]~~

~~[(58) 'equipment qualification' means establishing documented evidence that provides a high degree of assurance that a specific piece of equipment will consistently perform to predetermined specifications;]~~

~~(59) 'EDQM SoHO monograph' means a specification of the critical quality parameters of a particular SoHO preparation defined by the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe;~~

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

(61) 'reproductive ~~cells~~**SoHO'** means **human sperm, oocytes, ovarian and testicular tissue** ~~all cells~~ intended to be used for the purpose of medically assisted reproduction **or restoring endocrine function**. **For the purposes of this Regulation, embryos are ~~also~~ considered reproductive SoHO even though ~~if~~ they are not collected from the human body;**

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

(63) 'within couple use' means use of reproductive ~~cells~~**SoHO** for medically assisted reproduction from two persons with an intimate physical relationship~~, where one person supplies their own oocytes and the other person supplies their own sperm~~;

(64) 'compensation' means making good of any losses associated with donation;

(65) 'allogeneic use' means ~~collection~~**application** of **a** SoHO **collected** from **a person other than the SoHO recipient**~~one individual for subsequent application to another individual~~;

~~(66) 'SoHO supply alert' means a communication regarding a significant interruption to the supply of critical SoHOs that is to be transmitted to a competent authority, and when necessary, by a SoHO National Authority to the competent authorities of the Member States;~~

~~[(67) 'plasma master file' (PMF) means a compilation of the required scientific data, covering all aspects of the use of plasma, from collection to the creation of a plasma pool, on the quality and safety of human plasma relevant to the medicinal products, medical devices and investigational products that use human plasma in their manufacture;]~~

~~[(68) 'plasma for transfusion' means plasma separated from whole blood or collected by apheresis for the purpose of transfusion to a recipient;]~~

~~[(69) 'plasma for fractionation' means plasma separated from whole blood or collected by apheresis and used as the starting material for manufacturing of plasma-derived medicinal products;]~~

~~[(70) 'apheresis' means a process by which a specific blood component or type of stem cell is separated from whole blood during the donation, allowing the remaining blood components to be returned immediately to the donor.]~~

Article 4

More stringent Member State measures

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

2. **After the adoption,** Member States shall make available to the public details of **the more stringent** measures put in place in accordance with paragraph 1 without undue delay, including on the internet. The SoHO National Authority shall submit the details of any **such** more stringent measure**s** to the EU SoHO Platform ~~referred to in Chapter XI.~~

CHAPTER II

~~COMPETENT~~ MEMBER STATES' SoHO COMPETENT AUTHORITIES

Article 5

Designation of SoHO ~~competent~~ competentauthorities

1. Member States shall designate the **SoHO** competent authority or authorities ~~to~~ **to** which ~~they~~ confer responsibility for the SoHO supervisory activities ~~provided for in Chapter III~~. The ~~organisation~~ **authority** or ~~organisations~~ **authorities** designated shall be independent from any SoHO entity.

2. ~~For the same territory, a~~ **A** Member State may confer responsibilities for SoHO supervisory activities ~~to~~ **to** more than one **SoHO** competent authority, at national, regional or local level.

3. Member States shall ensure that **SoHO** competent authorities:

   (a) have the autonomy to act and make decisions independently and impartially while respecting **the constitutional, organisational and administrative structure of** ~~the internal administrative organisational requirements determined by the Constitutions of the~~ Member States;

   (b) have the necessary powers:

      (i) to properly perform the~~ir~~ **SoHO** supervisory activities **they have been made responsible for**, including **having** access to the premises of, and documents and samples kept by~~,~~ SoHO entities and any third parties contracted by a SoHO entity;

      (ii) to order the immediate suspension or cessation of a SoHO activity that poses immediate risk to SoHO donors, SoHO recipients**, offspring from medically assisted reproduction** or the general public;

      ~~(iii) to take decisions on the access and re-use of personal data;~~

(c) have**, or have access to,** sufficient resources, operational capacity, and expertise to achieve the aims of, and fulfil their obligations under, this Regulation;

(d) ~~are governed by appropriate~~**are subject to appropriate** confidentiality obligations in **order to comply** ~~accordance~~ with Article 75.

4. ~~Each~~ **When a** Member State **designates only one SoHO competent authority in accordance with paragraph 1, the SoHO competent authority** shall ~~designate a~~**also be appointed as the** ~~single~~ SoHO National Authority**. When a Member State designates more than one SoHO competent authorithies in accordance with paragraph 1, it shall appoint one SoHO National Authority among them**, ~~**without prejudice of**~~**in accordance with national law.** ~~in conformity with Member States' constitutional requirements,~~ **The SoHO National Authority shall be** responsible for ~~coordinating exchanges with the Commission and with other Member States' SoHO National Authorities~~**activities as referred to in Article 9(1a)**.

The ~~**appointment**~~ **designation of** ~~**one**~~**a single SoHO National Authority should not preclude the Member State from** ~~**delegating**~~ **assigning certain** ~~**activities**~~ **tasks to other SoHO competent authorities, in particular,** ~~**when there is a need**~~ **for** ~~**a**~~ **the management of rapid alerts to ensure an efficient and agile communication** ~~**of information related to when**~~ **serious adverse** ~~**events**~~ **reactions or serious adverse events**~~**reactions that have implications for**~~**involve more than one Member State.**

5. Member States shall submit to the EU SoHO Platform**, and keep updated, information on** ~~referred to in Chapter XI~~:

~~(a) the names and contact details of the competent authorities designated pursuant to paragraph 1;~~

(b) the name~~s~~ and contact details of the~~ir~~ SoHO National Authority referred to in paragraph 4;

(ba) the names and contact details of any SoHO competent authority designated pursuant to paragraph 1, when different from the SoHO National Authority referred to in paragraph 4.

~~6. Member States shall update the EU SoHO Platform without undue delay with any changes to the information referred to in paragraph 5.~~

~~*Article 6*~~

~~**Delegation by competent authorities of certain SoHO supervisory activities**~~

~~1. Member States or competent authorities may delegate certain SoHO supervisory activities to one or more delegated bodies in accordance with the conditions provided for in Article 10. Member States or competent authorities shall ensure that delegated bodies have the powers needed to effectively perform any activities delegated to them.~~

~~2. Where Member States or competent authorities decide to delegate certain SoHO supervisory activities to one or more delegated bodies, they shall submit information regarding such delegations to the EU SoHO Platform referred to in Chapter XI with details of the delegated supervisory tasks.~~

Article 7

Independence and impartiality

1. **When performing their tasks and excercising their powers, ~~C~~SoHO c**ompetent authorities shall act independently **and impartially**, in the public interest and free from any external **undue** influence.

2. **SoHO c~~C~~**ompetent authorities shall ensure that ~~their~~ personnel **performing SoHO supervisory activities** have no ~~direct or indirect economic,~~ financial or ~~personal~~ **other** interest that might be considered prejudicial to their independence and, in particular, that they are not in a situation that may, directly or indirectly, affect the impartiality of their professional conduct.

~~3. Paragraphs 1 and 2 shall also apply to delegated bodies.~~

Article 8

Transparency

1. ~~Without prejudice to Article 75,~~ **SoHO** competent authorities shall**:**

(a) carry out the~~ir~~ **SoHO** supervisory activities **they have been made responsible for** in a transparent manner**, at least by complying with the publication requirements provided for in this Regulation; and**

~~**and** they shall~~

(b) make **any enforcement decision, ~~in particular~~ according to Articles 19(1) point d~~)~~, 21(6)–(8), 27(3)–(5) or 29(9) point (g), and the reasons for it,** accessible and clear to the public ~~decisions taken~~ in cases where**:**

(i) a SoHO entity **does not comply with the provisions** ~~has failed to comply with an obligation under~~ **of** this Regulation**,** ~~and~~**or**

(ii) there is a serious~~where such a **non-compliance, or suspected non-compliance, implies**failure causes or may cause a serious~~ risk to **the safety of SoHO donors, recipients, offspring from medically assisted reproduction or public** ~~human~~ health.

2. Paragraph 1 shall ~~not affect~~ **be without prejudice to article 75 and to** national legislation on access to information~~.~~

3. **SoHO c**~~C~~ompetent authorities shall lay down **in their internal rules** practical arrangements for implementing the transparency rules referred to in paragraph 1 ~~in their internal rules~~.

~~4. Paragraphs 1, 2 and 3 shall also apply to delegated bodies.~~

Article 9

General responsibilities and obligations of SoHO competent authorities

1. **SoHO ~~C~~c**ompetent authorities shall be responsible for the SoHO supervisory activities ~~referred to in Chapter III~~ in order to verify the effective compliance ~~of~~ **by** SoHO entities ~~i~~**o**n their territory with the requirements set out in this Regulation.

1a. The SoHO National Authority appointed in accordance with Article 5(4) shall be responsible for coordinating the information exchanges with the Commission and with other Member States' SoHO National Authorities, as well as other tasks, provided for in Articles 4(2), 13~~,~~ (4), 14(1), (2) and (3), 18(1) ~~and (2), 35(10a) and (11)~~, 33(3~~1~~), 35(10) ~~point~~

a)) and ~~35~~(11), 36(2), -62, 63(3), 64(2) and (3), and 67(2) and ~~67~~(4). The SoHO National Authority may also be responsible for the task provided for in Article 13(1).

2. **SoHo c**~~C~~ompetent authorities shall ~~have in place~~:

(a) **have, or have access to,** a sufficient number of suitably qualified **and experienced** personnel to carry out the **SoHO** supervisory ~~functions~~ **activities they have been made responsible for**~~provided for in this Regulation~~**, efficiently and effectively**;

(aa) have procedures in place to ensure compliance with the confidentiality obligations set out in Article 75;

(b) ~~procedures to~~ ensure the independence, impartiality, effectiveness, quality, suitability for purpose and consistency of their SoHO supervisory activities;

(c) **have** appropriate and properly maintained ~~facilities~~ **premises** and equipment to ensure that **the** personnel can perform their SoHO supervisory activities efficiently and effectively;

(d) **have** a quality management system **or standardised documented procedures in place** for the~~ir~~ SoHO supervisory activities **they have been made responsible for** that includes a plan for continuity of their activities in case of ~~exceptional circumstances~~ **crisis situations that impede the normal performance of their tasks;**

(da) develop and implement, or provide access to, training programmes to ensure that personnel performing SoHO supervisory activities receive, for their area of competence, appropriate training;

(db) provide opportunities for their personnel to participate in the Union training referred to in Article 69 where such training is available and relevant.

~~3. Paragraphs 1 and 2 shall also apply to delegated bodies.~~

Article 10

~~Conditions for delegating~~Delegation of certain SoHO supervisory activities to ~~delegated~~ other bodies

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

1. **Member States shall ensure that the delegated bodies have the powers needed to effectively perform the activities delegated to them and fulfil the requirements in Article 11** ~~Member States and~~ **SoHO c**ompetent authorities that delegate ~~certain~~ SoHO supervisory activities **in accordance with paragraph -1a** to a delegated body ~~referred to in Article 6~~ shall ~~conclude~~ **have in place** a written **agreement** ~~agreement on the delegation~~**with that delegated body**.

~~2.~~ **The delegating SOHO c**~~C~~ompetent authorities shall ensure that ~~the~~ **such a the written agreement** ~~agreement referred to in paragraph 1~~ includes **at least** the following:

(a) a precise description of the SoHO supervisory activities that the delegated body is expected to perform, and the conditions under which those activities are expected to be performed;

(b) the condition~~s to be met by~~ **that** the delegated body ~~, including that the delegated body:~~

~~(i) has the expertise, equipment and infrastructure required to perform those SoHO supervisory activities delegated to it;~~

~~(ii) has a sufficient number of suitably qualified and experienced staff;~~

~~(iii)~~ participates in certification or other schemes at Union level, when available, to ensure the uniform application of principles of good practices required for their relevant sector;

~~(iv) has sufficient powers to perform the SoHO supervisory activities delegated to it;~~

(c) a precise description of **the** arrangements ensuring an efficient and effective coordination between the delegating **SoHO** competent authorit**y**~~ies~~ and the delegated body;

(d) provisions ~~for~~ **on** the fulfilment of the obligations ~~of the delegated body~~ as set out in Articles 11 and 12**;**~~.~~

(da) provisions on its termination in the case of withdrawal of the delegation pursuant to Article 12.

2a. SoHO competent authorities having delegated SoHO supervisory activities pursuant to paragraph -1a shall submit to the EU SoHO Platform the names and contact details of the delegated bodies, together with the details concerning the delegated SoHO supervisory activities.

Article 11

Obligations of the delegated bodies

1. Delegated bodies to which ~~certain~~ SoHO supervisory activities ~~have been~~**were** ~~are~~ **are** delegated in accordance with Article ~~6~~**10** shall:

(-aa) meet the requirements specified in Article 9(2);

(a) ~~communicate to~~**inform** the delegating **SoHO** competent authorities, on a regular basis and whenever those **delegating SoHO** competent authorities so request, **of** the outcome of the SoHO supervisory activities performed by them;

(b) immediately inform the delegating **SoHO** competent authorities whenever the outcome of the delegated SoHO supervisory activities indicates non-compliance or points to the likelihood of non-compliance, unless specific **written** arrangements established between those **delegating SoHO** competent authorities and the delegated bodies provide otherwise; and

(c) **fully** cooperate with the delegating **SoHO** competent authorities, including by providing access to their premises ~~and facilities~~ **and ~~information~~documentation, including IT systems**.

2. Delegated bodies ~~are~~ shall be subject to the provisions of Articles 7, 15 and 75 in full and, where relevant, to the provisions of Articles 24 and 32.

Article 12

Obligations of the delegating SoHO competent authorities

~~C~~**SoHO c**ompetent authorities that have delegated certain SoHO supervisory activities to delegated bodies in accordance with Article ~~6~~**10** shall:

(a) ~~organise~~ **conduct regularly** audits ~~or inspections~~ of ~~such~~ **the delegated** bodies~~, as necessary taking into account participation of such bodies in certification or other schemes referred to in Article 10(2), point (b)(iii)~~**. The interval between such audits shall be determined by the delegating SoHO competent authority, taking into account the participation of the delegated bodies in certification or other schemes referred to in Article 10(1), point (b), as well as the scope and the impact of the delegated SoHO supervisory activities on the quality and safety of SoHOs**;

(b) fully or partly withdraw the delegation without delay **when necessary, and** in particular in cases where:

(i) there is evidence that ~~such~~ **the** delegated bodies are failing to properly perform the **SoHO supervisory** activities delegated to them;

(ii) the delegated bodies **have** fail**ed** to take appropriate and timely action to remedy ~~the~~ **such** ~~shortcomings~~ **performance failures** identified; or

(iii) **there is evidence that** the independence or impartiality of the delegated bodies has ~~been shown to~~ be**en** compromised.

