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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 - *Letter to the Chair of the European Parliament Committee on the Environment, Public Health and Food Safety*

Following the meeting of the Permanent Representatives Committee on 30 January 2024, which endorsed the final compromise text with a view to agreement, delegations are informed that the Presidency sent the attached letter, together with its Annex, to the Chair of the European Parliament Committee on the Environment, Public Health and Food Safety.

Council of the
European Union

SGS 24 / 000641

Brussels, 30/01/2024

Mr Pascal CANFIN
Chair of the Committee on the Environment, Public Health and Food Safety
European Parliament
Rue Wiertz 60
B-1047 BRUSSELS

Subject: *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (Text with EEA relevance)*
2022/0216(COD)

Dear Mr CANFIN,

Following the informal negotiations on this proposal between the representatives of the three institutions, today the Permanent Representatives Committee agreed with the final compromise text.

I am therefore now in a position to inform you that, should the European Parliament adopt its position at first reading, in accordance with Article 294(3) TFEU, in the exact form of the text set out in the Annex to this letter (subject to revision by the lawyer-linguists of the two institutions), the Council, in accordance with Article 294(4) TFEU, will approve the European Parliament's position and the act shall be adopted in the wording which corresponds to the position of the European Parliament.

On behalf of the Council, I also wish to thank you for your close cooperation which should enable us to reach agreement on this file at first reading.

Yours sincerely,

Pierre CARTUYVELS
Chair of the
Permanent Representatives Committee (Part 1)

Copy:
- Ms Stella KYRIAKIDES, Commissioner
- Ms Nathalie COLIN-OESTERLE, European Parliament rapporteur

Rue de la Loi/Wetstraat 175 – 1048 Bruxelles/Brussel – Belgique/België
Tél./Tel. +32 (0)2 281 61 11

REGULATION (EU) 2024/…
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of …

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,

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

Whereas:

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

(2) Article 168(4), point (a), TFEU provides that the European Parliament and the Council should adopt measures setting high standards of quality and safety for organs and substances of human origin (***SoHO***), blood and blood derivatives. At the same time, Member States cannot be prevented from maintaining or introducing more stringent protective measures. ▌

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

(3) As regards Article 168(4), point (a), TFEU, standards for the safety and quality of organs and SoHOs, blood and blood derivatives should ensure a high level of human health protection. Therefore, this Regulation aims at setting high ***quality and safety*** standards by ensuring, amongst others, the protection of SoHO donors, taking into consideration their fundamental role in the provision of SoHOs and for recipients, as well as measures to monitor and support the sufficiency of the supply of SoHOs that are critical for the health of patients. ***In accordance with Article 3 of the Charter of Fundamental Rights of the European Union, those safety standards should be based on the fundamental principle that the human body or its parts cannot be a source of financial gain.***

(4) Directives 2002/98/EC[3] and 2004/23/EC[4] of the European Parliament and of the Council

[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).

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 resulted*** in divergences between national rules, which can create obstacles to cross-border sharing of these substances. A fundamental revision of those Directives is needed for a robust, transparent, up-to-date and sustainable regulatory framework for these substances, which achieves safety and quality ***of all SoHO***, enhances legal certainty ***for patients and stakeholders involved*** and supports continuous supply, ***including the cross-border exchange of SoHO*** 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*** in the ▌ 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 ▌ blood***,*** tissues and cells ▌ , it would be appropriate that it replaces these Directives and merges the revised provisions into one legal act***, taking into consideration the special characteristics of each type of substance, as recognised by the technical guidelines referred to in this Regulation***.

(6) This Regulation should apply to blood and blood components, as regulated by Directive 2002/98/EC, as well as to tissues and cells, including haematopoietic peripheral blood, umbilical-cord blood and bone-marrow stem cells, reproductive cells***, tissues and embryos***, foetal tissues and cells and adult and embryonic stem cells, as regulated by Directive 2004/23/EC. Since donation and human application of ***SoHO*** other than ***those regulated by Directives 2002/98/EC and 2004/23/EC*** are increasingly common, it is necessary to extend the scope of this Regulation to any SoHO, ***in order to avoid that certain groups of SoHO donors or SoHO recipients and offspring from medically assisted reproduction*** are not

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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).

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*** 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. ***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*** 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 infant with one's own breast milk should not fall within the scope of this Regulation. This includes also personal situations where one's own breast milk is handled or stored in a communal facility, such as a hospital, childcare facility or workplace, since it would be disproportionate to apply the provisions of this Regulation to those settings. However, if one's own breast milk is processed by a specialised SoHO entity, in particular if it is pasteurised, the provisions of this Regulation should apply.

(8) Ensuring the quality and safety of ***SoHO*** is crucial ***when*** 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 ▌ interaction with that body, such as in the case of wigs made from human hair.

(9) All ***SoHO*** that are intended to be applied to humans fall within the scope of this Regulation. ***SoHO*** can be prepared and stored in a variety of ways, becoming SoHO preparations, which can be applied to ***SoHO*** recipients. In these circumstances, this

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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).

Regulation should apply to all activities from ***SoHO*** donor ***registration*** to human application and ***clinical*** outcome monitoring ***registration. SoHO*** can also be used to manufacture products regulated by other Union legislation, ▌ 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 the Council[7]***,*** on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007 of the European Parliament and of the Council[8] ***and investigational medicinal*** products***, as*** defined in ▌ Regulation ***(EU) No 536/2014.*** This Regulation should apply without prejudice to Union legislation on genetically modified organisms.

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

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

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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).

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 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).

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

(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 should not be considered as processing for the purposes of this Regulation. The necessary procedures to be carried out, in accordance with the instructions provided with the preparation, immediately prior to human application, of released and distributed SoHO 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 authorised as a SoHO establishment. SoHO that are distributed or exported should first have been subjected to a formal release step. In cases where the receiving entity carries out a further processing step on released and distributed SoHO, those SoHO should be subjected to a second release step prior to re-distribution. In the case of autologous, bedside or in-surgery, processing of SoHO without storage, it would be impractical to require a formal release step prior to the re-application of the SoHO preparation to the recipient. In such cases, quality control steps and checks should instead be incorporated in the processing 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 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, safety and effectiveness of the imported SoHO are equivalent to those 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 quality and safety and entities performing import should be authorised as SoHO establishments. Following import, SoHO should be subject to release, prior to distribution within the Union. In certain cases, and in particular in the case of haematopoietic stem cells, national and international donor registries play a key role in the organisation of the import of matching stem cells for individual SoHO recipients in the Union. Such registries verify equivalence of quality and safety to the standards of this Regulation. As such, registries 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.

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

(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 in accordance with a previously approved clinical monitoring plan, when such a plan is required.

(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, reporting activity data and notifying adverse reactions or events, where relevant, and monitoring clinical outcomes when applying SoHO in the context of a plan for SoHO preparation authorisation. There are also obligations relating to not applying SoHO unnecessarily and to obtaining recipient consent. However, the clinical decisions relating to SoHO application and the clinical procedures for applying SoHO fall outside the scope of this Regulation and are governed by 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 ensures that data quality and data management procedures are robust and allow the data to be used for the purposes of SoHO preparation authorisation. The transfer of such outcome data from local or national registries 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) 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 within relationship 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 the medically assisted reproduction context are not addressed in the SoHO donor protection provisions of this Regulation, but are deemed duly protected under the SoHO recipient provisions.

(10) When ***SoHO*** are used in the autologous setting without any ▌ processing or storage, the application of this Regulation would not be proportionate to the limited quality and safety risks arising in such a setting. ***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 has therefore been demonstrated to achieve the intended result, and where the process carried out within the device does not meet the criteria for classification under another regulatory framework, this should be seen as analogous to non-removal from the surgical field and should not be considered as falling within the scope of this Regulation. However, this Regulation should apply*** to the ***processing of SoHO at the bedside or in the same surgical procedure by using medical devices for which quality, safety and effectiveness have not been proven as part of the CE marking process for that specific purpose***.

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

circumstances.

(11) When ***SoHO are collected with the purpose of manufacturing*** products regulated by other Union legislation, ***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 to ensure a high level of protection of recipients of those products manufactured using SoHO. Thus, without prejudice*** to Directive 2001/83/EC ***and Regulations (EC) No 1394/2007, (EU*****)*** ***2017/745 and (EU) No 536/2014, rules laid down in*** this Regulation should ***always*** apply to the ***registration, evaluation and testing of SoHO donors,*** as well as to ***SoHO collection and release. The provisions of this Regulation should also apply*** to the ***storage, import and export of SoHO until their distribution to a manufacturer*** regulated by other Union legislation. This means that close interaction between this regulatory framework and other related frameworks is essential to ensure ▌coherence between relevant legal frameworks, without gaps or overlaps.

(11a) The derogation of compliance with certain provisions of this Regulation should be foreseen for specific circumstances. In many Member States, military organisations are active in carrying out 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 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. Derogations of compliance with the provisions of this Regulation, in particular regarding the obligation to authorise SoHO preparations, should also be foreseen for specific SoHO recipients when justified by their clinical circumstances, or for specific groups of SoHO recipients in the context of health emergency situations or in man-made or natural disasters.