Article 13

Communication and coordination between ~~SoHO~~ SoHO competent authorities

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

2. **Within a Member State, ~~C~~SoHO c**ompetent authorities shall cooperate with each other ~~and with the Commission~~. They shall communicate information to each other and, in particular, to the SoHO National Authority as necessary for the effective implementation of the **SoHO**

supervisory ~~functions~~ **activities**~~provided for in this Regulation~~**including the activities of the SoHO National Authority as referred to in Article 9(1a)**.

3. In cases where **a SoHO** competent authorit**y**~~ies~~ ~~provide~~ **issues** an opinion[20] to a SoHO entity on the applicability of this Regulation to a particular substance**, product** or activity ~~within~~ **on**~~their~~ **its** territory, th**at**~~ose~~ **SoHO** competent authorit**y**~~ies~~ shall notify the SoHO National Authority **of that opinion[20] issued**, which, in turn, shall notify the ~~SoHO Coordination Board (~~'SCB'~~)~~[21] ~~of the opinion given to the SoHO entity~~.

4. Following a ~~reasoned~~ **duly substantiated** request from ~~a competent a~~**the SoHO National A**uthority of another Member State, the ~~competent a~~**SoHO National A**uthority shall without undue delay**, and ensuring consideration of aspects of confidentiality as set out in Article 75,** inform the requesting ~~competent a~~**SoHO National A**uthority of the outcome of **the SoHO** supervisory activities concerning a SoHO entity on its territory, and, as necessary and proportionate, provide the **requesting SoHO National Authority with the relevant documentation related to activities** ~~records~~ referred to in Articles 29 and 30.

Article 14

~~Obligations to c~~Consultation** **and cooperatio**n**e with authorities of other regulatory sectors**

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

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

[20] Art. 40(2) currently mentions 'advice'. It is proposed to change 'advice' in Article 40 to 'opinion'

[21] In case the SoHO Coordination Board would be introduced for the first time, the full name should be kept.

relevant regulatory status decision and take into account any relevant opinion included therein.

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

The **SoHO** competent authorities **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 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** 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 ~~SoHOs that are intended to be combined with medical devices, as referred to in~~ Article 2(4), the **SoHO** competent authority ~~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**, via their SoHO National Authority,** 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**[20] ~~from a SoHO entity, as referred to in Article 40~~.

6a. In case a SoHO competent authority 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 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).~~

Article 15

Right of appeal

1. Where decisions are taken by **SoHO** competent authorities concerning natural or legal persons, those decisions shall be subject to such persons' right of appeal in accordance with national legislation.

2. The right of appeal shall not affect the obligation of **SoHO** competent authorities to take prompt action to eliminate or contain the risks to human health in accordance with this Regulation.

~~3. Paragraphs 1 and 2 shall also apply to delegated bodies.~~

~~*Article 16*~~

~~**General obligations concerning the personnel of competent authorities**~~

~~1. Competent authorities shall:~~

~~(a) have, or have access to, a sufficient number of personnel so that SoHO supervisory activities can be performed efficiently and effectively;~~

~~(b) ensure that the personnel performing SoHO supervisory activities are suitably qualified and experienced;~~

~~(c) have procedures or arrangements in place to ensure that personnel performing SoHO supervisory activities are free from any conflict of interest;~~

~~(d) have procedures in place to ensure confidentiality and maintain professional secrecy.~~

~~2. Personnel performing SoHO supervisory activities shall:~~

~~(a) declare in writing any direct or indirect interests referred to in Article 7(2) and update that declaration yearly and whenever the declared information changes or any new interest arises;~~

~~(b) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and in a consistent manner;~~

~~(c) keep up-to-date in their area of competence and receive regular additional training as necessary;~~

~~(d) participate in training in the subject matter and on the obligations of competent authorities resulting from this Regulation, as referred to in paragraph 3.~~

~~3. Competent authorities, in cooperation with delegated bodies as necessary, shall develop and implement training programmes for the purpose of ensuring that personnel performing SoHO supervisory activities receive the training referred to in paragraph 2, points (b), (c) and (d). Competent authorities shall maintain records of the training undertaken by their personnel. Competent authorities shall provide opportunities for their personnel to participate in the Union training referred to in Article 69 where such Union training is available and appropriate.~~

~~4. Paragraphs 1, 2 and 3 shall also apply to delegated bodies.~~

Article 17

Obligations as regards Commission ~~controls~~verifications

SoHO c~~C~~ompetent authorities and delegated bodies shall cooperate with the Commission for the performance of Commission **verifications** referred to in Article 70. In particular, they shall:

(a) take appropriate follow-up measures to remedy the shortcomings identified through such **verifications**;

(b) ~~give~~ **provide** the necessary technical assistance and ~~provide~~ the available documentation, upon justified request, ~~and~~ **as well as** other ~~technical~~ support that **the** Commission ~~experts~~ request**s** to enable them to perform **verification**~~control~~s efficiently and effectively**, including facilitating**; ~~and~~

~~(c) give the necessary assistance to ensure that the Commission experts have~~ **give** access to all premises or part of premises, and to ~~information~~**documentation**, including IT systems, **of the SoHO competent authority or delegated body** relevant for the execution of their duties.

CHAPTER III

SoHO SUPERVISORY ACTIVITIES

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, the 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, SoHO National Authority may use the EU SoHO Platform as referred to in Chapter XI. In this case, the SoHO National Authority shall instruct competent authorities, where necessary, and SoHO entities to register directly on the EU SoHO Platform.~~

~~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 ~~the~~ **such** registries to the EU SoHO Platform~~ as referred to in Chapter XI~~. **SoHO c**~~C~~ompetent 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 **set of data to be published for registered SoHO entities, to facilitate the transfer of information** ~~compatibility and comparability~~ **procedures for the upload of data from** ~~of the~~ **national** registr**ie**~~sers of SoHO entities for~~ 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. **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 P~~p~~latform has provided the information pursuant to Article 37(1) before publication on the EU SoHO Platform. In cases where national registries are in place and following such verification the SoHO competent authority shall submit the information on the registration to the EU SoHO Platform.

1b. SoHO competent auhorities shall verify whether ~~and where~~ an authorisation is ~~not~~ required under Articles 21, 27 or 28 for a registered SoHO entity taking into account the declaration as referred in Article 37(1b). ~~, the SoHO competent authority 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 establishment pursuant to Article 49.~~

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-assessment done by the SoHO entity, where applicable as referred to in Article 37(1). SoHO competent authorities shall update the registration information accordingly.**

1d. **Where on the basis of the information submitted, an organisation ~~the SoHO entity~~ does ~~no longer~~ not 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, if applicable from the national registry, and inform the organisation ~~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, including in case of cessation of activities.

~~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 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~~ authorisation~~s~~ of SoHO preparations **to SoHO entities located** ~~**on**~~ **in 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**, 22a** and, where applicable, Article 23.

2a. The SoHO preparation authorisation may not be required for SoHO that are intended to be distributed for the manufacture of products regulated by other Union legislation, as referred to in Article 2(3).

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 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 for the design of clinical outcome monitoring plans** ~~**proposed**~~, **in accordance with Article 22a.** When developing these guidelines and templates, **SoHO** competent authorities **shall use the 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.

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 **or other third parties**, **in relation to the SoHO preparation,** where applicable;

(ba) request the applicant 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 apply, as well as~~ **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), when applicable,** grant or refuse the authorisation for the SoHO preparation **and, if any**, ~~as appropriate,~~**indicating which conditions apply**.

3. **SoHO** ~~C~~**c**ompetent authorities shall submit information regarding **the** ~~granted~~ **authorisation of the** SoHO preparation **including a summary of the evidence used to authorise each 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**ompetent authorities shall conclude the SoHO preparation authorisation ~~steps~~, referred to in paragraph 2 of this Article, **within the time limit set out** ~~within 3 months from receipt of the application,~~ **in accordance with national legislation or taking into account best practices agreed and documented by the SCB as referred to in Article 68(1), point (c),** ~~excluding the time needed for clinical outcome monitoring or~~ ~~studies~~. ~~**SoHO competent authorities** They may suspend this~~ **The** time limit **foreseen** for **the authorisation may be extended for:**

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

(b) the time needed to perform 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 that the medical device has been certified by the ~~competent~~ notified body under that framework.

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, in accordance with ~~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** ~~C~~**c**ompetent authorities may, in accordance with national legislation, suspend the authorisation of a SoHO preparation**, or the ~~realisation~~ implementation of its clinical monitoring outcome plan, in circumstances where** ~~if~~ SoHO supervisory activities demonstrate or give reasonable ground for suspecting that **such SoHO preparation, or any activities performed for that preparation:**

(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**

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

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** 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 **a suspension, as described in paragraph 6, is not sufficient to resolve the identified shortcomings.** ~~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,~~ **~~or 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** ~~status~~ of the **SoHO preparation 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 exceptionally authorise, at the request of ~~a prescribing physician or~~ the SoHO entity responsible for that application, the application of a SoHO preparation~~s~~ ~~for a defined group of~~ to a specific SoHO recipient~~s~~ 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~~ the SoHO preparation~~s~~ is foreseen for a specific SoHO recipient, in cases where the SoHO recipient has no therapeutic alternative, where treatment cannot be postponed or where the SoHO recipient's prognosis is life-threatening;

(b) the safety and effectiveness of the SoHO preparation ~~is presumed~~can reasonablye be assumed on the basis of the available clinical data; and

~~(c) there is the conformity of the SoHO entity responsible for the SoHO preparation; and~~

(~~c~~d) the SoHO recipient concerned ~~are~~ is informed that the SoHO preparation in question has not been authorised according to the provisions of this Regulation ~~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.~~

SoHO competent authorities shall inform the SoHO National Authority of that exceptional 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).

Article 22

Assessment of SoHO preparations

1. The assessment of a SoHO preparation~~,~~ shall include a review of all SoHO activities that are performed for that SoHO preparation and that might influence the ~~safety,~~ quality**, safety** and **effectiveness** ~~efficacy~~ of the SoHO preparation.

2. The assessment of SoHO preparations shall be carried out by **SoHO preparation** assessors meeting the requirements set out in Article 24.

3. In cases where the SoHO preparation**,** subject to the application for authorisation pursuant to Article 21**,** has been duly authorised in another SoHO entity in the same or in another Member State **~~or by the transitional provisions referred to in~~ Article 82**, **SoHO** competent authorities may authorise that SoHO preparation ~~in the applicant SoHO entity~~, provided that the **SoHO** competent authorities have verified**, with the consent of SoHO entities implied,** that the SoHO activities performed **and the steps of the processing applied** for the SoHO preparation are carried out by the applicant ~~SoHO entity~~ in a manner such that the **quality,** safety~~, quality~~ and **effectiveness** ~~efficacy~~ results **of the SoHO preparation** will be equivalent to those demonstrated in the SoHO entity where the SoHO preparation was first authorised.

4. In cases where the SoHO preparation, subject to the application for authorisation pursuant to Article 21, has not been ~~duly~~ authorised in another SoHO entity, **or the SoHO competent authority chooses not to take SoHO preparation authorisation in another Member State into account, SoHO** competent authorities **shall**:

(a) ~~shall~~ assess **the adequacy of** ~~all~~ the information provided by the applicant pursuant to Article 41**(2) point (a);**

(b) ~~shall review the SoHO preparation dossier referred to in Article 41(2), point (a);~~

(c) ~~shall~~ initiate the consultation described in Article 14~~(1)~~, if during the review of the **information** ~~SoHO preparation dossier~~ referred to in point (**a**~~ab~~), questions arise as to whether the SoHO preparation falls, in part or fully, within the scope of this Regulation or other Union legislation, taking into account the activities performed for the SoHO preparation and the intended human application;

(d) ~~shall review and~~ evaluate the ~~**results of a benefit**~~ **benefit**-risk assessment **carried out** ~~performed~~ by the applicant as pursuant to Article 41(2), point (b) **together with ~~an evaluation of~~ the scientific evidence and clinical data provided regarding the expected ~~risk and~~ benefit and risk**;

(e) ~~shall~~ evaluate the plan for clinical outcome monitoring**,** and its proportionality to the level of risk **and expected benefit** of the SoHO preparation **according to Article 22a, where relevant;** ~~paraghap 4a as referred to in Article 41(3), points (a), (b) and (c), as applicable;~~

(f) ~~shall may~~ consult the SCB, pursuant to Article 68(1) on the evidence necessary and sufficient for the authorisation of a particular SoHO preparation **where the guidance referred to in paragraph 7 is not sufficient**;

(g) ~~shall~~ assess, in the case of **an previously approved clinical outcome monitoring plan** ~~a conditional authorisation~~ pursuant to Article 21(2), point (c), the results of **that plan** ~~that plan the clinical outcome monitoring~~ **the clinical outcome monitoring upon completion and submission by the applicant**.

~~**4a. When evaluating clinical outcome monitoring plans, as referred to in paragraph 4 point (c), SoHO competent authorities shall verify that the plan proposes clinical outcome monitoring as follows:**~~

~~**(a) in cases of low risk, pro-active clinical follow-up of a defined number of SoHO recipients;**~~

~~**(b) in cases of moderate risk, in addition to point (a), a clinical study of a pre-defined number of SoHO recipients assessing pre-defined clinical endpoints;**~~

~~**(c) in cases of high risk, in addition to point (a), a clinical study of a pre-defined number of SoHO recipients assessing pre-defined clinical endpoints with a comparison to standard therapy.**~~

5. When assessing the SoHO preparation pursuant to paragraph 4, points (e) and (g), **SoHO** competent authorities shall **verify** ~~consider~~, in the cases where the applicant has proposed to record, and recorded, the results of the clinical outcome monitoring in an existing clinical registry, that this ~~is an acceptable method, provided that those competent authorities have verified that the~~ registry has data quality management procedures in place that ensure **adequate** accuracy and completeness **of data**~~of data~~.

6. **SoHO c**~~C~~ompetent authorities shall conduct the assessment ~~steps~~ referred to in paragraphs 3 and 4 of this Article by means of a remote document review. **SoHO c**~~C~~ompetent authorities may also, as part of the SoHO preparation assessment, carry out inspections pursuant to Articles 29, 30 and 31. **Member States shall ensure communication and cooperation between SoHO preparation assessors and inspectors pursuant to Article 13.**

7. When conducting the assessment steps referred to in paragraph 4 **and 4a** of this Article, **SoHO** competent authorities shall **take into account** ~~consult~~ the best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).

Article 22a

Clinical outcome monitoring plans

1. As a basis for the assessment of an authorisation for a new SoHO preparation, a clinical outcome monitoring plan from the applicant shall be approved by the SoHO compe~~n~~tent authority in cases where scientific and clinical evidence provided as part of the assessment carried out by the applicant, as referred to in Article 22(4)(d), are not sufficient or the risk is ~~other~~ more than negligible. The approved clinical outcome monitoring plan shall be implemented, and the results of the monitoring assessed, before the SoHO preparation authorisation is granted pursuant to Article 21.

2. Clinical outcome monitoring plans shall not be approved in cases where scientific and clinical data provided as part of the benefit-risk ~~analysis~~ assessment indicate a relevant level of risk without a significant expected benefit.

~~The clinical outcome monitoring plan shall include:~~

~~(a) clinical outcome monitoring according to 22a (3) point c, where scientific data for clinical use are not available or sparse, where benefit and risk are not evaluable, or when a negative benefit-risk analysis based on current knowledge is confirmed.~~

~~(b) clinical outcome monitoring according to 22a (3) point a, in a case of a relevant risk despite a positive benefit-risk analysis.~~

3. The design of the clinical outcome monitoring plan referred to in paragraph 1, shall be proportionate to the level of risk assessed by the applicant, together with the expected benefit, and shall take into account the guidance and templates provided by their SoHO competent authority, in accordance with Article 21(1).

4. The clinical outcome monitoring plan shall include the clinical outcome monitoring as follows:

(a) in cases of low ~~benefit~~ risk, and a positive benefit-risk assessment, pro-active clinical follow-up of a defined number of SoHO recipients;

(b) in cases of moderate ~~benefit~~ risk, and a positive benefit-risk assessment, and cases where risk or benefit are not evaluable due to a lack of scientific and clinical data or knowledge, in addition to point (a), a clinical study of a pre-specified number of SoHO recipients required to be able to assess~~ing~~ pre-defined clinical endpoints;

(c) in cases of high ~~benefit~~ risk, and a positive benefit-risk assessment, and cases where risk or benefit are not evaluable due to a lack of scientific and clinical data or knowledge, in addition to point (a), a clinical study of a pre-specified number of SoHO recipients required to be able to assess~~ing~~ pre-defined clinical endpoints with a comparison to standard therapy.

5. The applicant remains responsible for collecting the data and must be able to have these data available upon request from the SoHO competent authority. ~~To record the clinical data generated during the clinical outcome monitoring, the applicant shall record those data via their own registries or existing clinical registries. In cases where the applicant SoHO entity chooses to use existing clinical registries, those registries shall be verified by the SoHO competent authority, or shall be certified by an external institution, in terms of the reliability of their data quality management procedures.~~

6. In case where SoHO supervisory activities~~vigilance~~ ~~reports~~ indicate a risk for SoHO donors, SoHO recipients or offspring from medically assisted reproduction, SoHO competent authorities may stop clinical outcome monitoring and withdraw the previous approval of the clinical outcome monitoring plan.

Article 23

Joint SoHO preparation assessments

1. At the request of one or more **SoHO** competent authorities, **via their SoHO National Authority to another SoHO National Authority, ~~or a SoHO entity,~~** SoHO preparation assessments as referred to in Article 22 may be carried out by **SoHO preparation assessors assigned by** ~~competent authorities from~~ more than one Member State, as a joint SoHO preparation assessment.

2. **With the previous consent of the SoHO National Authority, t**~~T~~he **SoHO** competent authority receiving a request for a joint SoHO preparation assessment **shall make all reasonable efforts to accept such request, taking into account their available resources** ~~may accept such a request, and coordinate and support that assessment, where that competent authority agrees that there are reasonable grounds for conducting a joint assessment~~.

~~**2a. The SoHO competent authority receiving a request for a joint SoHO preparation assessment and in charge of the authorisation of the SoHO preparation shall be the leader of the joint SoHO preparation assessment.**~~

3. **The SoHO** ~~C~~competent authorities participating in a joint **SoHO preparation** assessment shall conclude a prior written agreement **to carry out** ~~on~~ the joint assessment. **Such written** ~~The~~ agreement shall **specify** at least ~~defines~~ the following:

(a) the scope of the joint assessment;

(b) the roles of the participating assessors during and following the assessment; ~~including the designation of an authority leading the assessment;~~

(c) the powers and responsibilities of each of the **SoHO competent** authorities **involved.**

The SoHO competent authorities participating in the joint SoHO preparation assessments shall commit themselves in that agreement to jointly accept the results of that assessment.

The agreement shall be signed by all the participating SoHO competent authorities, including the respective SoHO National Authorities, according to the requirements developed by the SCB.

4. Member States may set up joint **SoHO preparation** assessment programmes to facilitate frequent or routine joint assessments. **Member States may operate such programmes under a single written agreement as referred to** ~~In such cases, competent authorities may sign a single written agreement provided that agreement meets the requirements~~ in paragraph 3.

4a. For the purposes of coordinating and performing joint SoHO preparation assessments, as referred to in this Article, SoHO competent authorities shall take into

account the relevant best practices agreed and documented by the SCB, as referred to in Article 68(1), point(c).

5. ~~On completion of a joint SoHO preparation authorisation, the competent authority in the territory where the SoHO preparation authorisation holder is based shall submit the information, as pursuant to Article 21(3), regarding the new authorised SoHO preparation in the EU SoHO Platform~~.

Article 24

Specific obligations concerning SoHO preparation assessors

1. **SoHO preparation** ~~A~~**a**ssessors shall:

   (a) **be in** possess**ion of** a diploma, certificate or other evidence of formal qualifications in ~~the field of medical , or biological sciences~~**a relevant the field of medical, pharmaceutical or life sciences**, awarded on completion of a university course of study or a course **qualification** recognised as equivalent by the Member State concerned;

   (b) have expertise in the processes being assessed ~~and~~ **or** the human applications for which the SoHO preparations will be used.

2. The assessment of SoHO preparations as referred to in Article 22 may be done jointly by a team of persons which collectively have the qualifications and experience set out in paragraph 1.

3. In exceptional cases, **SoHO** competent authorities may consider that a person's considerable and relevant experience may exempt this person from the requirements set out in paragraph 1.

4. Before **SoHO preparation** assessors take up their duties, **SoHO** competent authorities shall provide **SoHO preparation** assessors with a specific induction training on the procedures to be followed for the assessment of SoHO preparations in accordance with Article 22.

5. **SoHO** ~~C~~**c**ompetent authorities shall ensure that the specific induction training is complemented by specialised training for assessment of processing methods and

technologies used for specific types of SoHO preparations and by continuous training, as appropriate, throughout the career of the **SoHO preparation** assessors. **SoHO** ~~C~~**c**ompetent authorities shall make all reasonable efforts to ensure that **SoHO preparation** assessors that participate in joint **SoHO preparation** assessments have completed the relevant Union training referred to in Article 69(1) and are included in the list referred to in Article 69(5).

6. **SoHO preparation** ~~A~~**a**ssessors may be assisted by technical experts provided that **SoHO** competent authorities ensure that those experts comply with the requirements of this Regulation, in particular with the obligations set out in Articles 7, **75** and 76.

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 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** ~~SoHOs~~**,meet the definition in A**~~**a**~~**rticle 3(40),** 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 establishment.

~~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. SoHO ~~C~~**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.

SoHO competent authorities shall inform the SoHO entity of such decision.

~~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).~~

~~*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 27

Authorisation of SoHO establishments

1. **SoHO c**~~C~~ompetent authorities shall provide guidelines and templates to allow that applications ~~from SoHO entities~~ for the~~ir~~ authorisation ~~as~~ **of** SoHO establishments are submitted in accordance with Article 49. When developing these guidelines and templates, **SoHO** competent authorities shall ~~consult~~ **take into account** the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c). **SoHO competent authorities may use the secure communication channel on the EU SoHO Platform for the exchange, with the SoHO establishment, of documents relating to the application for an authorisation.**

2. Upon receipt of an application for the authorisation of a SoHO establishment, **SoHO** competent authorities shall:

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

(b) assess the application;

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

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

(e) carry out an on-site ~~system~~ inspection of the applicant SoHO establishment **pursuant to Article 29,** and, where applicable, ~~of third parties~~ **SoHO entities or third parties** contracted by the SoHO establishment ~~to perform SoHO activities,~~ pursuant to Article **30**~~**(1)**29~~;

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

(g) grant or refuse the authorisation of the applicant SoHO establishment as a SoHO establishment, as appropriate, and indicate which **SoHO and which** SoHO activities **for each SoHO** are covered ~~**for each SoHO**~~ by the authorisation and which conditions apply, if any;

(h) ~~assess and, as appropriate, approve subsequent changes made by the SoHO establishment to the information provided in the application and communicated to them according to Article 49(2);~~

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

(j) assess and, as appropriate, ~~approve~~ **authorise any significant** ~~subsequent~~ changes made by the SoHO establishment to the information provided in the application and

communicated to them according to Article 49(2), **and update the information in the EU SoHO Platform**~~.~~[22]

3. **SoHO c**~~C~~ompetent authorities may**, in accordance with national legislation,** suspend the authorisation of a SoHO establishment, or of certain SoHO activities the establishment is authorised to perform, if SoHO supervisory activities demonstrate or give reasonable grounds for suspecting, that the SoHO establishment in question:

   (a) does not comply with the conditions of its authorisation**;** ~~or the provisions of this Regulation; and~~

   (b) **does not comply with the provisions of this Regulation; and**~~/~~**or**

   (c) ~~that non-compliance, or suspected non-compliance, implies~~ a risk to the safety of SoHO donors**,** ~~or~~ recipients or offspring from medically assisted reproduction**, or a risk of unnecessary wastage of SoHO**~~**s**~~**, is identified**.

   SoHO c~~C~~ompetent authorities shall specify a period of time for the investigation of a suspected non-compliance and for the SoHO establishment to rectify a confirmed non-compliance, during which the suspension will remain in place.

4. In cases where **SoHO** competent authorities have confirmed non-compliances referred to in paragraph 3 and SoHO establishments are not able to rectify them in the specified time period, **SoHO** competent authorities shall, in accordance with national legislation, withdraw the authorisation of a SoHO establishment.

5. **SoHO c**~~C~~ompetent authorities may, in accordance with national legislation, withdraw the authorisation of a SoHO establishment if **a suspension, as described in paragraph 3, is not sufficient to resolve the identified shortcomings.**~~the **SoHO** competent authorities have confirmed that the SoHO establishment no longer complies with updated criteria for authorisation or the SoHO establishment has repeatedly **does not** failed to comply with the conditions of its authorisation**, or a risk is identified which cannot be resolved during a suspension.**~~

6. In cases of authorisation suspension or withdrawal, as referred to in paragraphs 3, 4 and 5, **SoHO** competent authorities shall amend accordingly the authorisation status of the SoHO

[22] ~~Para j shows revision to the original para h that is proposed to be moved.~~

establishment concerned in the EU SoHO Platform ~~as referred to in Chapter XI~~ without undue delay.

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 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 Article 27(2). 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 quality, safety~~, ~~quality~~ **and effectiveness, to SoHOs preparations authorised according to the provisions of this Regulation.**

~~(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 specific SoHO recipient or to an operator for manufacturing a product under other Union legislation, as referred to in Article 2(3), SoHO competent authorities may choose to carry out only a document review-based inspection.

~~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. **SoHO** ~~C~~**c**ompetent authorities may require to inspect any ~~party in a~~ third country **supplier** ~~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 SoHO~~s~~ from the same ~~party~~**third country supplier**.

~~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~~ **shall be** 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 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 ~~on~~ **of those** SoHO establishments, **and where applicable, of SoHO entities or third parties contracted by SoHO establishments.**~~, as appropriate:~~

1a. 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 (d),~~ ~~Article~~ 28(4), ~~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~~ corrective and preventive **actions.** ~~actions~~.

~~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** means**, or by remote document review** ~~of a remote document review~~, provided that:

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

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

ba) protection of SoHO donors, SoHO recipients or offspring of medically assisted reproduction 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**~~Inspectors 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) t~~T~~he technical guidelines published by the ECDC and by the EDQM referred to in Articles 56(4), point (a), and 59(4), point (a), as applicable, the inspectors shall consider the standards ~~or elements thereof~~**set out in this Regulation**, to be met, insofar as they are addressed by the guidelines **referred to in this subparagraph**;

(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~~set out in this Regulation, to be met, insofar as they are addressed by the guidelines referred to in this subparagraph**~~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 referred to in paragraph 7a, first subparagraph, point (a) and the achievement of equivalent levels of quality and safety, as provided in this Regulation.** ~~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**a**, ~~second~~ **first** 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 one **or more** ~~or more~~ of the following activities**:** ~~:~~

(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 **compliance of** the procedures and the SoHO activities performed ~~in SoHO establishments and, where applicable, in facilities of third parties that are relevant to~~ **with** 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*;*

(da) evaluate the compliance with the vigilance system and the traceability system;

(e) take samples for analysis**,** ~~and~~ copies of documents**, and photographs~~ie~~ or videos ~~recording,~~** if required;

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

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

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, four 4 years.**~~, on a risk basis and with appropriate frequency.~~**. 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~~ **the** 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. 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, w~~**When the result of the inspection so requires,** the **SoHO** competent authorities ~~may~~**shall, as appropriate,** set out any corrective or preventive action needed or ~~may~~**shall** request the SoHO establishment to respond with a proposal for such actions, with 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).

Article 30

Inspections of ~~other~~ SoHO entities other than SoHO establishments and of third parties

1. **SoHO c**~~C~~ompetent authorities may carry out inspections pursuant to Article 29(1) ~~on~~ **of** SoHO entities other than SoHO establishments**, and of the third parties contracted,** as necessary and proportionate to the risks associated with the SoHO~~s~~ and the SoHO activities registered for that SoHO entity, and the SoHO entity's past **compliance** record**s**~~, in particular as regards the outcome of previous inspections carried out on it and its compliance with the rules of this Regulation~~.

2. In the cases referred to in paragraph 1, Article 29 shall apply, *mutatis mutandis*, to the inspection of SoHO entities other than SoHO establishments **and of the third parties contracted**.