(12) ***SoHO can*** be combined with other regulated products***, in particular with medical devices,*** before human application. In these circumstances, close interaction between this regulatory framework and other related frameworks is ▌necessary to ensure a high level of human health protection for all cases where these substances are ***intended for human application. In cases where a device element in a SoHO-medical device combination has the primary***

function, for example a hip prosthesis coated in demineralised bone to help promote integration in the patient, the final combination should be regulated as a medical device. Conversely, in cases where the device element has an ancillary function, for example in the case of demineralised bone that is mixed with a synthetic gel to facilitate delivery to the patient as a bone graft, the final combination should be regulated as a SoHO. In both cases, each element of the combination should be fully in compliance with the relevant regulatory framework. Thus, the provisions of this Regulation that relate to all activities for the preparation of the demineralised bone in these examples should have a SoHO preparation authorisation, to ensure the property of inducing bone formation has been preserved, and the medical device element should have a CE mark for the purpose for which it is being used. ***This applies regardless of whether the final product is regulated as a medical device or as a SoHO.***

(13) Given the special nature of ***SoHO***, resulting from their human origin, and the increasing demands for these substances for human application***, including for*** the manufacture of products regulated by other Union legislation, ▌ it is necessary to ensure a high level of health protection for ***living SoHO*** donors as well as for recipients ***and offspring from medically assisted reproduction. SoHO*** 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. ***This is particularly important where the*** donation ***involves significant risk to the SoHO donor's health, such as where there is a need for pre-treatment with medicinal products, for example in the case of donation of oocytes or of hematopoietic stem cells from peripheral blood, a medical intervention to collect the substance, for example in the case of*** donation ***of bone marrow, or the possibility for SoHO donors to donate frequently, for example in the case of donation of plasma. As different types of donation entail different risks for SoHO*** donors***, with varying levels of significance, the monitoring of donor's health*** should be ***proportionate to those levels of*** risk.

(14) When a ***serious*** genetic ***disorder that might result in a life-threatening, disabling or incapacitating*** condition is detected in the offspring resulting from medically assisted reproduction with third party donation, the transmission of that 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***. If they do so,*** Member States should ***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,*** and proportionate to the risk to human health ▌. They should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation, unless that measure or its application is objectively justified by a legitimate aim, and the means of achieving that aim are appropriate and necessary. ***Such measures could include, for instance, the presence of or the access to qualified medical professionals where SoHO collection takes place.***

(16) This Regulation should not interfere with national legislation in the health area with objectives other than quality and safety of ***SoHO, where such legislation*** 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***. This Regulation should also not interfere with decisions of an ethical nature made by Member States. ***However, such decisions should adhere to the Charter of Fundamental Rights of the European Union.*** Such ethical decisions might concern the use, or limitation of the use, of specific types of ***SoHO***, including reproductive ***SoHO*** and embryonic stem cells. When a Member State allows the use of such cells, this Regulation should apply in full with a view to ensuring safety and quality and to protecting human health. ***However, this Regulation does not require a specific use, the distribution or the import, of SoHO where prohibited under national legislation concerning ethical aspects.***

(17) This Regulation is not meant to cover research using ***SoHO*** when that research does not involve application to the human body, for example ***in vitro*** research or research in animals. However, ***SoHO*** used in research involving studies where they are applied to the human body should comply with the rules laid down in this Regulation. ***In order to avoid undermining the effectiveness of this Regulation, and in particular in view of the need to ensure a consistently high level of protection for donors, and sufficient availability of SoHO for recipients, the donation of SoHO that will be exclusively for use in research***

without any human application should also comply with the standards of voluntary and unpaid donation set out in this Regulation.

(18) ***Article 3 of the Charter of Fundamental Rights of the European Union prohibits the making of the human body and its parts, as such, a source of financial gain. The use of financial incentives for SoHO donations can have an impact on the quality and safety of SoHO, posing risks to the health of both SoHO donors and recipients*** and therefore to the protection of human health. ***Without affecting national responsibilities on the definition of health policies, the organisation and delivery of health services and medical care, donation of SoHO*** should be ***voluntary and unpaid, and be founded on the principles of altruism of the donor and solidarity between donor and recipient. Such solidarity should be built from the local and regional levels up to the national and Union levels, aiming for self-sufficiency of critical SoHO, spreading the responsibility of donation evenly across the Union population to the extent possible. Voluntary and unpaid SoHO donation contributes to the respect for human dignity*** and to ***protect the most vulnerable persons in society. It also contributes to high safety standards for SoHO and therefore to the protection of human health, increasing public trust in donation systems***.

(18a) It is recognised, including by the Council of Europe Committee on Bioethics[9], that while financial gain should be avoided, compensation may be acceptable to prevent that SoHO donors are financially disadvantaged by their donation. Thus, compensation to remove any such risk is deemed appropriate, as long as it endeavours to guarantee financial neutrality and does not result in a financial gain for the donor or constitute an incentive that would cause a donor to not disclose relevant aspects of their medical or behavioural history or to donate in any way that could pose risks to their own health and to that of prospective recipients, in particular by donating more frequently than is allowed. Compensation may consist of the reimbursement of expenses incurred in connection with SoHO donation or on making good of any losses, preferably based on quantifiable criteria, associated with the donation of SoHO. Whatever the form of compensation, including through financial and non-financial means, compensation schemes should not result in competition between SoHO entities for SoHO donors, including cross-

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

border competition and in particular between SoHO entities collecting SoHO for different purposes, such as the manufacture of medicinal products versus human application as a SoHO preparation. The setting of an upper limit for compensation at a national level and the application of compensation that is financially neutral for the SoHO donor, has the effect of removing any incentive for donors to donate to one SoHO entity rather than another, significantly mitigating the risk that compensation differences might result in competition between SoHO entities, in particular between public and private sectors. Member States may delegate the setting of such conditions to independent bodies, in accordance with national law. Prospective SoHO donors should be able to receive information regarding the possibility of having their expenses reimbursed or of receiving compensation for other losses, through information tools, such as website 'Question and Answer' pages, information email addresses or telephone lines or other such neutral channels of factual information dissemination. However, because of the risk of undermining the voluntary and unpaid character of SoHO donation, references to compensation schemes should not be included in advertising, promotion and publicity activities that form part of donor recruitment campaigns, for example using advertising bill-boards or posters, on television, newspaper, magazine or social media advertisements or similar.

(18b) 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 voluntary and unpaid donation. Refreshments and small gifts, such as pens or badges, should not be considered as inducements and the practice of offering them to SoHO donors is acceptable as a recognition of their efforts. Rewards or benefits such as payment of funeral expenses, or payment of health insurance unrelated to the SoHO collection should be considered as inducements, and as such contrary to voluntary and unpaid donation and should not be permitted.

(18c) 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 ***SoHO*** when applied to ***SoHO*** recipients should accurately reflect reliable scientific evidence ***and under no circumstance attribute or imply levels of safety or effectiveness that are not scientifically supported***. This should ensure that ***SoHO*** donors, or their families, are not coerced to donate by exaggerated descriptions of benefits and prospective ***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. 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. ***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 ***independent SoHO*** National Authority that ensures appropriately coordinated communication with other Member States'***SoHO National*** Authorities and with the Commission***, as well as other tasks pursuant to this Regulation***. The SoHO National Authority should be considered the same as the designated ***SoHO*** competent authority in Member States where only one ***SoHO*** competent authority is designated. ***The designation of a single SoHO National Authority should not preclude Member States from assigning certain tasks to other SoHO competent authorities of that Member State, in particular for certain tasks where there is a need to ensure an efficient or agile communication with the Commission or other Member States. The list of all SoHO National Authorities should be made publicly available on the EU SoHO Platform.***

(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 ***interference by*** industry ***or other actors*** 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 ▌ health risks, and the publication of information regarding those infringements can contribute to risk mitigation and the protection of ***SoHO*** donors, recipients***,*** 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 ***one*** that has infringed the Regulation.

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

products, ***advanced therapies,*** medical devices, organs or food, ***and the SoHO Coordination Board (SCB),*** with the aim of ensuring coherent procedures for the application of this Regulation ***and other relevant Union legislation***. Competent authorities should inform the ***SCB*** of the outcome of their consultations ***and submit a request to it for its opinion on the regulatory status of the substance.*** When ***SoHO*** or SoHO preparations are used to manufacture products regulated under other Union legislation, or as the starting and raw material thereof, competent authorities should cooperate with the relevant authorities on their territory. This cooperation should aim to reach an agreed approach for any subsequent communications between the authorities responsible for SoHO and for the other relevant sectors, as needed, regarding authorisation and monitoring of the ***SoHO*** or the product manufactured from ***SoHO***. It should ▌ 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, ***SoHO competent authorities*** should ***justify their decisions when they decide not to follow SCB's opinions, and the Commission should upon a*** duly substantiated request of a Member State ***or the SCB, or may on its own initiative***, decide on the regulatory status of a particular substance, product or activity under this Regulation.

(25) ***SoHO*** competent authorities should perform ***SoHO*** supervisory activities regularly, on the basis of a risk assessment and with appropriate frequency, on ***SoHO*** entities and activities governed by this Regulation. The frequency of ***SoHO*** supervisory activities and the mode ***inspections are carried out***, should be established by the ***SoHO*** competent authorities, having regard to the need to adjust the ***degree of*** control ▌ 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 ▌ should ***have the necessary experience and knowledge to*** be able to perform controls ***as to the*** Member States***'*** effective application of the relevant requirements ***systems set out in this Regulation. Such controls 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 should also serve to investigate and collect information on enforcement practices or problems, emergencies and new developments in Member States. ***Such*** controls should be performed by personnel

who are independent, free from any conflict of interest and in particular who are not in a situation which, directly or indirectly, could affect their ability to carry out their professional duties in an impartial manner.

(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 ***quality, safety*** and ***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 ***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 ***verify quality*** and ***safety***. This should apply for well-established SoHO preparations that are introduced in a new SoHO entity but have been robustly demonstrated as safe and effective by their use in other entities.