3. ~~For the purpose of a standardised approach to the inspection of SoHO entities other than SoHO establishments, competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).~~

Article 31

Joint inspections

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

2. **With the previous consent of the SoHO National Authority,** ~~T~~**t**he **SoHO** competent authority receiving a request for a joint inspection~~,~~ shall make all reasonable efforts to accept such request, **taking into account their available resources,** ~~and coordinate and support that inspection,~~ in cases where:

   (a) **the SoHO entity to be inspected performs SoHO activities in more than one Member State, that have impact in the requesting Member State** ~~it is demonstrated, or there is reasonable ground for suspecting, that the activities carried out on the~~

~~territory of another Member State pose a risk to the safety and quality of SoHOs distributed in the requesting Member State;~~

(b) **SoHO** competent authorities of the requesting Member State require specialist technical expertise of another Member State for that inspection;

(c) the **SoHO** competent authorit**iesy** ~~ ~~ of the Member States receiving the request ~~ agree~~s that there are **other reasonable** ~~other reasonable~~ grounds for conducting a joint inspection.

3. The **SoHO competent** authorities participating in a joint inspection shall conclude a~~n~~ **written** agreement prior to **carrying out** the inspection**. Such written agreement shall specify** ~~that defines~~ at least the following:

(a) the scope and objective of the joint inspection;

(b) the roles of the participating inspectors during and following the inspection, **including the designation of the SoHO competent authority leading the inspection**~~including the designation of an authority leading the inspection~~;

(c) the powers and responsibilities of each of the **SoHO competent** authorities **involved**.

The **SoHO competent** authorities participating **in the joint inspection** shall commit themselves in that agreement to jointly accept the results of the inspection. **The agreement shall be signed by all the participating SoHO competent authorities, including the respective SoHO National Authorities.**

4. The authority leading the joint inspection shall **be a SoHO competent authority** ~~ensure that joint inspections are carried out in accordance with the national legislation~~ of the Member State in which the joint inspection takes place **and shall ensure that the joint inspection is carried out in accordance with their national legislation**.

The SoHO competent authority supervising the SoHO entity to be inspected through a joint inspection shall inform the SoHO entitiy in advance about the inspection and its nature unless there are reasonable grounds, duly justified, to suspect that such prior communication would compromise its effectiveness. ~~The competent authority for the SoHO entity or SoHO establishment concerned shall, prior to the inspection, inform that SoHO~~

~~entity or SoHO establishment about the joint inspection, unlessthe competent authorities concerned have reasonable grounds to suspect illegal or fraudulent activity~~.

~~5. Articles 7, 8 and 76 shall apply to all competent authorities involved in joint inspections.~~

6. Member States may set up joint inspection programmes to facilitate routine joint inspections. Member States may operate such programmes under a single **written** agreement as referred to in paragraph 3.

6a. SoHO competent authorities shall take into account the relevant best practices agreed and documented by the SCB, as referred to in article 68(1), point (c).

Article 32

Specific obligations concerning inspectors

1. Inspectors shall possess a diploma**, certificate or other evidence of formal qualifications**~~, certificate or other evidence of formal qualifications~~ in a relevant field, **awarded on completion of a university course of study** ~~awarded on completion of a university course of study~~ or a **course** ~~course~~ recognised as equivalent by the Member State concerned.

   In exceptional cases, **SoHO** competent authorities may consider that a person's considerable and relevant experience may exempt this person from the requirement set out in the first subparagraph.

2. **SoHO** ~~C~~**c**ompetent authorities shall provide inspectors with a specific induction training before inspectors take up their duties. For the specific induction training, **SoHO** competent authorities shall **take into account**~~consult~~ the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).

3. **SoHO** ~~C~~**c**ompetent authorities shall ensure that the specific induction training includes at least the following:

   (a) the inspection techniques and procedures **to be followed, including practical exercises** ~~to be followed, including practical exercises~~;

(b) an overview of relevant Union and national inspection guidance, **where applicable,** and the best practices agreed and documented by the SCB as referred to in Article 68(1), point (c);

(c) **an**~~on~~ overview of the authorisation systems in the Member State concerned;

(d) the applicable legal framework for the performance of SoHO supervisory activities;

(e) **an overview of the** technical aspects concerning SoHO activities;

(f) SoHO technical guidelines as referred to in Articles 56 and 59;

(g) an overview of the organisation and functioning of national regulatory authorities in the field of SoHO~~s~~ and related fields;

(h) an overview of the national health system and SoHO organisational structures in the Member State concerned.

4. **SoHO** ~~C~~**c**ompetent authorities shall ensure that the specific induction training is complemented by **specialised** ~~specialised~~ training for inspection of specific types of establishments and by continuous training, as appropriate**.** ~~, throughout the career of the inspectors.~~ **SoHO** ~~C~~**c**ompetent authorities shall ~~make all reasonable efforts~~**endeavour** to ensure that inspectors that participate in joint inspections have completed the relevant Union training referred to in Article 69(1) and are included in the list referred to in Article 69(5).

5. Inspectors may be assisted by technical experts provided that the **SoHO** competent authorities ensure that those experts comply with the requirements of this Regulation~~, in particular with the obligations set out in Articles 7 and 76~~.

~~6. Paragraphs 1 to 5 shall also apply to delegated bodies.~~

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, via the EU SoHO Platform,** complete and accurate **an** annual reports of those activities**. The EU SoHO Platform shall allow the compilation of the annual reports submitted by the SoHO entities and provides the SoHO competent authorities with an aggregated annual 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 may decide if that SoHO entities submitmay delegate the submission of the activity data referred to in Article 44(1) to SoHO competent authorities through national or international registries, in cases where such registries collect activity data matching the data sets defined in the EU SoHO Platform. In this case, the SoHO competent authorities shall submit an annual aggregated report to the EU SoHO platform.

2. **SoHO c**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.**

3. The Commission shall compile the annual aggregated reports from the SoHO competent authorities, prepare and, after having shared the report with the SoHO National Authorities for review and approval, publish and make available on the EU SoHO platform an aAnnual SoHO Activity Report.

Article 34

Traceability and coding

1. **SoHO C**competent authorities shall verify that SoHO entities have appropriate procedures in place to ensure traceability and coding of SoHOs as referred to in Article 45.

2. **SoHO C**competent authorities shall establish procedures for **ensuring** the unique identification of SoHO establishments **entities** that are subject to the provisions on the Single European Code in Article 46. **SoHO c**Competent authorities shall **ensure**ensure **verify** that

such identification complies with the technical standards defined for that coding system. For this purpose, **SoHO** competent authorities may use a SoHO establishment identification code generated by the EU SoHO Platform.

Article 35

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). SoHO competent authorities shall also establish procedures for the receipt of SAR or SAE notifications, 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 **SARE or SAER 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~~**SARE or SAER** 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 corrections are required**.

5. **SoHO** ~~C~~**c**ompetent authorities may carry out inspections, pursuant to Articles 29 or 30, as appropriate, when the **SARE or SAER** ~~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**~~ **constitute a public health threat**.

6. Upon receipt of a **SARE or SAER** ~~SAO~~ notification with implications for **quality,** safety, ~~quality~~ or supply of a ~~**SoHO-derived**~~ product manufactured **from a SoHO** under other Union legislation ~~from 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 Regulation (EU) 2017/745, or information regarding a serious adverse reaction 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 without undue delay the information to the SoHO establishment that ~~supplied~~ released 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 ,** 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** ~~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~~ **SAR~~E~~ or SAE~~R~~** 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 **SAR~~E~~ and SAE~~R~~** ~~SAO~~ notifications and **the** ~~SAO~~ investigation reports ~~of~~ **confirmed SAR or SAE** ~~received~~. **This report shall include recommendations, arising from an analysis of the SAR~~E~~ and SAE~~R~~ reported, where necessary.**

10a. ~~The~~ SoHO National Authorities shall submit an annual summary of **confirmed SAR or SAE** ~~those SAO~~ notifications and investigation reports 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 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).

Article 36

SoHO rapid alerts

1. **SoHO c**~~C~~ompetent authorities shall, upon receipt of a notification of a S**AR or a SAE**~~AO~~ or other information with implications for **quality,** safety ~~or quality~~ or supply of SoHO~~s~~ in ~~one or~~ more **than one** Member State~~s~~**, inform their SoHO National Authorities, which shall, in turn** launch a SoHO rapid alert on the EU SoHO Platform ~~referred to in Chapter XI~~.

2. **SoHO National** ~~Competent~~ **A**~~a~~uthorities shall launch a SoHO rapid alert in particular in the following circumstances:

   (a) a risk to the quality or safety of SoHO~~s~~ has been identified concerning SoHO~~s~~ that have been distributed from their Member State to at least one other Member State;

(b) an outbreak of a communicable disease has occurred in their Member State and they have put in place donor deferral or testing measures to mitigate the risks of transmission by SoHOs~~s~~;

(c) a defect or serious supply interruption has occurred concerning equipment, devices, materials or reagents that are critical for the collection, processing, storage or distribution of SoHOs~~s~~ and that might be used in other Member States;

(d) other information is available to the **SoHO National** ~~competent a~~**A**uthorities that could reasonably be considered useful in other Member States to reduce risks to the **quality or** safety ~~or quality~~ of SoHOs**:** ~~;~~ and where

~~**(e)**~~ the launch of a SoHO rapid alert ~~would be~~**is** proportionate and necessary.

3. The ECDC, with the support of its SoHO expert network, may also launch an alert in the EU SoHO Platform when surveillance of communicable diseases indicates a new risk to the safety of SoHOs. The ECDC may indicate in such an alert that it has provided guidelines on the mitigation of risks associated with communicable disease outbreaks, in particular concerning the eligibility and testing of SoHO donors.

4. **SoHO National c**~~Competent a~~**A**uthorities that receive a SoHO rapid alert shall communicate **relevant** information to **SoHO competent authorities in their Member State and to** the relevant ~~organisations representing groups of~~ SoHO entities ~~or professionals~~ without undue delay with a view to ensuring that risk mitigating actions can be taken promptly and that relevant information available **among professionals** ~~at~~ **in** the SoHO **sector** ~~professional level~~ can be shared with the **SoHO** competent authorities. **SoHO National** ~~Competent a~~**A**uthorities may also supplement the information provided in the alert with further information such as details of relevant mitigating actions taken in their Member State.

5. **SoHO National** ~~Competent a~~**A**uthorities and the ECDC shall **take into account** ~~consult~~ the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c), when launching and handling a SoHO rapid alert.

CHAPTER IV

GENERAL OBLIGATIONS ON SOHO ENTITIES

Article 37

SoHO entity registration

1. Entities shall register as a SoHO entity before commencing any **of the** SoHO activity~~y~~**ies referred to in Article 2(1a)**. ~~**SoHO entities shall not carry out any of the activities without prior confirmation of verification by the SoHO competent authority.**~~

1a. SoHO activities shall not be carried out by individuals that are not operating within a registered SoHO entity.

1b. ~~-~~To register, the~~y~~ **SoHO entity** shall provide the **following** information ~~as referred to in Article 18.~~:

(a) name of the SoHO entity and all addresses where the SoHO activities are performed by the SoHO entity;

(b) name and contact details of the ~~person~~ responsible person~~for communication with the relevant SoHO competent authority~~ as referred in Article 37a;

~~**(c) a declaration that the SoHO entity will maintain a quality management system appropriate to its activities;**~~

(d) acknowledgment from the SoHO entity that it may be inspected pursuant to Article 30 and that it will cooperate with the relevant SoHO competent authority in any matter relating to the conduct of supervisory activities included in this Regulation;

(e) a list of the SoHO~~s~~ and SoHO~~its~~ activities, as listed in Article 2(1~~a~~c), that the SoHO entity ~~is~~ carries~~ying~~ out; when the SoHO entity carries out the activity referred to in Article 2(1c), point (iv), they shall also provide the name of the SoHO establishment responsible for the SoHO release prior to distribution;

(f) where applicable, a list of SoHO establishment(s) for which the SoHO entity performs SoHO activities covered by an agreement.;

(g) where applicable, details of any accreditation or certification received from an external body;

(h) where applicable, information regarding activities carried out and regulated under other Union legislation, as referred to in Article 14 ~~(-1a)~~;

1b. SoHO entities shall~~may~~ declare, when registering, that they need an authorisation pursuant to Articles 21, 27 or 28. They shall~~may~~ also conduct a self-assessment of whether they meet the criteria for being a critical SoHO entity and communicate the result.

~~SoHO entities~~**Organisations** may request from their **SoHO** competent authorities**, within their territory** an opinion on **whether the activities they are carrying out are subject to** ~~the applicability of~~ the registration requirements in this Chapter ~~to the SoHO activities concerned prior to the registration~~.

2. In Member States where the EU SoHO Platform is used for registration of SoHO entities, as referred to in Article 18(**1**~~2~~), organisations meeting the definition of a SoHO entity shall register directly in the EU SoHO Platform in accordance with their **SoHO** competent authorities' instructions.

3. SoHO entities ~~that implement changes to their SoHO activities or contact details~~ shall register ~~those changes~~ without undue delay **changes to information registered pursuant to paragraph 1a points (a), (b), (e), (f), (g) and (h)**. Where such changes imply SoHO activities including ~~both~~ **either** processing and storage**, or release, or import or export** ~~-~~of SoHO**s**, those SoHO entities shall ~~comply with the requirements of Articles 48 and 49~~**apply for an authorisation as SoHO establishment**.

~~**If the SoHO entity stores SoHO for autologous application, the person that donated the material shall be informed of the cessation of the activities by the SoHO entity.**~~

3a. In case a registered SoHO entity partially or totally ceases to carry out its SoHO activities, it shall communicate this change on the register for SoHO entities without

undue delay, indicating to which SoHO entity it will transfer SoHO for storage, and the data referred to in Article 45, when applicable.

3b. In case of storage of SoHO intended for autologous or within couple use, or highly matched SoHO for a specific SoHO recipient, if the SoHO entity ceases activities affecting the storage or the possible use of such SoHO, it shall inform the persons from whom such SoHO were collected, and provide them with information about the new SoHO entity that will store them.

Article 37a

Responsible Person

1. SoHO entities shall designate a person responsible, within their entity, for ensuring that SoHO activities carried out by the SoHO entity comply with the requirements of this Regulation ~~and reporting obligations~~, as relevant to the SoHO activities carried out, are fulfilled.

1a. The responsible person shall be in possession of a diploma, certificate or other evidence of formal qualifications in the field of medical, pharmaceutical or life sciences awarded on completion of a university course of study or a course qualification recognised as equivalent by the Member State concerned and shall have at least two~~2~~ years of experience in the relevant field.

2. SoHO entities shall inform their SoHO competent authority of the name and contact details of the responsible person ~~referred to in paragraph 1~~. Where the responsible person is permanently or temporarily replaced, the SoHO entity shall inform without undue delay their SoHO competent authorities of the name and contact details of the new responsible person and the date on which the duties of that person commence.

2a. ~~Responsible persons ofSoHO establishments shall designate one or more releasing officers as referred to in Article 38 and a physician, as referred to in Article 51.~~ The responsible person may ~~also~~fulfil the roles of releasing officer, as referred to in Article 49a, or the role of physician, as referred to in Article 49b, in cases where they are in possession of the required qualifications or experience as laid down in those articles.

Article ***37b*** ~~*50*~~[23]

Quality management system

1. SoHO e**ntities**~~stablishments~~ shall establish, maintain and update~~, as necessary,~~ a quality management system**, appropriate to 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.**

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;

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

(d) quality control, **and monitoring of key performance indicators** ~~as applicable,~~ of SoHO activities;

(da) quarantine and release

(e) withdrawal of SoHOs from the inventory of released SoHOs and recalls~~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** 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).

Article 40

SoHO preparation authorisation

1. SoHO entities shall not release or, in an autologous context **as referred to in Article 2(2)(a),** prepare and apply ~~immediately~~ to a **SoHO** recipient, SoHO preparations without prior SoHO preparation authorisation**, other than in the context of implementing an**

approved clinical outcome monitoring plan as part of SoHO preparation authorisation. ~~In cases where a SoHO entity modifies an activity carried out for an authorised SoHO preparation, it shall obtain an authorisation for that modified SoHO preparation.~~

2. SoHO entities may request **an opinion** ~~advice~~ from their **SoHO** competent authorities on the applicability of the authorisation requirements in this Regulation to their SoHO activities prior to submitting an application for a **SoHO** preparation authorisation.

3. SoHO entities may request to their **SoHO** competent authorities a derogation from the requirement for a SoHO preparation authorisation in ~~the~~ **emergency situations** ~~exceptional circumstances~~ referred to in Article 64**, or for a specific SoHO recipient when justified by the clinical circumstances, as referred to in Article 21(9a)**.

Article 41

Application for ~~the authorisation of~~ SoHO preparation authorisation

1. SoHO entities shall ~~send~~ **submit** applications for ~~the authorisation of a~~ SoHO preparation **authorisation** to the~~ir~~ **SoHO** competent authorit**y**~~ies~~ **of their territory**~~ies~~. ~~The applicant shall provide the name and contact details of the prospective SoHO preparation authorisation holder responsible for the application. This paragraph shall be without prejudice to Article 38(1).~~

2. The **applications for SoHO preparation authorisation** ~~applicant~~ shall **include** ~~provide~~ the following:

(-a) the name and contact details of the applicant SoHO entity responsible for the SoHO preparation authorisation;

(a) ~~a SoHO preparation dossier describing the~~ details of the SoHO activities performed for that SoHO preparation and including at least:

(-i) a description of the SoHO used for the SoHO preparation;

(i) **a ~~summary~~ list of** ~~any specific~~ **the specific** SoHO donor eligibility **criteria including ~~and~~** SoHO donor test**s specific for the SoHO preparation**~~ing procedures~~;

(ii) **a summary of** ~~any specific~~ SoHO collection procedures **and any specific quality controls carried out on the collected SoHO prior to processing**;

(iii) a description of the **steps of the** processing applied including **details of relevant materials and equipment used, environmental conditions and the process parameters and controls at each step** ~~details s of the air quality standards maintained in the processing facilities and the rationale for the air quality standard applied;~~

(iv) a description of equipment, reagents and materials **coming into direct contact with the SoHO during processing** ~~used~~ and their certification status in accordance with Regulation (EU) 2017/745 ~~**or Regulation (EU) 2017/746,**~~ **when applicable, and, in the case of the use of in-house developed equipment, reagents or materials, a** ~~**justification**~~ **evidence of the validation of their quality**;

(v) any specific storage **and transport** conditions and storage time limits **including validation of those conditions and limits**;

(vi) **a specification of the SoHO preparation including** ~~any~~ quality control and release parameters;

(vii) data ~~concerning procedures performed for~~ **resulting from** process validation and equipment qualification;

(viii) details of any **SoHO entities or** third parties contracted ~~by the SoHO entity~~ to perform activities **or relevant steps of the processing applied** for the SoHO preparation;

(ix) the clinical indications for which the SoHO preparation is to be applied **and the clinical data justifying this indication**;

(x) where relevant, non-clinical data on efficacy and toxicity of the preparation.

(b) the results of a **benefit-**risk assessment conducted on the combination of SoHO activities performed for the SoHO preparation, together with the intended clinical

indication for which **the application for authorisation is submited** ~~it is intended to be applied~~, taking into account:

(i) whether the SoHO preparation is described in, and aligned with, an EDQM SoHO monograph included in the technical guidelines referred to in Article 59(4) **or a specification included in technical guidelines referred to in Article 59(4),** ~~, point (a) or point (b)~~;

(ii) whether the SoHO preparation meets the defined quality criteria in the EDQM SoHO monograph referred to in point (i) and is intended to be used for the indication and with the mode of application to which that monograph refers, where such details are provided in that monograph **or meets** ~~**national**~~ **requirements as referred to in Article 59(4) point (b)**;

(iii) information regarding previous use and authorisation of the SoHO preparation **or a comparable SoHO preparation** in other SoHO entities, as available in the EU SoHO Platform;

(iv) **where applicable, clinical functionality** evidence generated as part of **conformity assessment procedures**~~the process of certification~~, in accordance with Regulation (EU) 2017/745, of **a** certified medical device **that is critical to the specific processing** ~~used~~ for the SoHO preparation**, in cases where the applicant has access to such data;** ~~, where available~~;

(v) documentation of a **standardised** ~~systematic~~ process of identification, quantification and evaluation of any risks to **SoHO** ~~the~~ donor**s**, **SoHO** ~~or the~~ recipient**s or the offspring from medically assisted reproduction** arising from the chain of activities performed for the SoHO preparation **and taking into account the technical guidelines published by EDQM for the performance of such risk assessments, as referred to in Articles 56(4)(a) and 59(4)(a)**;

~~**(ba) an evaluation of the potential benefits for SoHO recipients weighed against the risks identified in the assessment referred to in point (2)(b)(v).**~~

(c) in cases where the indicated risk is ~~other~~ **greater** than negligible, **or the expected clinical effectiveness is unknown,** a **proposed plan** ~~proposal~~ for clinical outcome

monitoring ~~to demonstrate safety, quality and efficacy~~ **for providing evidence, where necessary,** of the SoHO preparation, in line with the results of the **benefit-**risk assessment **and pursuant to Article 22(~~4a~~)**;

(d) an indication of the data which should be regarded as proprietary accompanied by verifiable justification, where appropriate.

3. ~~In the proposal referred to in paragraph 2, point (c), the applicant shall . propose a clinical outcome monitoring plan as follows:~~ **If the application for SoHO preparation authorisation includes recording the results of the clinical outcome monitoring in an existing clinical registry, in accordance with Article 22~~a~~(45), the applicant shall request approval for the use of such registry to their SoHO competent authorities.**

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

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

~~(c) in cases of high risk, in addition to point (a), a clinical investigation study of a statistically significant number of patients assessing pre-defined clinical endpoints with a comparison to standard therapy.~~

4. SoHO entities shall **prepare and distribute the SoHO preparation in question solely for the performance, and within the limitations of** ~~perform~~ the clinical outcome monitoring **after approval of the clinical outcome monitoring plan by the SoHO competent authority,** ~~once a conditional authorisation has been granted~~ pursuant to Article 21(2), point (c), and submit the results **and their analysis** to their **SoHO** competent authorities **according to the timeline set in the approval**. ~~In conducting the clinical investigation study as referred to in paragraph 3, points (b) and (c), for the SoHO preparation concerned, the applicant may use an existing clinical registry to record its results provided that their competent authorities have verified that the registry has data quality management procedures in place that ensure accuracy and completeness of data~~.

5. SoHO entities shall not make any **significant** change **within** ~~to the chain of~~ **steps of the processing applied or in the** activities performed for **an authorized** SoHO preparation ~~**subject to the authorisation**~~, without the prior written **authorisation** ~~approval~~ of their **SoHO** competent authorities.

SoHO entities shall also **inform, without undue delay,** ~~inform~~ their **SoHO** competent authorities **of any** changes **that might affect the authorisation, including the changes related to** ~~in the SoHO preparation authorisation holder's~~ **name and contact** details **of the SoHO entity previously authorised for the SoHO preparation**.

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

Article 42[24]

Importing SoHO ~~entity~~ establishment authorisation

1. SoHO ~~entities~~ **establishments** shall not import SoHO~~s~~ 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.~~

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 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 regarding the import of SoHOs in order to verify equivalent standards of quality, and safety of such imports.~~

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

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 regarding the import of SoHO in order to verify equivalent standards of quality, and safety of such imports..

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) documentation of the accreditation, designation, authorisation or licence of the third country supplier by a competent authority or authorities for the purposes of these activities.

(a) a written agreement as referred to in paragraph 1~~between the applicant SoHO establishment and any third country supplier contracted to supply SoHO. Such written agreement~~ shall include, at least:

(i) details of the third country supplier contracted;

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

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

(b) documentation describing the SoHO imported and proving that the procedures the third country suppliers have in place will ensure that the imported SoHOs will be equivalent, in terms of quality, 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~~**specific 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 and effectiveness requirements specified in the agreement referred to in paragraph 2 of this Article and when the physical and documentation controls referred to in paragraph 4 are satisfactory. In the case of national or international donor 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).~~

6. The Commission shall adopt implementing acts specifying the information to be provided in an application for an authorisation for importing SoHO 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).

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).

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 criteria defined in the SoHO platform and such registries have been verified by competent authorities as having in place data quality management procedures that ensure accuracy and completeness of data, SoHO entities may delegate the submission of the activity data referred to in this Article to such registries. The Commission shall aggregate the annual summaries of the SoHO entities, prepare and publish an Annual SoHO Activity Report.~~

4a. By derogation from paragraph 4, where SoHO competent authorities require SoHO entities to report activity data as referred to in Article 33(1a), SoHO entities shall submit their annual report of activity data to the indicated registries, before 30 June of the subsequent year.

Article 45

Traceability and coding

1. SoHO entities shall implement a traceability system**,** in order to unmistakably link each SoHO donor **or the person from whom SoHO are collected for autologous use,** to their SoHO ~~donation~~ and to all **the documents, samples, SoHO preparations and SoHO entities that are associated with that SoHO at any point.** ~~documents, samples, SoHO preparations and SoHO entities that are associated with that SoHO from the point of collection to human application and outcome monitoring. With regard to imported SoHOs,~~ **I**~~i~~mporting SoHO

~~entities~~ **establishments** shall ensure an equivalent level of traceability **with regard to imported SoHO**.

1a. The traceability system referred to in paragraph 1 should have the ability to:

(a) identify the SoHO donor or the person from whom SoHO are collected for autologous use and the establishment releasing the SoHO;

(b) identify the SoHO recipient at the SoHO entity applying the SoHO to the SoHO recipient, or the manufacturer of products regulated by other Union legislation, as provided for in Article 2(3);

(c) locate and identify all relevant data relating to the safety and quality of the SoHO and any materials or equipments coming into contact with those SoHO that might pose a risk to their ~~safety or~~ quality or safety.

2. SoHO entities distributing SoHO~~s~~ shall ~~generate~~ **apply** a code that contains the information included in the **requirements of the** traceability system referred to in paragraph 1. ~~They~~ **They** shall ensure that the code **generated**:

(a) is unique within the Union;

(b) is machine-readable, unless the size or storage conditions mean that a machine-readable code cannot be applied;

(c) does not reveal the identity of the **SoHO** donor **or the person from whom SoHO are donated in the case of autologous use**;

(d) complies with technical rules for the Single European Code (SEC) for SoHOs, referred to in Article 46, where applicable as indicated in that Article.

3. SoHO entities shall include the codes referred to in paragraph 2**, prior to distribution,** on the labels ~~to be~~ applied to the SoHO**,** ~~or SoHO preparations prior to distribution~~, or on the documents accompanying the distributed SoHO**,** ~~or SoHO preparations~~ where it can be

guaranteed that such documents will not be separated from the SoHO ~~or SoHO preparation~~ **or will be kept digitally linked to the SoHO** concerned.

4. SoHO entities shall use a labelling system that meets the labelling requirements set out in the relevant technical guidelines referred to in Articles 56(4) and 59(4).

4a. SoHO entities shall keep the data necessary to ensure traceability, **appropriately safeguarded and accessible to the SoHO competent authority,** for a minimum of 30 years **from the SoHO application date**. They may store the data in electronic form. **In case a SoHO entity ceases its activity, the traceability data shall be transferred to a contracted SoHO entity for the completion of the traceability period, with the prior ~~authorisation~~ information to~~of~~ the corresponding SoHO competent authorities.**

4b. The Commission shall adopt implementing acts concerning the minimum SoHO donor and SoHO recipient data set to be kept to ensure traceability.
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

Article 46

European coding systems

1. SoHO entities shall apply a Single European Code ('SEC') to SoHO ~~preparations~~ distributed for human application. In cases where SoHO~~s or SoHO preparations~~ are transferred for further processing in another SoHO **entity** ~~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** ~~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[25]. The SEC shall **also** appear on the **primary** packaging

[25] '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.

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;

   (c) SoHO~~s~~ applied to a **SoHO** recipient without being stored~~**, when donation and application of their own SoHO are carried out in the same 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);~~

   (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 SoHO~~s~~ at the point of distribution ~~or point of transport and delivery for further processing~~.

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

Article 47

Vigilance and reporting

1. SoHO entities shall maintain a system for detecting, investigating and recording information concerning adverse **reactions** ~~occurrences~~ **and adverse events**, including ~~adverse~~ **those**

~~occurrences~~ detected during clinical outcome monitoring as part of a SoHO preparation authorisation application as referred to in Article 41.

2. ~~Where applicable,~~ SoHO entities shall make all reasonable efforts to encourage prospective parents of children born from third party donation ~~to commit~~ to communicat~~e~~ information concerning ~~any~~ genetic conditions **as soon as they** ~~that~~ emerge **in the children**~~, as those children grow up~~, to the SoHO entity where they were treated. Th**at**~~e~~ **SoHO** entity shall communicate, without undue delay, th**at**~~e~~ information to the SoHO e~~ntity~~**stablishment** that **released**~~distributed or applied~~ the reproductive ~~cells~~**SoHO for application or distribution** with a view to **investigating the suspected SAR and** preventing further distribution of SoHO from the implicated SoHO donor**, in accordance with national legislation on the storage and use of reproductive SoHO**.