(28) With regard to SoHO preparations that pose a ▌ risk ***other than negligible***, the applicant should propose a plan for clinical outcome monitoring that should fulfil different requirements appropriate to the risk indicated. The most up-to-date guidance of the European Directorate for the Quality of Medicines & HealthCare (EDQM, a Directorate of the Council of Europe) should be considered relevant in the design of clinical follow-up ***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 ***SoHO recipients***. For moderate ▌ risk ***and a positive benefit-risk assessment***, in addition to the mandatory vigilance reporting and the clinical follow-up, the applicant should propose clinical investigation studies with monitoring of pre-defined clinical end-points. In case of high risk ***and a positive benefit-risk assessment, and cases where risk or benefit are not evaluable due to a lack of scientific and clinical data or knowledge***, these should include a comparison with ***a*** standard ***therapy***, ideally in a study with ***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. ***In SoHO clinical studies, patients' rights, safety, dignity and well-being should always be the priority and the clinical study should be designed in a way that leads to reliable and robust data and conclusions.***

(29) In the interests of efficiency, it should be permitted***, without changing the regulatory status of the SoHO concerned,*** to conduct clinical outcome ***monitoring plans*** 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 ▌, when ***SoHO entities*** wish to do so. Whilst applicants can choose to record the clinical data generated during the clinical outcome monitoring ***plans*** themselves, they should also be permitted to use existing clinical ▌ 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. ***The existence of a registry of approved SoHO clinical studies at Union level is critical to facilitate patient participation in such clinical studies, to boost multi-centre studies and to foster collaboration to generate more robust results and conclusions, and to make such generated knowledge available to other researchers, healthcare professionals, participants themselves and the general public.***

(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 ***through the EU SoHO platform***, including for the validation of certified medical devices used for SoHO collection, processing, storage or application to ***SoHO recipients***. Such sharing could allow ***SoHO competent*** authorities to accept previous authorisations granted to other ***SoHO*** entities, including in other Member States and ▌ thus significantly reduce the requirements to generate evidence. ***SoHO competent authorities should also share with each other information on approved SoHO clinical studies, via the EU SoHO Platform.***

(31) A broad range of public and private organisations influence the ***quality, safety*** and ***effectiveness*** of SoHOs, even if they do not ***store*** those SoHOs. Many organisations carry out a single SoHO activity, such as collection or ***SoHO*** donor testing on behalf of one or many organisations that ***store SoHO***. The SoHO entity concept includes this broad range

of organisations, from ***SoHO*** donor registries to ***hospitals and clinics where SoHO are applied to SoHO*** recipients or ▌ 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 or donating breast milk to the infant of a friend or relative, and respecting the principles of voluntary and unpaid donation, should not be considered as SoHO activities. However, if such activities were to be carried out repeatedly as a service for multiple individuals, or for many families, they should be considered as SoHO activities and should fall under the scope of this Regulation.***

(32) ***SoHO*** competent authorities should ***periodically*** 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,*** are inspected and authorised as SoHO establishments before starting those activities. A SoHO establishment authorisation should refer to the legal entity, even when one SoHO establishment has many physical sites. ***SoHO*** competent authorities should consider the impact on ***quality, safety*** and ***effectiveness*** of the SoHO activities carried out ***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 establishments*** due to the risk or scale associated with their activities. Similarly, SoHO entities that have a poor record in terms of compliance with reporting or other obligations might be suitable candidates for authorisation ***and inspection.***

(32a) SoHO entities should keep a record of their activities, including the types and quantities of SoHO, as part of its working procedures and quality management systems, and report data relating to certain SoHO activities; at least the data sets included in the EU SoHO Platform. In cases where national or international registries collect activity data meeting the criteria defined in the SoHO Platform and such registries have been verified by 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 ***the protection of SoHO donors, SoHO recipients*** and offspring ***from medically assisted reproduction***, this Regulation should provide ▌ rules for their implementation. As risks and technologies change, ***these*** rules should facilitate an efficient and responsive uptake of the most up-to-date guidelines***, based on available scientific evidence,*** for implementing the standards set out in this Regulation. ***For the purpose of this Regulation, reconstructive surgery should not be considered an aesthetic use.*** In the absence of Union legislation describing particular procedures to be applied and followed to meet the standards set out in this Regulation, following the guidelines of the European Centre for Disease Prevention and Control (ECDC) and the EDQM should be considered ***an appropriate*** means to demonstrate compliance with ▌ this Regulation ***and the standards thereof*** to ensure high level of quality, safety and ***effectiveness. It*** should be ***recalled that SoHO National Authorities are involved in the process of establishing these guidelines through their participation in the governance bodies of ECDC and EDQM, respectively. Member States may adopt*** other guidelines, ***as reference for SoHO entities located in their territory. For such adoption, Member States should demonstrate*** that those other guidelines achieve ***compliance with the standards set by this Regulation***. In cases of detailed technical issues for which neither Union legislation nor the ECDC and the EDQM***, nor other guidelines,*** have defined a technical guideline or rule, ***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 persons with an intimate physical relationship use their own sperm and oocytes for treatment by medically assisted reproduction, testing for genetic conditions fall outside of the scope of this Regulation as these are associated with particular ethical concerns that fall outside the scope of this Regulation.

(34) Where evidence demonstrates that specific ***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. ▌

(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[10], 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 ***quality*** and ***safety*** of blood, tissues and cells, should be considered an important contribution to the field of ***SoHO*** in the Union***. The guidelines are developed on the basis of scientific knowledge, including an evaluation of up-to-date scientific evidence. They*** 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 ***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 ▌ standards provided for in this Regulation. ***Within the financial framework partnership agreement between the Union and the Council of Europe, the Commission supports the EDQM with multi-year contribution agreements in order to effectively contribute to the development and update of technical guidelines on safety and quality of SoHO. The Commission is always empowered to adopt binding rules to establish Union-wide standards for quality and safety where the necessity to guarantee a coherent approach at Union level is identified.***

(36) The ECDC, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council[11], is a Union agency with the mission of strengthening Europe's defences

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10 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).

11 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).

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

(37) It is necessary ***and beneficial to all parties*** to promote information and awareness campaigns at national and Union level on the importance of ***SoHO donation***. The aim of these campaigns should be to ***ensure the broadest possible donor base, with a view to a more resilient supply for critical SoHO, and*** 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*** for medical treatments, Member States ***and the Union*** should ***support the establishment of public donation facilities and*** promote the ***voluntary and unpaid*** donation of ***SoHO***, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union. ***For that purpose, Member States should consider taking measures to ensure availability and accessibility of SoHO within the Union.*** Member States are also urged to take steps to encourage a strong ***involvement of all relevant sectors, both*** public and non-profit***,*** in the provision of SoHO services, in particular for critical ***SoHO*** and the related research and development***, and to take steps to promote affordability of the collected SoHO within the Union***.

(37a) The COVID-19 pandemic can be considered one of the biggest health crises that has affected Europe. It had an adverse impact on the resilience of the SoHO donor base in some countries whose collection systems rely on a small number of persons donating SoHO more frequently than elsewhere. This crisis highlighted the vulnerabilities of the

Union in very different aspects, ranging from the lack of coordination between Member States, which is essential to addressing such situations, to the Union's strong dependence on third countries for developing medical treatments. In the case of SoHO, the pandemic drastically reduced the number of SoHO donors and imports from third countries, putting the Union in a situation of shortages of some SoHO and patients at serious risk due to a lack of adequate treatments. In this context, the initiatives for a strong European Health Union should work in favour of European self-sufficiency, in particular as regards the supply of critical SoHO and the ability to minimise the risk of shortages. The lessons learned and the resulting measures taken at Union level should serve as a reference for the prevention, detection and resolution of future health crises. Regulation (EU) 2022/2371 of the European Parliament and of the Council[12] *lays down the guidelines to be followed for that purpose. To increase European self-sufficiency in terms of SoHO, Member States should be urged to increase their collection capacity and donor base for critical SoHO, in particular plasma, by developing non-profit and public plasmapheresis programmes.*

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

(37b) In order to ensure self-sufficiency and sustainability of supply of critical SoHO, Member States should establish national SoHO emergency and continuity of supply plans setting out measures for cases where the supply situation for critical SoHO presents or is likely to present a serious risk to human health. Such plans should incorporate measures, that impact the demand for critical SoHO, donor recruitment and retainment strategies and

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12 *Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26).*

arrangements for cooperation between SoHO competent authorities, experts and relevant stakeholders. National SoHO emergency and continuity of supply plans contribute to European self-sufficiency in terms of supply of critical SoHO. Providing training and better information for the prescribers would reduce the risk of unnecessary application of SoHO. Furthermore, it is important that Member States improve patients' safety by minimising the risks associated with application of SoHO, and improve patient outcomes, while at the same time ensuring sufficiency of SoHO supplies and reducing financial pressure on health systems. Some Member States do so, inter alia, via the Patient Blood Management (PBM) approach.

(37c) In cases where the availability of critical SoHO or products manufactured from critical SoHO depends on potential commercial interests, such as those related to the production and distribution of plasma-derived products, there is a risk of not having the interests of patients and research at the forefront, and thus to jeopardise the quality and safety of SoHOs, their donors and their recipients. There could even be situations in which some products with low profitability are no longer produced, thereby hampering their accessibility for patients. Hence, by considering all reasonable efforts for an appropriate and continuous supply of critical SoHO, Member States contribute to limiting the risk of shortages of products manufactured from critical SoHO.

(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 ▌ 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*** 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***.

(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***. The SCB should receive relevant information on national decisions made on cases where questions were raised on the regulatory status of ***SoHO***. 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 ▌ 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.

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(41) In order to limit administrative burden on ***SoHO*** competent authorities and the Commission, the latter should establish an online platform (the 'EU SoHO Platform') to facilitate timely submission of data and reports***. The EU SoHO Platform should contribute to improve transparency of reporting and SoHO supervisory activities and to the exchange of information between relevant parties, including decisions on the regulatory status of substances, products or activities. The EU SoHO Platform should also serve as a reliable source of information for the general public regarding the work of the SCB, SoHO*** National ***Authorities, expert bodies, including the EDQM and the ECDC, and SoHO entities. The online platform should be further used for the sharing of best practices agreed and documented by the SCB on SoHO*** supervisory activities.