3. In cases where SoHO entities detect or suspect that an adverse **reaction or adverse event** ~~occurrence~~ meets the definition of a **SAR or a SAE** ~~serious adverse occurrence (SAO)~~, they shall submit a ~~SAO~~ notification to their **SoHO** competent authorities with**out**~~in~~ **undue delay and** ~~five working days. SoHO entities~~ shall include the following **information**~~in the notification~~:

   (a) a ~~full~~ description of the suspected SA**R or SAE**~~O~~;

   (b) a preliminary assessment of the level of imputability**, if applicable** ~~of the suspected SAO~~;

   ~~(c) a plan for an investigation to establish the level of imputability and the root cause;~~

   (d) **details of any immediate steps taken to limit harm, where applicable**~~proposed mitigation strategies~~;

   (e) a preliminary assessment of the seriousness of the consequences of the **suspected** SA**R or SAE**~~O for a donor, a recipient or the offspring from medically assisted reproduction or for public health in general.~~

3a. SoHO entities ~~that are not~~other than SoHO establishments shall communicate adverse reactions or adverse events to the SoHO establishment for which they carry out SoHO activities in the context of an agreement or to the SoHO establishment that distributed the SoHO to them, as appropriate. In such cases, the SoHO establishments receiving the

communication shall be responsible for the investigation and shall report to their SoHO competent authorities when the adverse reaction or adverse event concerned is deemed a SAR or a SAE ~~serious~~. All other SoHO entities shall investigate and report ~~serious adverse reactions~~SAR or SAE ~~events~~ directly to their SoHO competent authorities.

3b. Upon receipt of information regarding a serious incident and field safety corrective action within the meaning of Regulation (EU) 2017/745 or Regulation (EU) 2017/746, concerning a medical device or in-vitro diagnostic device that is used by a SoHO entity, the SoHO entity receiveing such information shall communicate it to its SoHO competent authority.

4. SoHO entities shall have in place a procedure to accurately, efficiently and verifiably withdraw from distribution or use those SoHO~~s~~ affected by adverse **reactions or adverse events**~~occurrence~~ referred to in paragraph **3**~~1~~, as appropriate**. In the case of reproductive SoHO, those procedures shall be in accordance with national legislation.**

5. SoHO entities shall conduct an investigation of each SA**R or SAE**~~O~~ detected. On completion of **that**~~an~~ investigation ~~of a SAO~~, SoHO entities shall provide a**n** ~~SAO~~ investigation report to their **SoHO** competent authorities pursuant to Article 35(4). The SoHO entities shall include in the report:

   (a) a full description of the investigation and the final assessment of the imputability ~~of the SAO~~ to the donation or application of the SoHO**, if applicable**~~;~~

   (b) the final assessment of the seriousness of the consequences ~~of the SAO~~ for a **SoHO** donor, a **SoHO** recipient or the offspring of medically assisted reproduction or for public health in general**, including a risk assessment of the likelihood of the recurrence risk, where relevant**;

   (c) a description of the corrective or preventive actions that have been taken to limit any harm or to prevent recurrence.

6. SoHO entities shall **communicate** ~~report~~ information concerning a SA**R or a SAE** to other SoHO entities engaged in the collection, processing, testing, storage and distribution of SoHO collected from the same **SoHO** donor, or otherwise possibly affected ~~by the SAO concerned~~. They shall only **communicate**~~report~~ information necessary and appropriate in order to facilitate traceability and ensure quality and safety in such cases, and shall, in particular, limit

the information to details necessary to take mitigating actions. **A risk assessment of the seriousness and likelihood of recurrence shall be included in the communication.** SoHO entities**, where relevant,** shall also **communicate** ~~report~~ such information to organ procurement organisations in cases where **the SoHO** ~~a~~ donor who is implicated in the SA~~O~~**R or SAE** has also donated organs **or** ~~**SoHOs**~~ **to manufacturers in cases where SoHO collected from that SoHO donor have been distributed to manufacture products regulated by other Union legislation, as referred to in Article 2(3)**.

CHAPTER V

GENERAL OBLIGATIONS ON SoHO ESTABLISHMENTS

Article 48

SoHO establishment authorisation

1. SoHO establishments shall not carry out any **of the SoHO** activities **that qualify them as an establishment according to art 3 (40),** without prior SoHO establishment authorisation. **In case of a need for an authorisation under Article 25(3), the establishment shall not carry out the activity motivating such a need for authorisation as communicated by the SoHO competent authority, without prior SoHO establishment authorisation.** This shall apply whether all activities are carried out by the SoHO establishment itself or one or more are contracted to another SoHO entity.

2. In cases where SoHO establishments contract other SoHO entities to perform part or all of certain SoHO activities, the SoHO establishments shall ensure that those contracted SoHO entities carry out those contracted activities in compliance with the provisions of this Regulation. Such contracted **SoHO** entities **may** ~~shall agree to~~ be audited by the **contracting** SoHO establishment~~s~~ **or inspected by the SoHO competent authority, in particular in cases where the contracted entity has not been accredited, certified or authorised, as part of a national programme, for the specific activities carried out under the contract.**~~to verify that the contracted activities are carried out in compliance with this Regulation. In addition, the contracted entities shall agree to be inspected by competent authorities if the~~

~~authorities require such inspection. The SoHO establishments shall document these agreements.~~

3. The requirement to obtain a SoHO establishment authorisation shall be without prejudice to more stringent measures put in place by a Member State pursuant to Article 4 and directly affecting the activities carried out in the SoHO establishment or contracted SoHO entities concerned pursuant to paragraph 2 of this Article.

Article 49

Application for SoHO establishment authorisations

1. SoHO entities shall ~~send~~ **submit** the application for authorisations as SoHO establishments to the~~ir~~ **SoHO** competent authorities **of their territories**.

2. The applicant SoHO establishment shall provide the name and contact details of the ~~prospective~~**responsible person**~~SoHO establishment authorisation holder responsible~~ for ~~the application and~~ carrying out the SoHO activities subject to the authorisation**, pursuant to Article 37a.** ~~. This paragraph shall be without prejudice to Article 38(1).~~ The ~~applicant~~ SoHO establishment shall not make any **significant** ~~substantial~~ changes ~~to~~ **with regards to** ~~the~~ **SoHO or** SoHO activities subject to the authorisation without the prior written ~~approval~~ **authorisation** of the **SoHO** competent authority. ~~The same shall apply in case of changes in the SoHO establishment authorisation holder's details.~~

2a. Significant changes for which an application for an updated authorisation shall be required pursuant to paragraph 2 are those relating to the types of SoHOs concerned, to the types of SoHO activities carried out, to the use of new premises or to the modification of premises having an impact on the conditions under which SoHO activities are carried out.

2b. SoHO establishments shall also, without undue delay, inform their SoHO competent authorities of any changes of an administrative nature, related to the SoHO establishment authorisation, including a change of responsible person.

3. The legal entity that holds the authorisation for the SoHO establishment ~~authorisation holders~~ shall be based in **the Member State where the SoHO establishment is authorised**~~the Union~~.

*Article **49a**~~38~~*[26]

Releasing officer~~sponsible person for release of SoHOs~~

1. In cases where a SoHO e**stablishment**~~ntity~~ releases SoHOs ~~or SoHO preparations~~ **for human application,** ~~for distribution for human application, or for the manufacture of products regulated by other Union legislation, or as the starting and raw material thereof, as referred to in Article 60,~~ **the responsible person, as referred to in Article 37a,** ~~that entity~~ **, it** shall designate **one or more releasing officers**~~a person responsible for release~~.

~~**1a. The nominated releasing officers shall be communicated to the SoHO competent authority.**~~

2. **The releasing officer** ~~The responsible person for release of SoHOs~~ shall be in possession of a diploma, certificate or other evidence of formal qualifications in the field of medical**, pharmaceutical** or ~~biological~~ **life** sciences awarded on completion of a university course of study or a course **qualification** recognised as equivalent by the Member State concerned and shall have at least **two** ~~2~~ years of experience in **the** ~~the~~ relevant field.

3. **The releasing officer** ~~The responsible person for release of SoHOs~~ may delegate the tasks **to carry out the activity** specified in paragraph 1 to other persons who shall be qualified by training and experience to perform such tasks. In such cases, that person shall perform those tasks under the responsibility of the **releasing officer who will always be responsible for the release.** ~~responsible person for release of SoHOs.~~ **The responsibility of releasing SoHOs may be delegated to an alternate in case of short term absence of a releasing officer, on condition that the alternate meets the requirements specified in paragraph 2.**

*Article **49b**~~51~~*[27]

~~P~~Physician

[26] This Article is adapted based on Article 38 which will be moved here. Moreover, the provisions of Article 49a as presented in 11823/23 are now reflected in Article 37a as presented in 12955/23

[27] This Article is adapted based on Article 51 which will be moved here.

1. ~~Each~~ SoHO establishment**s** shall designate a ~~-~~physician who ~~resides and~~ carries out its tasks in the same Member State and who shall at least fulfil the following conditions and have the following qualifications:

   (a) possession of formal qualification as a physician **and**

   (b) at least two years' practical experience in **the** relevant fields~~.~~

2. The ~~responsible~~ physician referred to in paragraph 1 shall be responsible for at least the following tasks:

   (a) development, review and approval of ~~policies and~~ procedures for establishing and applying SoHO donor eligibility criteria**, procedures for SoHO collection** and criteria for the allocation of SoHO**s** ~~and SoHOs preparations~~;

   (aa) supervision of the implementation of ~~policies and~~ procedures referred to in point (a) when they are carried out by SoHO entities contracted by the SoHO establishment;

   (b) **the clinical aspects of** investigation of suspected adverse **reactions** ~~occurrences~~ in SoHO donors**, SoHO** ~~and~~ recipients **and offspring from medically assisted reproduction from the perspective of the SoHO establishment;~~.~~**

   (c) design and supervision**, in collaboration with treating physicians,** of clinical data collection activities to **acquire**~~support~~ evidence gathering to support applications for SoHO preparation authorisations pursuant to Article 41;

   (d) other tasks of relevance to the health of **SoHO** donors**,** ~~and~~ **SoHO** recipients **and offspring from medically assisted reproduction** of SoHOs collected or supplied by the SoHO establishment.

2a. The physician may delegate the tasks specified in paragraph 2 to other persons who shall be qualified by training and experience to perform such tasks. In such cases, that person shall perform those tasks under the responsibility of the physician.

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

Article ~~49c~~39[28]

Export

new 1. SoHO e**stablishments**~~ntities~~ shall ensure that SoHO**s** ~~or SoHO preparations~~ **released for export** ~~exported or re-exported from the Union~~ comply with the ~~relevant~~ requirements of this Regulation**.**

~~unless the SoHO entity can demonstrate **SoHO** that the authorities of the importing country or the laws, regulations, standards, codes of practice or other legal and administrative procedures as may be in force in the importing country indicate that a deviation from the requirements of this Regulation is acceptable.~~

new 2. By derogation from paragraph new 1, SoHOs not complying with all the relevant standards and guidelines referred to in Articles 58 and 59 may be released for export in the circumstances of exceptional release pursuant to Article 61(new 3).

SoHO e**stablishments** ~~ntities~~ shall**, also in these circumstances,** not deviate from the standards referred to in Chapter VI~~.~~**, as well as those related to vigilance and traceability.**

CHAPTER VI

SoHO DONOR PROTECTION

Article 52

Objectives regarding SoHO donor protection

1. SoHO entities shall ensure ~~high levels of safety~~**respect for the dignity and integrity** of SoHO donors.

2. SoHO entities shall **ensure high levels of safety and** protect the health of living **SoHO** donors **from risks related to the donation. They shall do so, by identifying and minimising such risks** before, during and after the **SoHO collection**~~donation~~.

28 This Article is adapted based on Article 39 which will be moved here.

2a. SoHO competent authorities shall verify the compliance of the provisions laid down in this chapter as well as the national provisions on consent and voluntary and unpaid donation.

Article 53

Standards concerning SoHO donor protection

1. In case of collection of SoHOs 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;~~[29]

(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;

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

(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~~**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~~**monitor 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 **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 SoHO~~s~~ 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 **with a frequency that might negatively influence their health** ~~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 to in 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 shall ensure that any risks associated with the collection are explained to the individuals and are outweighed by the potential benefit for those individuals.~~

5a. In case of collection of SoHO~~s~~ from deceased SoHO donors, in accordance with national legislation, the paragraphs 1(a), (b), ~~(d),~~ (e) and (l) shall apply.

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 54

Standards concerning voluntary and unpaid nature of SoHO donations

1. SoHO entities shall not provide financial incentives or inducements to **SoHO** donors or ~~their relatives or~~ any persons granting ~~authorisation~~**consent** on their behalf**~~, in accordance with national legislation~~**, in accordance with national legislation~~.

2. Member States may allow for the ~~compensation or~~ reimbursement **of SoHO donors for** ~~from~~**actual expenses incurred in connection with SoHO donation or for** the **compensation of** SoHO ~~entities to~~ donors for losses related to their participation in **SoHO** donations**, including** through fixed rate allowances. In ~~such~~ case~~,~~ Member States **decide to reimburse or compensate SoHO donors,** ~~shall establish~~ the conditions for such **reimbursement or** ~~allowances~~ **compensation shall be established** in national legislation, including the setting of an upper limit that ensures ~~that allowances are financially neutral and~~**financial neutrality** consistent with the standards laid down in this Article. ~~They~~**Member States** may delegate the setting of conditions for such **reimbursement or** ~~allowances~~ **compensation** to independent bodies that are established in accordance with national legislation.

2a. When Member States allow for the reimbursement or compensation of SoHO donors as referred to in paragraph 2, t~~T~~he conditions for such reimbursement or compensation applied by each Member State shall be made available on the EU SoHO Platform and be updated without undue delay if modified.

2b. Member States shall take all necessary measures to ensure that any promotion and publicity activities in support of the donation of SoHO does not include the compensation or reimbursement as a~~n~~ promotional element of such activities.

3. SoHO entities may **reimburse or** compensate ~~or reimburse~~**SoHO** donors as provided for by their ~~competent authorities~~**Member States,** pursuant to paragraph 2.

3a. Member States shall take appropriate measures to ensure transparency in the fees for technical services required for making SoHO available.

Article 55

Standards concerning information to be provided prior to consent ~~or authorisation~~

1. SoHO entities shall provide ~~prospective~~ **living** SoHO donors~~, their relatives~~ or**, if applicable,** any persons granting ~~authorisation~~**consent** on their behalf, ~~in accordance with~~

~~national legislation,~~with all appropriate information relating to the donation ~~and collection~~ process**,** in accordance with national legislation~~, including a general description of the potential uses and benefits of the donation~~.

2. SoHO entities shall provide the information referred to in paragraph 1 before the consent ~~is given or authorisation~~**to donate** is granted ~~for the donation~~. SoHO entities shall provide the information in an accurate and clear manner, using terms that are easily understood by the ~~prospective~~ **SoHO** donors or**, if applicable,** ~~the~~**any** persons ~~to~~ **granting** consent ~~or authorise the donation. It shall not mislead the prospective donors or persons granting authorisation~~ on their behalf~~.~~**. The information shall not be misleading,** in particular, as to the benefits of the donation to future recipients of the SoHO concerned~~.~~

3. In case of living **SoHO** donors **or, if applicable, persons granting consent on their behalf**, SoHO entities shall provide information regarding:

(a) the purpose and nature of the donation;

(aa) the intended use of the donated SoHO, specifically covering proven benefits for the future SoHO recipients and any possible research or commercial uses of SoHO, including the use to manufacture products ~~for patients treated with products manufactured from SoHO and~~ regulated by other Union legislation, as provided for in Article 2(3), to which specific consent shall be granted;

(b) the consequences and risks of the donation;

(ba) the obligation for consent, in accordance with national legislation, in order for SoHO collection to be carried out;

(c) the right to ~~withdraw~~**revoke** consent and any restrictions on ~~the~~**that** right **after the collection**~~to withdraw consent following donation;~~

~~(d) the intended use of the donated SoHO, in particular covering proven benefits for the future recipients and any possible research or commercial uses to which the donor should consent;~~

(e) the **purpose of the** ~~analytical~~ tests that will be performed in course of the donor health evaluation**, in accordance with Article 53(2)**;

(f) the right of the ~~donor~~**SoHO donor or, if applicable, the person granting consent on their behalf** to receive the confirmed results of the ~~analytical~~ tests **when relevant for their health,** ~~when relevant for their health~~ **in accordance with national legislation**;

(g) the recording and protection of ~~donor~~**SoHO donor**'s personal ~~and~~**data, including** health data**,** and medical confidentiality, including any potential sharing of data in the interest of **the SoHO** donor health monitoring and of public health, as necessary and proportionate**, in accordance with Article 76**;

(ga) the possibility that the SoHO donor identity may be revealed to offspring born from their SoHO donation in cases where national legislation grants this right to such offspring;

(h) ~~the~~**other** applicable safeguards ~~intended~~ to protect the **SoHO donor.**

~~(i) the obligation for consent and authorisation, as applicable in the Member State, in order for SoHOs collection to be carried out.~~

3a. In case of deceased SoHO donors, SoHO entities shall provide any persons granting consent to donation, ~~according to the national law~~ and in accordance with national legislation, with the information referred to in paragraphs 3(a), (aa), ~~(ba),~~ and (c)~~, (e), and (g), as well as 3(f) for those cases in which the results of the health evaluation may affect persons related to the SoHO~~ donor ~~and their personal data;~~**.**

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**~~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 technical~~ **other** guidelines**, adopted by Member States, 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 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 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

Article 57

Objectives regarding SoHO recipient and offspring protection

SoHO entities shall protect the health of SoHO recipients and offspring from medically assisted reproduction from risks posed by SoHO ~~preparations~~**, within the scope of their respective competences**. They shall do so by identifying, minimising or eliminating those risks.

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 **that are potentially**

life-threatening, disabling or incapacitating, attributable to the donated SoHO that was applied, are not transmitted to **SoHO** recipients or offspring from medically assisted reproduction~~.~~**, to the extent that national legislation allows for genetic testing, 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 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, **taking 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 SoHO concerned,** including **serious** genetic conditions and cancer, from **SoHO** donors to the **SoHO** recipients or to offspring from medically assisted reproduction by combining, at least, the following measures:

(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**; 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 SoHO** during collection, processing, storage and distribution ~~by~~**. Such** measures ~~that~~**shall** ensure that physical contact between SoHO~~s~~ from different **SoHO** donors **, SoHO collected from different individuals for future autologous or within couple use,** is avoided or, in cases where ~~combining donations~~**pooling SoHO** is necessary for ~~efficacy~~**effectiveness or feasibility** of the SoHO preparation, is ~~minimised~~**limited to the ~~necessary~~ justifiable 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 hygiene procedures of the personnel of the SoHO entity in contact with the SoHO throughout the SoHO preparation chain;

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

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

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

(ca) quality control~~**testing**~~ **of SoHO for microbial** ~~**bacterial**~~ **contamination, when appropriate and 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 **harmful**~~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 **and use**;

(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 SoHO** 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** 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**~~, when such matching is necessary;~~

(aa) **including procedures~~using processing technologies~~ to reduce, when feasible, those elements of SoHO 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 SoHO from third party donation shall comply with rules established in national legislation regarding the limits of offspring from medically assisted reproduction or applications with reproductive SoHO from a single SoHO donor, if applicable. SoHO entities shall monitor compliance with such limits via registries for gamete donors, in accordance with the national legislation . Without prejudice of the former, when reproductive SoHO are distributed to another Member State, the applicable limits 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 is 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)**.**~~,~~ **or**, ~~**Further exceptions are**~~ **in the context of use pursuant to Article 21(9a), an individual treatment attempt with respect to the** ~~**freedom**~~ **clinician's decisions of on 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 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 allogenic SoHO for purposes other than the prevention or treatment of a medical condition, or for medically assisted reproduction.

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 **from a living SoHO donor** ~~after death,~~**or, if applicable, with any persons granting consent on their behalf; or**

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

In case of ~~**living**~~ **donation, from a living SoHO donor, 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 questionnaires 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 SoHO 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 SoHO** ~~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 **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**~~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~~ **other** ~~technical~~ guidelines**, adopted by Member States, 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 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 (**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.

Article 60

SoHO release

A SoHO **establishment**~~entity~~ that releases SoHO~~s~~ for ~~human application~~**distribution or export** ~~or for manufacture of products regulated by other Union legislation, or as the starting and raw material thereof,~~**as referred to in Article 2(3),** shall have a procedure in place, under the control of the ~~responsible person for SoHO release~~**releasing officer,** as referred to in Article **49a**, **for SoHO release,** to ensure that the standards or elements of a standard referred to in Article**s** 58 and **59 and** their implementation~~, as referred to in Article 59~~, have been verified and documented prior to release and that all conditions included in any applicable authorisations in accordance with this Regulation have been complied with.

SoHO processed for autologous or within couple use, without SoHO storage, shall not require release before application if this is envisaged in the SoHO preparation authorization.

Article 61

Exceptional release

new 1. ~~The physician referred to in Article 51~~ **SoHO competent authorities. The physician referred to in Article 49b** may authorise ~~the responsible person for release of SoHOs~~**a releasing officer in a SoHO establishment** pursuant to Article **49a**, to release **for distribution** a certain SoHO **preparation** ~~preparation~~ for **its** application to a certain **SoHO** recipient in cases where that SoHO preparation does not meet all of the relevant standards ~~and guidelines~~referred to in Article**s 58 and** 59**, or their implementation, does not comply with the SoHO preparation authorisation provisions in Article 21, or has been imported under the derogation referred to in Article 28(9),** when the ~~significant~~ potential benefit for the **SoHO** recipient outweighs the risks and no alternative is available. ~~The physician shall authorise such an~~ **The** exceptional release **condition shall be**

explicitly indicated on the label or in the accompanying documentation associated with the released SoHO preparation.

new 2. Exceptional release, as referred to in paragraph 1, shall only **be authorised in the case of release for distribution, on the basis of a documented request from** ~~when~~ the physician treating the intended **SoHO** recipient**, where such a request includes a confirmation of full knowledge and agreement of any deviation from the provisions of this Regulation** ~~is in agreement~~. The physician referred to in Article **49b** shall document the decision process in a risk-benefit assessment. In such circumstances, the intended **SoHO** recipient**, or person granting consent on their behalf,** shall be informed of the exceptional release and shall give consent in accordance with national legislation prior to the SoHO application.

The SoHO establishment which releases for distribution, in coordination with the SoHO entity which applies the SoHO preparation, when applicable, shall establish a plan for monitoring SoHO recipient's health after application. The plan shall monitor the risks associated with the exceptional SoHO release. The SoHO establishment, in coordination which that SoHO entity, shall lay down a time period during which the monitoring shall continue.

new 3. Exceptional release, as referred to in paragraph new 1, may also be authorised in the case of release for export, on the basis of a documented request from a treating physician, or from a regulatory authority, in a third country, where such a request includes a confirmation of full knowledge of any deviation from the provisions of this Regulation.

new 4. Exceptional release, as referred to in paragraph new 1, may also be authorised in the case of certain SoHO to be used for the manufacture of a product regulated under other Union legislation and intended for a specific recipient, in cases where the SoHO do not meet all of the relevant standards and guidelines referred to in Articles 58 or 59 and on the basis of a documented request from the manufacturer, where such a request includes a confirmation of full knowledge and agreement of any deviation from the provisions of this Regulation.

CHAPTER VIII

SUPPLY CONTINUITY

Article -62

Critical SoHO supply sufficiency

1. Member States, in collaboration with SoHO National Authorities, SoHO competent authorities and SoHO entities within their respective tasks, shall strive for ~~make all reasonable efforts within their territories to ensure~~ a sufficient, adequate, affordable and resilient supply of critical SoHO~~s and to ensure that~~ aimed to ~~recipients needs are~~ to appropriately meet recipients' needs.

2. Member States shall make all reasonable efforts to facilitate public participation in SoHO donation activities for critical SoHO~~s~~, with a view to ensuring a broad SoHO donor base and a sufficient, adequate and resilient supply and responsive increases in donation rates when risks of shortage are detected, in accordance with Article 54. In so doing, they shall encourage the collection of SoHO with a strong public and non-profit sector involvement.

3. Critical SoHO entities shall establish appropriate mechanisms for the continuous monitoring of their stocks of critical SoHO and shall be in a position to communicate this information to SoHO competent authorities that shall establish appropriate mechanisms to receive this information~~for the continuous monitoring of the supply continuity of critical SoHO within their territory~~.

Article 62

~~Establishment of~~ N~~n~~ational 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~~ present~~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 SoHO** ~~to be involved~~;

(ba) critical SoHO entities emergency plans

(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 SoHO 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 **cooperate with** ~~inform~~ **the critical SoHO entities in the elaboration of their national SoHO emergency plans and shall** review **at least every four4 years such** ~~regularly their national SoHO emergency~~ plans **in order** to take into account changes in **the designation of critical SoHO entities,** the organisation of **SoHO** competent authorities and **the** experience gained from implementing the plans and simulation exercises.

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

Article 63

Supply alerts for critical SoHOs

1. Critical SoHO entities shall**,** without undue delay**, send**~~launch~~ a SoHO supply alert to their **SoHO** competent authorities in case of ~~a~~ significant **shortages**~~interruption~~ **of supply of critical SoHOs**, indicating the underlying reason**s**, the expected impact on **recipients** ~~patients~~ and any mitigating actions taken**,** including possible alternative supply channels if appropriate. ~~Interruptions~~ **Shortages** shall be considered significant when**:**

   (a) the application of critical SoHO **or the distribution of critical SoHO for the manufacture of products defined in other Union legislation, as referred to in Article 2(3),** is cancelled or postponed**, or is a significant risk of being cancelled or postponed,** due to unavailability**;** and

   (b) the situation referred to in point (a) ~~this~~ poses a serious risk to health.

2. **SoHO** ~~C~~**c**ompetent authorities that receive an alert referred to in paragraph 1 shall:

   (a) communicate the SoHO supply alert to their SoHO National Authority;

   (b) implement **appropriate** measures to mitigate the risks, ~~if and~~ to the extent possible; and

   (c) take into account the information received in accordance with paragraph 1 of this Article in the ~~regular~~ review of their national SoHO emergency plans referred to in Article 62.

3. The SoHO National Authorities **shall**~~may~~**may** ~~may~~ submit to the EU SoHO Platform the SoHO supply alert received **~~indicating, when possible, whether~~** ~~in cases where~~ **in cases where** the supply interruption might affect other Member States ~~or~~ **and may do so** where such interruption might be addressed through cooperation between Member States pursuant to Article 62(3), point (d).

Article 64

Derogation from the obligations to authorise SoHO preparations in health emergency situations

1. By way of derogation from Article 21, **SoHO** competent authorities may permit, on a request from a SoHO entity duly justified by a health emergency, the distribution or preparation for immediate application of SoHO preparations within their territory in cases where the procedures referred to in that Article have not been carried out, provided that**:**

(a) the use of those SoHO preparations is in the interest of public health**;**

(b) the SoHO preparations have a level of quality and safety that is acceptable to what is~~that~~ required by this Regulation or the available data indicate a positive benefit-risk assessment, and

(c) the SoHO preparation is for immediate application to a defined group of recipients, who has no therapeutic alternative, the treatment cannot be postponed and where the prognosis is life-threatening and the expected benefit outweighs the risks.

The intended SoHO recipients or, where applicable, persons granting consent on their behalf, shall be informed of the derogation and shall give their consent to the immediate application of that SoHO preparation, in accordance with national legislation, prior to the SoHO application itself.

1a. SoHO ~~C~~competent authorities shall**:**

(a) indicate the period of time for which ~~the permission~~ **the permit referred to in paragraph 1** is granted~~or shall define conditions enabling to clearly establish that period of time.~~ **and if such SoHO preparations may be distributed to other Member States**;

(b) instruct the requesting SoHO entity to submit an application for a SoHO preparation authorisation pursuant to article 41 and collect retrospectively data on the use of the SoHO preparation during the health emergency;

(c) inform the SoHO National Authority of the permit as referred to in paragraph 1 provided for the SoHO preparation concerned.

2. ~~Competent authorities shall inform the SoHO National Authority of the emergency authorisation.~~ The SoHO National Authority shall inform the Commission and the other Member States **via the EU SoHO Platform** of any decision to permit the distribution or preparation for immediate application of SoHO preparations in accordance with **paragraph 1.**

3. In~~, in~~ cases where such SoHO preparations might be distributed to other Member States**, the SoHO National Authority of the receiving Member State shall confirm the validity of the permit within its territory before the distribution takes place**.

~~*Article 65*~~

~~**Additional emergency measures by Member States**~~

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

Article 66

SoHO entity emergency plans

1. Each **critical** SoHO entity ~~carrying out SoHO activities that concern critical SoHOs~~ shall ~~have~~ **draw up** a SoHO entity emergency plan that ~~supports the implementation~~**implements** ~~of~~ the national SoHO emergency plan as referred to in Article 62.

1a. Member States may consider that the measures set out in Chapter VIII of this Regulation are at least equivalent to the obligations laid down in Directive (EU) 2022/2557.