(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*** activities ***laid down*** in this Regulation.

(44) This Regulation respects the fundamental rights and observes the principles recognised ▌by the Charter of Fundamental Rights of the European Union***,*** in particular human dignity, the integrity of the person ***and the prohibition of making the human body and its parts a source of financial gain***, the protection of ***natural persons with regard to the processing of their*** personal data, the freedom of art and science and to conduct business, non-discrimination, the right to health protection and access to health care, and the rights of the child. To achieve these aims, all supervisory and SoHO activities should always be carried out in a manner that fully respects those rights and principles. The right for dignity and integrity of ***SoHO*** donors, ***SoHO*** recipients and ▌offspring ▌ 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*** in humans is not promoted for commercial purposes or with false or misleading information regarding ***effectiveness*** so that the ***SoHO*** donors and ***SoHO*** recipients can make well-informed and deliberate choices, that activities are conducted in a transparent manner that prioritises the safety of ***SoHO*** donors***,*** recipients ▌and ***offspring from medically assisted reproduction. In addition,*** allocation and equitable access to ***SoHO should be in accordance with national law***, on the basis of an objective evaluation of medical needs***, such that the health of recipients and offspring is not compromised by SoHO allocation actions that do not respect their dignity***. This Regulation should therefore be applied accordingly.

(44a) Due to the high sensitivity of donor anonymity and taking into account the rights of offspring from medically assisted reproduction following third party donation, SoHO entities should, in the case of unrelated donation, refrain from revealing the SoHO's

donor identity to the SoHO recipient or the offspring from medically assisted reproduction, apart from circumstances where such information exchange is permitted in the Member State concerned.

(45) ***SoHO***, by definition, relate to persons, and there are circumstances where the processing of personal data ▌ 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 ***effectiveness*** of new SoHO preparations ▌ should also be shared, with appropriate protective measures, to allow aggregation at Union level for more robust evidence gathering ▌ 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 ▌ such data.

(47) The exchange of ***SoHO*** between Member States is necessary for ensuring optimal patient access and sufficiency of supply, particularly in the case of local crises or shortages. For certain ***SoHO*** that need to be matched between the ***SoHO*** donor and the ***SoHO*** recipient, such exchanges are essential to allow ***SoHO recipients*** to receive the treatment they need ***in the optimal timeframe. This is for instance the case of hematopoietic stem cell transplants, for which the level of compatibility between the SoHO donor and the SoHO***

recipient has to be high, which requires coordination at a global level, so that each SoHO recipient has as many options as possible to identify a compatible SoHO donor. In this context, the objective of this Regulation, namely to ensure quality and safety of ***SoHO*** 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***, 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. ***This Regulation should also serve to increase coordination between Member States.***

(48) In order 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, and*** additional rules on the authorisation of importing SoHO ***establishments***, on obligations and procedures for importing SoHO ***establishments***, and on data protection, the ***Commission should*** adopt ***delegated*** acts in accordance with Article 290 TFEU ▌. 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[13]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(49) In order to ensure uniform conditions for the implementation of this Regulation regarding the ▌ application for importing SoHO ***establishment authorisation***, the activity data collection and reporting by SoHO entities, the ***minimum data to ensure traceability, the European coding system***, 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

13 OJ L 123, 12.5.2016, p. 1.

the determination of the regulatory status of a substance, product or activity, ***the data set for SoHO entities to register into the EU SoHO Platform, the authorisation*** of SoHO ***preparations, common elements for the quality management system*** of SoHO ***entities and for*** the inspections of SoHO establishments, the consultation and coordination related to vigilance, the ***implementation of the standards concerning the protection of SoHO donors, in particular with regards to the frequency of donations when such frequency implies a risk, SoHO*** recipients and offspring from medically assisted reproduction, the ▌ tasks of the ***SCB***, 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[14]***. In addition to those implementing acts that relate directly to the protection of human health, and therefore fall within the scope of Article 5(4), second subparagraph, point (a), of Regulation (EU) No 182/2011, the implementing acts provided for by this Regulation also relate to consultation and communication tools, supervisory functions, traceability and import rules and monitoring (activity volumes). These implementing acts will have significant impact on the Member States' public services in the field of health and the way their health authorities work and cooperate in practice; it should therefore be provided that the Commission cannot adopt a draft implementing act where the Committee delivers no opinion, in accordance with Article 5(4), second subparagraph, point (b), of Regulation (EU) No 182/2011.***

(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*** are discarded unnecessarily. A transitional regime for establishments already designated, authorised, accredited or licensed before the date of application of this Regulation should be introduced to ensure legal certainty and clarity. In particular, there should be clarity for the establishments concerned as regards their registration and authorisation status as well as their tasks and responsibilities under this Regulation, whilst allowing ***SoHO*** competent authorities additional time to transfer the relevant information

[14] 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).

to the systems introduced by this Regulation. To allow for a smooth transition, it is also appropriate that those preparation processes already authorised and lawfully used under the former regimes are still valid, and that ***SoHO*** 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 ***7 September 2022***[15]**.**

HAVE ADOPTED THIS REGULATION:

[15] OJ C ***450, 28.11.2022, p. 7-9***.

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation establishes measures setting high standards of quality and safety for all substances of human origin ('SoHOs') intended for human application and for activities related to those substances***. It ensures*** a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted reproduction***, including by strengthening the continuity of supply of critical SoHO***.

Article 2

Scope

1. This Regulation shall apply to ▌:

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

(b) SoHO ***donors, SoHO recipients and offspring from medically assisted reproduction***;

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

(i) donor registration;

(ii) donor history review and medical examination;

(iii) testing of SoHO donors or of persons from whom SoHO are collected for autologous use;

(iv) collection;

(v) processing;

(vi) quality control;

(vii) storage;

(viii) release;

(ix) distribution;

(x) import;

(xi) export;

(xii) human application;

(xiii) clinical outcome registration.

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 carried out by a SoHO entity.

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.

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

2. In ***case of SoHO intended for autologous use*** where:

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

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

3. ***In case of SoHO that are collected with the purpose of manufacturing,*** medical devices, ***as*** regulated by Regulation (EU) 2017/745, ▌ medicinal products, regulated by ▌ Directive 2001/83/EC, ▌ advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007 ***or investigational medicinal products, as defined in*** Regulation (***EU***) ***No 536/2014***, the provisions of this Regulation applicable to the ***SoHO activities referred to in paragraph (1c) point (i), (ii), (iii), (iv) and (viii), shall apply in all cases***. Insofar as the activities of SoHO ***referred to in paragraph (1c) point (vii), (ix), (x) and (xi)*** relate to ***SoHO until*** their distribution to ***a manufacturer*** regulated by ▌ other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also 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*** 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*** or their derivatives is principal ▌ to that of the device, ***this Regulation shall apply in full on*** the non-viable ***SoHO*** or their derivatives ***and the final combination*** shall be ***subject to the provisions of*** this Regulation. If the action of the non-viable ***SoHO*** or their derivatives is ancillary to that of the device***, this Regulation shall apply for all SoHO activities to which the non-viable SoHO or their derivatives are subjected until distributed for integration into the medical device, and the final combination shall be subject to the provisions of Regulation (EU) 2017/745***.

Article 3

Definitions

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

▌

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

▌

(5) ‘substance of human origin’ (SoHO) means any substance collected from the human body ▌, whether it contains cells or not and whether those cells are living or not***, including SoHO preparations resulting from the processing of that substance***;

(6) ‘human application’ means inserted, implanted, injected, infused, transfused, transplanted, ingested, transferred ▌, inseminated or otherwise added to the human body in order to create a biological ▌ interaction with that body;

▌

(7a) ‘effectiveness of SoHO’ means the extent to which the use of SoHO reaches the intended biological or clinical outcome in the SoHO recipient;

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

(8) ‘SoHO donor’ means ***a living or deceased SoHO donor***;

(8a) 'living SoHO donor’ means a living person who has volunteered 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, for the purpose of use in a person other than themselves, and other than situations of within relationship use as defined in point (63);

(8b) 'deceased SoHO donor’ means a 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*** 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) 'consent' means the permission given freely without coercion by:

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

(b) any person granting consent on 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 an action to proceed in the living SoHO donor or the SoHO recipient, or

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

(10) 'medically assisted reproduction' means ***any laboratory or medical intervention, including any preparatory steps, that involves the handling of reproductive SoHO for the purpose of the facilitation of pregnancy or for preservation of fertility***;

(10a) 'preservation of fertility' means the process of saving or protecting a person's reproductive SoHO intended to be used later in that person's life.