CHAPTER IX

SOHO COORDINATION BOARD

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 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 SCB may also invite, where relevant, ~~O~~**o**ther 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 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**. ~~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. 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~~ **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) **the 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) **the** 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) **the** 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 A~~a~~uthorities,** 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;

(aa) By [one year after the date~~a~~ 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. This list shall be updated at the discretion of the SCB;

(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 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 Platform;

(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~~ or 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~~ for the performance of the SCB tasks**.

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

CHAPTER X

UNION ACTIVITIES

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.~~

Article 70

Commission verifications~~controls~~

1. The Commission shall perform **verifications to confirm whether** ~~controls, including audits, in the~~ Member States **effectively apply** ~~to verify the effective application of~~ the requirements relating to:

   (a) **SoHO** competent authorities and delegated bodies provided for in Chapter II;

(b) the SoHO supervisory activities ~~provided for in Chapter III as~~ carried out by **SoHO** competent authorities and delegated bodies;

(c) the notification and reporting requirements of this Regulation.

2. The Commission shall organise the ~~controls~~ **verifications** referred to in paragraph 1 in cooperation with the **SoHO National Authorities** ~~Member States~~, and shall carry them out in a manner that avoids unnecessary administrative burden.

3. When performing the ~~controls~~ **verifications** referred to in paragraph 1, the Commission ~~experts~~ shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c), on ~~inspection, vigilance and any other~~ SoHO supervisory activities ~~as needed.~~

4. ~~Experts from the Member States may assist~~ **T**~~t~~he Commission ~~experts~~**,** in carrying out the ~~controls~~ **verifications** referred to in paragraph 1, **may be supported by experts from the SoHO competent authorities**~~. The Commission shall~~ select**ed** ~~the experts from the Member States~~, whenever possible**,** from the list referred to in Article 69(5)~~,and~~**. Experts from the SoHO competent authorities** shall **be** give**n** the~~m~~ same rights of access as the Commission ~~experts~~.

5. Following each **verification**~~control~~, the Commission shall:

(a) prepare a draft report on the findings and, where appropriate, include recommendations **addressing** ~~on how best to address~~ the shortcomings **identified**;

(b) send a copy of the draft report referred to in point (a) to the concerned **SoHO National Authority**~~Member State~~ for its comments;

(c) take the comments ~~of the Member State~~ referred to in point (b) into account in preparing the final report; and

(d) make publicly available **a summary of** the final report **on the EU SoHO Platform** ~~referred to in point (c) and the comments of the Member State referred to in point (b).~~

Article 71

Cooperation with the EDQM

The ~~Commission~~ **Union** shall establish and maintain **a framework of** cooperation with the EDQM**,** ~~**in the form of a cooperation agreement,**~~ **notably** in relation to the guidelines published by the EDQM.

Article 72

Assistance by the Union

1. To facilitate the fulfilment of the requirements provided for in this Regulation, the Commission shall support implementation by:

   (a) providing secretariat and technical, scientific and logistic support to the SCB and its working groups;

   (b) funding Commission **verifications**~~controls~~ in Member States, including the costs of Member State experts assisting the Commission ~~in such controls~~;

   (c) providing funding from the relevant Union programme**s** in support of public health to:

      (i) support collaborative work between **SoHO** competent authorities and organisations representing groups of SoHO entities and SoHO professionals with the aim to facilitate effective and efficient implementation of this Regulation, including for training activities **referred to in article 69(1) and programmes for the exchange of SoHO competent authorities' personnel referred to in article 69(4)**;

      (ii) **if applicable, support financially in accordance with the relevant Union programmes, the** ~~co-finance a cooperation agreement with the EDQM to support the~~ development and updating of technical guidelines **with a view to contributing to the** ~~supporting **in order to support** the coherent~~ **consistent** implementation of this Regulation.

   (ca) establishing, managing and maintaining the EU SoHO Platform.~~;~~

(cb) facilitating the cooperation between the SCB and advisory bodies established by other Union legislation as referred to in Article 2(3), in particular through the organisation of joint meetings on the experience acquired with the application of Article 68(1)(b).

2. With regard to the support referred to in paragraph 1, point (a), the Commission shall, in particular, organise the meetings of the SCB and its working groups, the travel ~~of members of the SCB~~, reimbursement and special allowances for ~~scientific~~ **participants** ~~experts that participate~~ in those meetings~~, and ensure the appropriate follow-up~~.

3. Upon request from Member States, technical support may be provided, through the Technical Support Instrument established by Regulation (EU) 2021/240 of the European Parliament and of the Council[30], for the reform of national or regional SoHO supply supervision, provided those reforms aim to achieve compliance with this Regulation.

4. In order to perform the activities referred to in paragraph 1 to the mutual benefit of the Commission and of the beneficiaries, relating to preparation, management, monitoring **and verifications**~~, audit, and control~~, as well as to support expenditure, the Commission shall have recourse to the technical and administrative assistance it might need.

CHAPTER XI

EU SoHO PLATFORM

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").**

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

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, including health 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~~e~~ 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

SoHOs, **and SoHO activities**, including the submission, retrieval, storage, management, handling, exchange, analysis, publication**, tracking** and deletion of such data and documents as provided for in this Regulation.

2. The EU SoHO **P**platform shall also provide **a secure 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 a**A**uthorities 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, in relation to alerts related to communicable diseases, where applicable; and.

(f) ~~**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;

(c) the a~~A~~**annual Union SoHO Activity Report and annual Union 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 and non-communicable diseases published by the ECDC and the EDQM, and concerning SoHO donor, SoHO recipient and offspring protection ~~other than from transmission of communicable diseases published by the EDQM~~;

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

(h) the SoHO compendium;

~~. shall 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 **management, maintenance and** 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

Article 75

Confidentiality

1. Unless otherwise provided for in this Regulation or in national legislation on confidentiality, and without prejudice to Regulation (EC) No 1049/2001 of the European

Parliament and of the Council[31], each party involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect ~~the following:~~

~~(a) personal data in accordance with Article 76;~~

~~(b)~~ the effective implementation of this Regulation, in particular for the purpose of authorisations, inspections, **investigations**~~investigations~~ or Commission ~~controls~~**verifications**.

2. Information **and data** may be exchanged on a confidential basis between **SoHO** competent authorities and between **SoHO** ~~competent~~ **Nnational** **Aa**uthorities and the Commission, ~~but~~ **and** shall not be disclosed without the prior agreement of the **SoHO competent** authorities from whom that information originates.

3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and **SoHO** competent authorities with regard to the exchange of information and the dissemination of alerts, nor the obligations of persons to provide information under national criminal law.

4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries **with which they have concluded bilateral or multilateral confidentiality arrangements,** as necessary and proportionate for the protection of human health.

5. **Without prejudice to national legislation on the publication of the outcome of SoHO supervisory activities, SoHO** ~~C~~**c**ompetent authorities may publish or make otherwise available to the public the outcome of SoHO supervisory activities regarding individual SoHO entities provided that the following conditions are met:

   (a) the SoHO entity concerned is given the opportunity to comment on the information that the **SoHO** competent authority intends to publish or make otherwise available to the public, prior to its publication or release, taking into account the urgency of the situation;

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[31] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

(b) the information **or data** which is published or made otherwise available to the public takes into account the comments expressed by the SoHO entity concerned or is published or released together with such comments;

(c) the information **or data** concerned is made available in the interest of public health protection and is proportionate to the severity, extent and nature of the associated risk**;** ~~.~~

(ca) the information or data made available to the public does not unnecessarily undermine the protection of ~~commercial interests~~legal rights of the SoHO entity or any other natural or legal person;

(cb) the information or data made available to the public does not undermine the protection of court proceedings and legal advice.

6. Regarding information or data that is, by its nature, covered by professional secrecy and that is obtained by **SoHO** competent authorities in carrying out SoHO supervisory activities, **SoHO** competent authorities may only publish or make that information or data available to the public, **without prejudice to national legislation,** provided that the **conditions described in paragraph 5 points (c) apply.**~~following conditions are met:~~

~~(a) the information or data made available to the public is in the interest of public health protection and is necessary and proportionate to the severity, extent and nature of the associated risk;~~

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

~~(c) the information or data made available to the public does not undermine the protection of court proceedings and legal advice.~~

~~7. The provisions of this Article shall also apply to delegated bodies.~~

Article 76

Data protection

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 Articless 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.~~**

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 **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.

Article 77

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

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

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

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to the provisions listed in paragraph 2 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 78

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 77(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

Article 79

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. **Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.**

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 80

Penalties

Member States shall **take the necessary legal measures to** lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, by … [OP please insert the date = ~~3~~ **4** years after the date of entry into force of this Regulation], notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

CHAPTER XIII

TRANSITIONAL PROVISIONS

Article 81

Transitional provisions concerning establishments designated, authorised, accredited or licensed under Directives 2002/98/EC and 2004/23/EC

1. Blood establishments designated, authorised, accredited or licensed based on Article 5(1) of Directive 2002/98/EC and tissue establishments designated, authorised, accredited or licensed on the basis of Article 6(2) of Directive 2004/23/EC before the date of application of this Regulation shall be deemed to be registered as SoHO entities and deemed to be authorised as SoHO establishments, in accordance with this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.

2. Tissue establishments that are designated, authorised, accredited or licensed as importing tissue establishments on the basis of Article ~~6~~**9**(2) of Directive 2004/23/EC before the date of application of this Regulation shall be deemed to be authorised as importing SoHO **establishments** ~~entities~~ in accordance with this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.

3. For blood establishments referred to in paragraph 1, **SoHO** competent authorities shall:

   (a) verify whether those establishments meet the definition of SoHO establishment in Article 3, point (40);

   (b) submit the information referred to in Article ~~18(3)~~**37(1a)**, points (a) and (~~d~~**e**), and information regarding the registration and authorisation status according to the verification referred to in point (a) of this paragraph to the EU SoHO Platform as referred to in Chapter XI.

4. For tissue establishments referred to in paragraph**s** 1 **and 2**, the Commission shall:

   (a) verify whether those establishments meet the definition of SoHO establishment in Article 3, point (40);

   (b) transfer the relevant information from the EU Tissue Establishment Compendium of the EU Coding Platform laid down in Directive 2006/86/EC, including the information regarding the registration and authorisation status according to the verification referred to in point (a) of this paragraph, to the EU SoHO Platform ~~as referred to in Chapter XI of this Regulation~~;

   (c) inform the **SoHO** competent authorities of the establishments that do not meet the definition of SoHO establishment according to the verification referred to in point (a).

5. **SoHO c**~~C~~ompetent authorities shall inform those establishments not meeting the definition of SoHO establishment, according to the verification referred to in paragraph 3, point (a), and paragraph 4, point (a) and based on the information referred to in paragraph 4, point (c), that they are deemed to be registered as SoHO entities only and that they, as such, are subject to the obligations relevant for SoHO entities provided for under this Regulation.

~~6. For tissue establishments referred to in paragraph 2 of this Article, the Commission shall transfer the relevant information from the EU Tissue Establishment Compendium of the EU Coding Platform laid down in Directive 2006/86/EC to the EU SoHO Platform as referred to in Chapter XI of this Regulation.~~

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).

Article 82a

Transitional provisions concerning SoHO not addressed expressly in Directives 2002/98/EC nor 2004/23/EC

Organisations carrying out one or more of the SoHO activities as listed in Article 2(1)(c), point (ai), (div), (ev), (fvi), (gvii), (hviii), (ix) and (lxii) with SoHOs not addressed expressly in Directives 2002/98/EC nor 2004/23/EC, before …[OP please insert the date = three months after the day of application of this Regulation] shall be allowed to continue their activities regarding those SoHO until [OP please insert the date = one year after the date of application of this Regulation], without applying this Regulation, except for the following requirements, that should be applied from [OP please insert the date = three months after the date of application of this Regulation:

(a) registration as SoHO entities pursuant to Article 37;

(b) application for any and all relevant SoHO preparation authorisation, where required pursuant to Article 40;

(c) application for a SoHO establishment authorisation, where required pursuant to Article 48;

(d) compliance with the standards referred to in Chapters VI and VII for the SoHO activities carried out during the transition phase.

Such SoHO entities shall comply with the requirements referred to in points (b) and (c) before [[OP please insert the date = three months after the date of application of this Regulation].

After [OP please insert the date = one year after the date of application of this Regulation], such SoHO entities shall fully comply with the provisions of this Regulation.

Article 83

Status of SoHOs released for distribution, distributed or in storage before the application of this Regulation

1. SoHOs already **in storage** ~~released for distribution~~ before … [OP please insert the date = date of application of this Regulation] shall not be subject to the relevant obligations provided for under this Regulation, ~~provided those SoHOs are distributed at the latest by … [OP please insert the date = one year after the date of application of this Regulation]~~ **provided those SoHO are released and distributed before [OP please insert the date = one year after the date of application of this Regulation]** ~~and~~ under the condition that those SoHOs were fully compliant with the applicable Union legislation and national law in force at the time when those SoHOs were ~~released for distribution~~ **collected**.

2. SoHOs which have been distributed before … [OP please insert the date = date of application of this Regulation] and kept under appropriate control conditions until that date shall not be subject to the relevant obligations provided for under this Regulation.

3. SoHOs already in storage before … [OP please insert the date = date of application of this Regulation], **and not distributed according to paragraph 1**, and for which no alternative SoHO~~s~~ are available, in particular because the SoHO~~s~~ are autologous, intended for within couple use or highly matched for a specific **SoHO** recipient, shall only be subject to Article 61. Those SoHOs shall be subject to that Article from… [OP please insert date = date of application of this Regulation].

Article 84

Transitional measures for the adoption of certain delegated and implementing acts

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

CHAPTER XIV

FINAL PROVISIONS

Article 85

Repeals

Directives 2002/98/EC and 2004/23/EC are repealed with effect from … [OP please insert the date = t**hree**~~wo~~ years after the date of entry into force of this Regulation].

Article 86

Evaluation

The Commission shall, by … [OP please insert the date = five years after the date of application of this Regulation] assess the application of this Regulation, produce an evaluation report on the progress towards achievement of the objectives of this Regulation and present the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.

The Commission shall use aggregated and anonymised data and information gathered from supervisory and SoHO activities and information submitted to the EU SoHO Platform for the purposes of the evaluation report.

Member States shall provide the Commission with additional information necessary and proportionate for the preparation of the evaluation report.

Article 87

Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

   Unless otherwise provided for in paragraph 2, it shall apply from … [OP please insert the date = ~~two~~ **three** years after the date of entry into force of this Regulation].

2. Article **80,** 81(3) to (6) and Article 82(3) shall apply from … [OP please insert the date = ~~three~~ **four** years after the date of entry into force of this Regulation].