(11) 'offspring from medically assisted reproduction' means ▌children ▌born following medically assisted reproduction;

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

(a) has been subjected to ***processing and, where relevant,*** one or more ***other*** SoHO activities, ***as listed in Article 2(1c)***;

(b) ***has a specific clinical indication***; and

(c) is intended for application to a ***SoHO recipient*** or is intended for distribution ▌;

(13) 'donor recruitment' means any activity aimed at ***informing*** persons ***about activities related to SoHO donation or at encouraging them to donate SoHO***;

(13a) 'SoHO donor registration' means recording in a registry, and transferring to other registries where appropriate, the information on a SoHO donor that is essential for identifying a match with a prospective SoHO recipient;

(14) 'collection' means a process by which ***SoHO*** are ▌ obtained ***from a person***, including any preparatory steps, such as hormone treatment ▌ needed to facilitate the process ***at, or under the supervision of, a SoHO entity***;

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

(16) 'quality control' means ***a pre-defined test, set of*** tests or checks to confirm that ▌ pre-defined quality criteria ***are met***;

(17) 'storage' means the maintenance of ***SoHO*** under appropriate controlled conditions ▌ ;

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

(19) 'distribution' means ***providing***, within the Union, ▌ released ***SoHO:***

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

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

(c) intended for the manufacture of products regulated under other Union legislation, ▌ as ***provided for in Article 2(3), to a manufacturer of such products;***

(20) ‘import’ means activities carried out to bring ***SoHO*** into the Union from a third country ***before their*** release;

(20a) ‘third country supplier’ means an organisation, located outside the Union, which is contracted to supply SoHO or to perform activities that might influence the quality and safety of the SoHO imported;

(21) ‘export’ means ***activities carried out to send SoHO from the Union to a*** third ***country***;

(22) ‘clinical outcome ***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***;

(22a) 'clinical outcome monitoring plan’ means a programme for evaluating the safety and effectiveness of a SoHO preparation;

(23) ‘autologous use’ means ***application*** of ***a*** SoHO ***collected*** from ***a person*** to the same ***person***;

(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(1c)***;

(25) ‘SoHO preparation authorisation’ means the formal approval by a competent authority of a SoHO preparation ▌;

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

(27) ‘adverse ***reaction***’ 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, ▌to a SoHO recipient or to offspring from medically assisted reproduction ▌;

(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***’ (***SAR***) means an adverse ***reaction*** that ***results*** in ▌ 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 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 relationship 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;

▌

(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 SoHO that causes human applications to be postponed or cancelled;

(d) loss of highly matched or autologous SoHO;

(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 SoHO;

▌

(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 ***10***;

(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 ▌;

▌

(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;

(41) ‘critical SoHO’ means a SoHO for which an insufficient supply will result in serious harm or risk of harm to ***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 SoHO entity’ means a SoHO entity that carries out activities contributing to the supply of critical ***SoHO*** and the scale of those activities is such that a failure to carry them out cannot be compensated by activities of other entities or alternative substances or products for ***recipients***;

▌

(47) ‘traceability’ means the ability to locate and identify ***SoHO*** from collection ***to human application, disposal or distribution for the manufacture of products regulated by other Union legislation, as provided for in Article 2(3);***

▌

(48) ‘Single European Code’ (SEC) means the unique identifier applied to certain SoHOs distributed in the Union;

▌

(51) ‘imputability’ means the likelihood that ***an*** adverse ***reaction***, in a SoHO donor, is ***associated with the collection*** process or, in a ***SoHO*** recipient ***or offspring from medically assisted reproduction, with*** the application of the ***SoHO***;

(52) ‘seriousness’ means the degree of severity of an adverse ***reaction***, 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***;

▌

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

▌

(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;

▌

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

(62) ‘third party donation’ means a donation of reproductive ***SoHO to be used for a SoHO recipient*** with whom the donor does not have an intimate physical relationship;

(63) ‘within ***relationship*** use’ means use of reproductive ***SoHO*** for medically assisted reproduction ***between*** persons with an intimate physical relationship ▌;

(64) ‘compensation’ means making good of any losses ***or the reimbursement of expenses*** associated with ***SoHO*** donation;

(64a) ‘financial neutrality of donation’ means that no financial gain or loss will be incurred by the SoHO donor as a result of the donation;

(65) ‘allogeneic use’ means ***application*** of ***a*** SoHO ***collected*** from ***a person other than the SoHO recipient***;

▌

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

(70b) ‘SoHO clinical study’ means an experimental evaluation of a SoHO preparation, with the objective of drawing conclusions regarding its safety and effectiveness;

(70c) ‘European self-sufficiency’ means the Union’s degree of independence from third countries in relation to the collection, the distribution and any other SoHO activity, related to critical SoHO.

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 ▌ compatible with Union law, and are proportionate to the risk to human health***, including in light of the relevant scientific knowledge***.

2. Member States shall make available to the public details of ***the more stringent*** measures ***adopted*** in accordance with paragraph 1 without undue delay, including on the internet. The SoHO National Authority shall submit the details of any ***such*** more stringent ***measures*** to the EU SoHO Platform ▌.

CHAPTER II

MEMBER STATES' SoHO COMPETENT AUTHORITIES

Article 5

Designation of ***SoHO*** competent authorities

1. Member States shall designate the ***SoHO*** competent authority or authorities to which ▌ confer responsibility for the SoHO supervisory activities***. The authority or authorities*** designated shall be independent from any SoHO entity.

2. ▌ A Member State may confer responsibilities for SoHO supervisory activities 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 internal administrative organisational requirements determined ***in national legislation***;

   (b) have the necessary powers:

      (i) to properly perform ***the 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;

▌

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

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

4. ***When a*** Member State ***designates only one SoHO competent authority in accordance with paragraph 1, the SoHO competent authority*** shall ***also be appointed as the SoHO National Authority. When a Member State designates more than one SoHO competent authorithies in accordance with paragraph 1, it shall appoint one*** SoHO National Authority ***among them, in accordance with national law. The SoHO National Authority shall be*** responsible for ***activities as referred to in Article 9(1a). The designation of a single SoHO National Authority should not preclude the*** Member ***State from assigning certain tasks to other SoHO competent*** authorities***, in particular, for the management of rapid alerts to ensure an efficient and agile communication when serious adverse reactions or serious adverse events involve more than one Member State***.

5. Member States shall submit to the EU SoHO Platform***, and keep updated, information on***:

▌

(b) the ***name*** and contact details of ***the*** 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.

▌

Article 7

Independence and impartiality

1. ***When performing their tasks and exercising their powers, SoHO*** competent authorities shall act independently ***and impartially***, in the public interest and free from any external influence***, such as political influence or industry interference***.

2. ***SoHO*** competent authorities shall ensure that ▌ personnel ***performing SoHO supervisory activities, including inspectors and assessors have no*** financial or ***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. ***Personnel performing SoHO supervisory activities shall provide a regularly updated declaration of their interests. The authorities, on that basis, shall take the relevant measures to mitigate the risk of conflicts of interest.***

▌

Article 8

Transparency

1. ***SoHO*** competent authorities shall***:***

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

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

      (i) a SoHO entity does not comply with the provisions of this Regulation, or

      (ii) there is a serious risk to the safety of SoHO donors, recipients, offspring from medically assisted reproduction or public health.

2. Paragraph 1 shall ***be without prejudice to Article 75 and to*** national legislation on access to information.

3. ***SoHO*** competent authorities shall lay down ***in their internal rules*** practical arrangements for implementing the transparency rules referred to in paragraph 1 ▌.

▌

Article 9

General responsibilities and obligations ***of SoHO competent authorities***

1. ***SoHO*** competent authorities shall be responsible***, within their territory, for*** SoHO supervisory activities ▌ in order to verify the effective compliance of***:***

(a) SoHO entities ▌ with the requirements set out in this Regulation***, and***

(b) SoHO preparations with their corresponding authorisation.

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

2. ***SoHO*** competent authorities shall ▌:

(a) ***have, or have access to,*** a sufficient number of suitably qualified ***and experienced*** personnel***, human and financial resources, operational capacity, and expertise, including technical expertise,*** to carry out the ***SoHO*** supervisory ***activities they have been made responsible for, efficiently and effectively***;

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

(b) ▌ ensure the independence, impartiality***, transparency***, effectiveness, quality, suitability for purpose and consistency of their SoHO supervisory activities;

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

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

(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.

▌

Article 10

Delegation of certain SoHO supervisory activities to ***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. SoHO*** competent authorities that delegate ▌ SoHO supervisory activities ***in accordance with paragraph -1a to a delegated body*** shall ***have in place*** a written agreement ***with that delegated body***.

2. ***The delegating SoHO*** competent authorities shall ensure that the ***written*** agreement ***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 that*** the delegated body ***participates in certification or other schemes at Union level, when available, to ensure the uniform application of principles of good practices required for their relevant sector;***

▌

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

(d) provisions ***on*** the fulfilment of the obligations ▌ 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 ▌ SoHO supervisory activities ***are*** delegated in accordance with Article ***10*** shall:

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

(a) ***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 ***documentation, including IT systems.***

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

Article 12

Obligations of the delegating ***SoHO*** competent authorities

SoHO competent authorities that have delegated certain SoHO supervisory activities to delegated bodies in accordance with Article ***10*** shall:

(a) ***conduct regularly*** audits ***of the delegated bodies. 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 SoHO***;

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

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

(ii) the delegated bodies ***have failed*** to take appropriate and timely action to remedy the shortcomings identified ***in the course of conducting supervisory activities; or***

(iii) ***there is evidence that*** the independence or impartiality of the delegated bodies has been ▌ compromised.

Article 13

Communication and coordination between 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 ***or the SoHO National Authority*** shall ensure efficient and effective coordination between all ***the*** SoHO competent authorities ***concerned in order to guarantee*** consistency and effectiveness of ***the*** SoHO supervisory activities ***performed on*** its territory.

2. ***Within a Member State, SoHO*** competent authorities shall cooperate with each other ▌. 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 ***activities*** provided for in this Regulation***, as well as the tasks of the SoHO National Authority as referred to in Article 9(1a)***.

3. In cases where ***a SoHO*** competent ***authority issues*** an opinion to a SoHO entity on the applicability of this Regulation to a particular substance***, product*** or activity ***on its*** territory, ***that SoHO*** competent ***authority*** shall notify the SoHO National Authority ***of that opinion issued***, which, in turn, shall notify the ***SCB, for publication in*** the SoHO ***compendium***.

4. Following a ***duly substantiated*** request from ***the SoHO National*** Authority of another Member State, the ***SoHO National*** Authority shall without undue delay***, and ensuring consideration of aspects of confidentiality as set out in Article 75,*** inform the requesting ***SoHO National*** Authority 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*** referred to in Articles 29and 30.

Article 14

Consultation and cooperation 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*** referred to in ***paragraph -1a, as appropriate, with a view to reaching a decision on the regulatory status***. In such cases, ***SoHO*** competent authorities ***involved in the consultation*** shall also consult the ***SoHO*** compendium***, and consider any relevant regulatory status decision and take into account any relevant opinion included therein***.

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 ***an*** opinion on the regulatory status of the substance, product or activity under this Regulation***. The SoHO competent authorities*** shall do so in all cases where the ***consultations referred to in paragraph 1, have not lead to a decision on the regulatory status of such substance, product or activity in the Member State concerned.***

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

The SoHO competent authorities involved in the consultation shall take into account the opinion issued by the SCB following such a request.

3. ***When a consultation referred to in paragraph 1 and, if relevant, paragraph 2, leads to a regulatory status decision, the SoHO*** competent authorities shall***, via the SoHO National Authority,*** inform the SCB of the ▌ decision taken in ***its*** Member State ***with a view to the publication thereof by the SCB in the SoHO compendium, pursuant to Article 68(1) point (d). The SoHO competent authorities shall include a description of the reasons for the decision, and in case the decision taken differs from*** the SCB ***opinion, provide a justification***.

4. The Commission ***shall***, upon a duly substantiated request ***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 ***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 ***consultations conducted in accordance with Article 68(1), point (b)*** between the SCB and the advisory bodies established ***under*** other relevant Union legislation ***as referred to in Article 2(3)***.

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

5. ***In the case of SoHO*** as referred to in Article 2(3) ***or*** Article 2(4), the ***SoHO*** competent authority shall cooperate with the authorities responsible for the supervisory activities under ***other*** relevant Union legislation ***as referred to in Article 2(3)***, with a view to ensuring coherent oversight. During ***that*** process, the ***SoHO*** competent authorities may seek***, via their SoHO National Authority,*** the assistance ***and advice*** of the SCB ***concerning, inter alia, good cooperation practices that ensure coherent oversight when SoHO change regulatory status***.

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 an opinion***.

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.

▌

Article 17

Obligations as regards Commission controls

SoHO competent authorities and delegated bodies shall cooperate with the Commission for the performance of Commission controls referred to in Article 70. In particular, they shall:

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

(b) ***provide*** the necessary technical assistance and ▌ the available documentation, upon justified request, ***as well as*** other ▌ support that ***the*** Commission ***requests*** to enable them to perform controls efficiently and effectively***, including facilitating access to all premises or part of premises, and to documentation, including IT systems, of the SoHO competent authority or delegated body relevant for the execution of their duties.***

▌

Article 17a

Transparency regarding fees for technical services required for making SoHO available

Member States may take appropriate measures to aim for transparency in the fees for technical services required for making SoHO available.

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.***

▌

4. In cases where SoHO National Authorities establish ▌ registries of SoHO entities ***outside the EU SoHO Platform, the SoHO competent authorities*** shall submit the information included in ***such*** registries to the EU SoHO Platform ▌ . ***SoHO*** competent authorities shall be responsible for ensuring that the information regarding the SoHO entities on their territory pursuant 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 from national registries*** 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*** competent authorities shall have procedures in place for the registration of SoHO entities in accordance with Article 37.

1a. SoHO competent authorities shall verify that each registered SoHO entity on a national registry or the EU SoHO Platform has provided the information pursuant to Article 37(1) 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 an authorisation is required under Articles 21, 27 or 28 for a registered SoHO entity taking into account the declaration as referred in Article 37(1b).

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

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

2. ***SoHO*** competent authorities shall:

(a) acknowledge receipt of the registration ***without undue delay;***

(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***;

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

(e) ***inform the SoHO entity that its registration has been verified and published in*** the EU SoHO Platform ▌.

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

▌

Article 20

SoHO preparation authorisation system

1. ***SoHO*** competent authorities shall establish and maintain a system for ***granting authorisation of SoHO preparations to SoHO entities located 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*** competent authorities shall authorise SoHO preparations pursuant to Articles 21, 22***, 22a*** and, where applicable, Article 23.

2a. The SoHO preparation authorisation requirement is waived for SoHO that are intended to be distributed for the manufacture of products regulated by other Union legislation, as referred to in Article 2(3).

3. SoHO preparation authorisations shall be valid throughout the Union for the period defined in the ▌authorisation, ***pursuant to Article 21 (2), point (d)*** or until ***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 ▌.

▌

Article 21

Authorisation of SoHO preparations

1. ***SoHO*** competent authorities 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, in accordance with Article 22a***. When developing these guidelines and templates, ***SoHO*** competent authorities shall ***use the templates and shall take into account*** the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c). ***SoHO*** competent authorities may establish simplified procedures for applications concerning modifications to previously authorised SoHO preparations. ***SoHO competent authorities may use the secure communication channel on the EU SoHO Platform for the exchange, with the SoHO entity, of documents relating to the application and authorisation of SoHO preparations.***

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***;

   (b) assess the SoHO preparation pursuant to Article 22 and examine agreements between the applicant ▌ and any third parties contracted by that SoHO entity ***to perform*** activities ***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*** clinical outcome ***monitoring plans, as appropriate***, pursuant to Article 22(4), points (d) and (e); ***and indicate a time limit for the applicant to submit the results of the approved clinical outcome monitoring;***

   (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, indicate which conditions apply***.

3. ***SoHO*** competent authorities shall submit information regarding ***the authorisation of the*** SoHO preparation ▌ including a summary of the evidence used to authorise each SoHO preparation, to the EU SoHO Platform ▌ and, for each SoHO preparation, amend accordingly the authorisation ***information*** of the SoHO entity ***concerned***.

4. ***SoHO*** competent authorities shall conclude the SoHO preparation authorisation ▌, referred to in paragraph 2 of this Article, within ***the time limit set out taking into account best practices agreed and documented by the SCB as referred to in Article 68(1), point (c). The time limit foreseen for the authorisation may be extended for:***

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

(b) the time needed for preparation and submission of a response to 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 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 Annex IX (5) (3)(1) of Regulation (EU) 2017/745*** , and inform the SCB of the opinion provided.

6. ***SoHO*** competent authorities may, in accordance with national legislation, suspend the authorisation of a SoHO preparation***, in circumstances where*** SoHO supervisory activities demonstrate or give reasonable ground for suspecting that ***such SoHO preparation, or any activities performed for that preparation do not comply with the conditions of its authorisation or with the provisions of this Regulation and shall do so when an imminent risk to the safety of SoHO donors, recipients or offspring from medically assisted reproduction, or an imminent risk of unnecessary wastage of critical SoHO is identified.***

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

7. In cases where SoHO ***competent authorities have*** confirmed non-compliances referred to in paragraph 6***, and SoHO entities are not able to rectify them*** in the specified time period, ***SoHO*** competent authorities shall, in accordance with national legislation, withdraw the authorisation of the SoHO preparation ***from the SoHO entities*** concerned.

8. ***SoHO*** competent 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***.

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 of the SoHO preparation*** of the SoHO entity concerned in the EU SoHO Platform***.***

9a. SoHO competent authorities may exceptionally authorise, at the request of the SoHO entity responsible for that application, the application of a SoHO preparation to a specific SoHO recipient within their territory in cases where the procedures referred to in this Article have not been carried out, provided that:

(a) the intended specific 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 can reasonably be assumed on the basis of the available clinical data; and

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

SoHO competent authorities may require the SoHO entity concerned to provide a summary of the clinical outcome in the specific case and shall inform the SoHO National Authority of that exceptional authorisation without undue delay.

▌

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 ***quality, safety and effectiveness*** 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, ***SoHO*** competent authorities may authorise that SoHO preparation ▌, provided that the ***SoHO*** competent authorities have verified***, with the permission 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 ▌ in a manner such that the ***quality, safety and effectiveness*** results ***of the SoHO preparation*** will be equivalent to those demonstrated in the SoHO entity where the SoHO preparation was first authorised.

4. In cases where the SoHO preparation, subject to the application for authorisation pursuant to Article 21, has not been ▌ 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) ▌ assess ***the adequacy of*** the information provided by the applicant pursuant to Article ***41(2) point (a)***;

▌

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

(d) ▌ evaluate the ***benefit-risk*** assessment ***carried out*** by the applicant as pursuant to Article 41(2), point (b) ***including the scientific evidence and clinical data provided regarding the expected benefit and risk***;

(e) ***in cases where the evidence provided at point (d) is not sufficient to provide certainty that benefit outweighs risk or where the risk is more than negligible,*** evaluate the plan ***to gather further evidence of safety and effectiveness through*** clinical outcome monitoring***,*** and its proportionality to the level of risk ***and expected benefit*** of the SoHO preparation ***according to*** Article ***22a;***

(f) ▌ 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) ▌ assess, in the case of a ***previously approved clinical outcome monitoring plan*** pursuant to Article 21(2), point (c), the results of the clinical outcome monitoring ***upon completion and submission by the applicant***.

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

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

7. When conducting the assessment steps referred to in paragraph 4 of this Article, ***SoHO*** competent authorities shall ***take into account*** 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. In cases where scientific and clinical evidence provided as part of the benefit-risk assessment carried out by the applicant, as referred to in Article 22(4)(d), is not sufficient, or the risk is more than negligible, a clinical outcome monitoring plan shall be submitted by the applicant and shall be approved by the SoHO competent authority. The approved plan shall be the basis for the gathering of further evidence to allow the assessment and authorisation of the new SoHO preparation or a new indication for SoHo preparation.

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

4. The clinical outcome monitoring plan shall include the following:

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

(b) in cases of moderate risk, and an expected positive benefit-risk assessment, in addition to point (a), a clinical study of a pre-specified number of SoHO recipients required to be able to assess pre-defined clinical end-points;

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

4a. In cases referred to in paragraph 4 points (b) and (c), SoHO competent authorities shall register each approved SoHO clinical study on the EU SoHO Platform, providing the following information:

(a) the name and address of the SoHO entity carrying out the clinical study;

(b) a description of the SoHO type and the intended clinical indication;

(c) a short summary of the processing methodology;

(d) a summary of the study design; (e) planned date of commencement and completion of the study;

6. In case where SoHO supervisory activities indicate a risk for SoHO donors, SoHO recipients or offspring from medically assisted reproduction, SoHO competent authorities may withdraw the previous approval of the clinical outcome monitoring plan. In such cases, the record on the SoHO platform shall be modifed without undue delay.

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,*** SoHO preparation assessments as referred to in Article 22 may be carried out by ***SoHO preparation assessors assigned by*** more than one Member State, as a joint SoHO preparation assessment.

2. ***With the previous consent of the SoHO National Authority, the SoHO competent authority receiving*** a request ***for a joint SoHO preparation*** assessment ***shall make all reasonable efforts to accept such request, taking into account their available resources***.

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

(a) the scope of the joint assessment;

(b) the roles of the participating assessors during and following 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.

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 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).

Article 24

Specific obligations concerning SoHO preparation assessors

1. ***SoHO preparation*** assessors shall:

   (a) ***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;

   (b) have expertise in the processes being assessed ***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 ***and 22a***.

5. ***SoHO*** competent 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*** competent authorities shall make all reasonable efforts to ensure that ***SoHO preparation*** assessors that participate in joint ***SoHO preparation*** assessments have completed the relevant Union training referred to in Article 69(1) and are included in the list referred to in Article 69(5).

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

Article 25

SoHO establishment authorisation system

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

2. ***SoHO*** competent authorities shall authorise as SoHO establishments the SoHO entities that ***meet the definition in Article 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. ***SoHO*** 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 and of the resulting obligation to comply with all provisions for SoHO establishments, including the submission of an application for SoHO establishment authorisation.

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 ***until it has verified compliance with*** the more stringent measure .

Article 27

Authorisation of SoHO establishments

1. ***SoHO*** competent authorities shall provide guidelines and templates to allow that applications ***for the*** authorisation ***of*** SoHO establishments are submitted in accordance with Article 49. When developing these guidelines and templates, ***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). ***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***;

   (b) assess the application;

   (c) examine agreements between the applicant SoHO establishment and any ***SoHO entities*** 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 ▌ inspection of the applicant SoHO establishment ***pursuant to Article 29,*** and, where applicable, ***of SoHO entities or*** third parties contracted by the SoHO establishment ▌ pursuant to Article ***30***;

(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) ▌ ;

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

▌

(i) submit information regarding the ***granted authorisation*** of the SoHO ***establishment, by amending the status*** of the SoHO ***entity to SoHO establishment*** in the EU SoHO Platform ▌ without undue delay***;***

(j) assess and, as appropriate, authorise any significant 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.

3. ***SoHO*** competent authorities may***, in accordance with national legislation,*** suspend the authorisation of a SoHO establishment, or of certain SoHO activities the establishment is authorised to perform, if SoHO supervisory activities demonstrate or give reasonable grounds for suspecting, that the SoHO establishment in question ***does not comply with the condition of its authorisation or with the provisions of this regulation, and shall do so when an imminent risk to the SoHO donors, recipients or offspring of medical assisted reproduction, or an imminent risk of unnecessary wastage of SoHO, is identified.***

▌

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

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*** competent 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***.

6. In cases of authorisation suspension or withdrawal, as referred to in paragraphs 3, 4 and 5, ***SoHO*** competent authorities shall amend accordingly the authorisation status of the SoHO establishment concerned in the EU SoHO Platform ▌ without undue delay.

Article 28

Authorisation of importing SoHO ***establishments***

1. ***SoHO*** competent authorities shall ***authorise as SoHO establishments those*** SoHO entities ***that import SoHO,*** as referred to in Article ***25(2)***.

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

2. Upon receipt of an application for ***an importing SoHO 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 and effectiveness, to SoHOs preparations authorised according to the provisions of this Regulation.***

▌

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.

4. ***SoHO*** competent authorities may require to inspect any third country ***supplier*** to the applicant prior to granting or refusing the importing SoHO ***establishment*** authorisation, in particular in cases where the application concerns regular and repeated import of ***SoHO*** from the same ***third country supplier***.

9. By ***way of*** derogation from paragraph 1, ***SoHO*** competent authorities may authorise imports of ***a SoHO*** for immediate ***human*** application to a specific ***SoHO*** recipient***, when requested by the SoHO entity responsible for that application and when duly*** justified by the clinical circumstances on a case-by-case basis.***SoHO competent authorities may also authorise imports of SoHO in emergency situations for immediate human application to SoHO recipients whose health would be seriously endangered without such an import.***

10. The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this Regulation by laying down specific criteria for the ***assessment of the applications,*** 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*** competent authorities ***of the Member States where SoHO establishments are located*** shall carry out inspections ***of those*** SoHO establishments, ***and where applicable, of SoHO entities or third parties contracted by SoHO establishments.***

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 ***for the investigation*** of fraudulent or other illegal activities, or on the basis of information that might indicate non-compliance with ▌ this Regulation;

(c) ***announced or unannounced*** inspections ***targeted at a specific activity or topicas provided for in Articles 22(6***, ***28(4),*** 31 and ▌ 35(5).

2. ***SoHO*** competent authorities that during inspections identify non-compliances with the rules of this Regulation may include follow-up inspections, where necessary and proportionate, to verify that SoHO establishments have undertaken ***appropriate*** corrective and preventive actions.

▌

5. ***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, provided that:

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

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

(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 ***10*** is not exceeded.

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

▌

7a. The inspections shall include the verification that SoHO establishments comply with the standards or elements set out in Chapter VI and VII of this Regulation.

In cases where the SoHO establishments follow:

(a) the technical guidelines published by the ECDC and by the EDQM referred to in Articles 56(4), point (a), and 59(4), point (a), as applicable, the inspectors shall consider the standards ***set out in this Regulation*** to be met, insofar as they are addressed by ***these*** guidelines;

(b) other guidelines as referred to in Articles 56(4), point (b), and 59(4), point (b), ***adopted by the Member State according to paragraph 8, the inspectors shall consider the standards set out in this Regulation to be met, insofar as they are addressed by such guidelines***;

(c) ***guidelines other than those defined in points (a) or (b), or*** other technical methods ***not addressed in guidelines, applied in specific circumstances,*** as referred to in Articles 56(4), point (c), and 59(4), point (c), the inspectors shall evaluate the ***steps taken by the SoHO establishment to ensure the adequacy of such guidelines or methods, and their compliance with the standards set out in this Regulation. For this evaluation, the SoHO establishments shall provide the inspectors with all the necessary information, pursuant to Articles 56(7) and 59(7)***.

8. ***When adopting the guidelines referred to in paragraph 7a***, point (b)***, the Member State***, prior to the inspection, ***shall verify and document that those guidelines are adequate to achieve compliance with the standards set out in Chapters VI and VII of this Regulation and shall make those guidelines available at the EU SoHO Platform. These guidelines shall be deemed to be adequate to achieve compliance with the standards of this Regulation where they have been established*** to be ***equivalent with the technical guidelines published*** by the ***ECDC and by the EDQM referred to in paragraph 7a, point (a)***.

9. Inspectors ***shall*** carry out one or more of the following activities:

(a) inspect ***premises;***

(b) evaluate and verify ***compliance of*** the procedures and the SoHO activities performed ***with*** the requirements of this Regulation;

(c) examine any documents or other records ▌ relating to the requirements of this Regulation ▌ ;

(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***,*** copies of documents***, and photographs or videos,*** 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*** competent authorities shall carry out ***periodic*** inspections pursuant to paragraph ***1a***, point (a), ***so that the interval between two on-site inspections shall not exceed, in any event, four years. The frequency of inspections shall take*** account of:

(a) identified risks associated with ***the type of SoHO that are subject to the authorisation and the SoHO activities carried out;***

▌

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

(c) ***the*** certification or accreditation by international bodies, where ***relevant***; ▌

(d) the reliability and effectiveness of the quality management systems referred to in Article ***37b***.

▌

14. Following each inspection, the ***SoHO*** competent authorities shall draw up a report on the findings of the inspection ▌ and provide it to the SoHO establishment concerned. ***When the result of the inspection so requires, the SoHO*** competent authorities ***shall, as appropriate,***

set out any corrective or preventive action needed or ***shall*** request the SoHO establishment to respond with a proposal for such actions, with associated dates for completion.

▌

16. For the purpose of ▌ inspections referred to in paragraph 1 of this Article, ***SoHO*** competent authorities shall ***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 ***technical elements of*** 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 ***SoHO entities*** other ***than SoHO establishments and of third parties***

1. ***SoHO*** competent authorities may carry out inspections pursuant to Article 29(1) ***of*** SoHO entities other than SoHO establishments***, and of the third parties contracted,*** as necessary and proportionate to the risks associated with the ***SoHO*** and the SoHO activities registered for that SoHO entity, and the SoHO entity's past ▌ compliance ***records***.

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***.

▌

Article 31

Joint inspections

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

2. ***With the previous consent of the SoHO National Authority, the 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***, 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;

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

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

2a. The SoHO competent authority receiving the request for joint inspection may decline that request, in particular if:

(i) there has been a joint inspection in that SoHO entity within the previous year;

(ii) a joint inspection of that SoHO entity is already being planned.

3. The ***SoHO competent*** authorities participating in a joint inspection shall conclude ***a written*** agreement prior to ***carrying out*** the inspection***. Such written agreement shall specify*** 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;

(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 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***.

▌

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 in a relevant field, awarded on completion of a university course of study or a 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*** competent authorities shall provide inspectors with a specific induction training before inspectors take up their duties. For the specific induction training, ***SoHO*** competent authorities shall ***take into account*** the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).

3. ***SoHO*** competent 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;

(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*** 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*** and related fields;

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

4. ***SoHO*** competent authorities shall ensure that the specific induction training is complemented by specialised training for inspection of specific types of establishments and by continuous training, as appropriate***.*** ***SoHO*** competent authorities shall ***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 ▌.

▌

Article 33

Activity data extraction***, submission*** and publication

1. ***SoHO*** competent authorities shall verify that SoHO entities that have activity data collection and reporting obligations pursuant to Article 44 submit ***to their SoHO competent authorities, via the EU SoHO Platform, an*** annual ***report*** of those activities***.*** The EU SoHO Platform ***shall allow the compilation of the annual reports submitted by***

the SoHO entities and provide the SoHO competent authorities with an aggregated annual report with the activity data from their SoHO entities.

1a. By derogation from paragraph 1, Member States may decide that SoHO entities submit the activity data referred to in Article 44(1) to SoHO competent authorities through national or international registries, in cases where such registries collect activity data matching the data sets defined in the EU SoHO Platform. In this case, the SoHO competent authorities shall submit these data, as will be further specified in the Implementing Act, mentioned in Article 44(3).

2. ***SoHO*** competent authorities shall ***ensure that the*** annual ***aggregated*** report of SoHO activity data for their SoHO entities ***is made 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***.

2a. The Commission shall compile the annual aggregated reports from the SoHO competent authorities, prepare and, after having shared the report with the SoHO National Authorities for review and approval, publish and make available on the EU SoHO platform an annual SoHO Activity Report.

Article 34

Traceability

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

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

Article 35

Vigilance

1. ***SoHO*** competent authorities shall be responsible for the ***supervision*** of vigilance associated with SoHO activities. ▌

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

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

▌

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

▌

(d) respond to the submitting SoHO entity ***if additional documentation or corrections are required***.

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

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

(b) request contributing advice from the SCB pursuant to Article 68(1).

In case the SAR notification concerns a transmission of a communicable disease that is rare, or unexpected for that SoHO type, SoHO National Authorities shall inform the ECDC. In such cases, the SoHO National Authority shall take into account any advice or information provided by the ECDC or its SoHO expert network.

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

▌

(b) verify that the ▌ 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 ***assessment, if corrections are required***.

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

5a. Where a SAR or SAE notification concerns a risk to public health , competent authorities shall, without delay, communicate essential information to other competent authorities via the rapid alert procedure referred to in Article 36. Competent authorities receiving that information shall communicate it to the general public, where relevant.

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

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 released the SoHO, 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 ***within the meaning of*** Regulation (EU) 2017/745 ***and Regulation (EU) 2017/746 , the SoHO*** competent authorities receiving such information shall ***communicate it to*** the SoHO

entities ***that may be using the device*** concerned ***when carrying out their SoHO activities . The SoHO*** competent authorities shall ***also*** submit that information to their ▌ SoHO ***National*** Authority, provided that the incident meets the definition of a ***SAE or SAR***.

▌

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

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

10a. SoHO National Authorities shall submit an annual summary of confirmed SAR or SAE notifications and investigation reports to the EU SoHO Platform before 30 June of the subsequent year and shall make an aggregated version of that summary available to the public in their Member State, including on the internet. They shall include the numbers and types of SAR or SAE notifications reported to them that meet thresholds of seriousness and imputability that are agreed and documented as best practices by the SCB, as referred to in Article 68(1), point (c).

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*** with the SoHO National Authorities for review and approval. ***The report should include overall pattern analysis and recommendations.***

▌

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*** 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*** competent authorities shall, upon receipt of a notification of a ***SAR or a SAE*** or other information with implications for ▌ quality***, safety*** or supply of ***SoHO in more than one*** Member ***State, inform their SoHO National Authorities, which shall, in turn*** launch a SoHO rapid alert on the EU SoHO Platform ▌ .

2. ***SoHO National*** Authorities shall launch a SoHO rapid alert in particular in the following circumstances:

   (a) a risk to the quality or safety of ***SoHO*** has been identified concerning ***SoHO*** 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 ***SoHO***;

   (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 ***SoHO*** and that might be used in other Member States;

   (d) other information is available to the ***SoHO National*** Authorities that could reasonably be considered useful in other Member States to reduce risks to the ***quality or safety of SoHO*** and where the launch of a SoHO rapid alert ***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*** Authorities that receive a SoHO rapid alert shall communicate ***relevant*** information to ***SoHO competent authorities in their Member State and to the relevant***

SoHO entities ▌ without undue delay with a view to ensuring that risk mitigating actions can be taken promptly and that relevant information available ***among professionals in*** the SoHO ***sector*** can be shared with the ***SoHO*** competent authorities. ***SoHO National*** Authorities may also supplement the information provided in the alert with further information such as details of relevant mitigating actions taken in their Member State.

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

CHAPTER IV

GENERAL OBLIGATIONS ON SOHO ENTITIES

Article 37

SoHO entity registration

1. Entities shall register as a SoHO entity before commencing any ***of the SoHO activities*** referred to in Article ***2(1a).***

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

1b. To register, the SoHO entity shall provide the following information:

(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 responsible person as referred in Article 37a;

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

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

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

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

(g) where applicable, information regarding activities carried out and regulated under other Union legislation, as referred to in Article 14.

1c. SoHO entities shall declare, when registering, that they need an authorisation pursuant to Articles 21, 27 or 28. They shall also conduct a self-assessment of whether they meet the criteria for being a critical SoHO entity and communicate the result. Organisations may request from their SoHO competent authorities, within their territory an opinion on whether the activities they are carrying out are subject to the registration requirements in this Chapter.

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

3. SoHO entities ***shall register without undue delay*** changes to ***information registered pursuant to paragraph 1b points (a), (b), (d), (e), (f) and (g)***. Where such changes imply SoHO activities including ***either*** processing and storage***, or release, or import or export of SoHO***, those SoHO entities shall ***apply for an authorisation as SoHO establishment***.

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 relationship 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, 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 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. 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. The responsible person may 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

Quality management system

1. SoHO entities shall establish, maintain and update a quality management system, appropriate to their activities, achieving a high level of quality of SoHOs.

2. SoHO entities shall design the quality management system to ensure that SoHO activities are carried out in a consistent manner, by personnel that have documented and periodically assessed competenceto perform the tasks allocated to them and in facilities that are designed and maintained in a manner that prevents SoHO contamination, or cross-contamination between SoHO, or loss of traceability. In so doing, SoHO entities shall take into account the technical guidelines for quality management published by the EDQM, together with the EDQM Good Practice Guidelines, as indicated in the EU SoHO Platform. Alternative approaches to the design of the quality management system

may be applied where SoHO entities can demonstrate to their SoHO competent authorities, that they achieve an equivalent level of quality.

3. SoHO entities shall put in place procedures and specifications covering, when applicable to their activities, the following:

(a) documentation of roles, 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, ,including information technology systems;

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

(d) quality control, and monitoring of key performance indicators of SoHO activities;

(da) quarantine and release;

(e) withdrawal of SoHOs from the inventory of released SoHOs and recalls;

(f) internal audits;

(g) management of contracted third parties;

(h) management of cases where procedures have not been followed or specifications have not been met;

(ha) complaints;

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

(hc) continuity planning.

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

5. The Commission may adopt implementing acts regarding selected elements of and specifications of the quality management system in order to ensure uniform quality management.

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 ▌ 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 ▌ .

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

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

Article 41

Application for ***SoHO preparation*** authorisation ▌

1. SoHO entities shall ***submit*** applications for ▌ SoHO preparation authorisation ***to the SoHO competent authority of their territory***.

2. ***Applications for SoHO preparation authorisation*** shall ***include*** the following:

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

(a) ▌ 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 list of the*** specific SoHO donor eligibility ***criteria including*** SoHO donor ***tests specific for the SoHO preparation***;

(ii) ***a summary of*** 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***;

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

(vii) data ***resulting from*** process validation and equipment qualification;

(viii) details of any ***SoHO entities or*** third parties contracted ***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 submitted***, 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), point (a) ***or a specification included in technical guidelines referred to in Article 59(4), points (b) or (c)***;

(ii) whether the SoHO preparation meets the defined quality criteria in ***a monograph or specification as*** referred to in point (i) and is intended to be used for the indication and with the mode of application to which that monograph ***or specification*** refers, where such details are provided in that monograph ***or meets 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***, in accordance with Regulation (EU) 2017/745, of ***a*** certified medical device ***that is critical to the specific processing*** for the SoHO preparation, ***in cases*** where ***the applicant has access to such data***;

(v) documentation of a ***standardised*** process of identification, quantification and evaluation of any risks to ***SoHO donors, SoHO recipients*** 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)***;

(c) in cases where the indicated risk is ***greater*** than negligible, ***or the expected clinical effectiveness is unknown, a proposed plan*** for clinical outcome monitoring ***for providing further evidence, where necessary,*** of the SoHO preparation, in line with the results of the ***benefit-risk*** assessment ***and pursuant to paragraph 2b of this Article***;

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

3. ***If the application for SoHO preparation authorisation includes clinical outcome registration, in accordance with Article 22(5)***, the applicant shall ***provide details of the registry to the SoHO competent authority and request approval for its use.***

▌

4. ***Where applicable, in accordance with Article 22(4), point (e) and Article 22a,*** SoHO entities shall ***prepare and distribute the SoHO preparation in question solely for the performance, and within the limitations of a*** clinical outcome monitoring ***plan that has been approved by the SoHO competent authority,*** pursuant to Article 21(2), point (c), and submit the results ***and*** their ***analysis to their SoHO*** competent ***authority according to the timeline set in the approval.***

4a. The applicant ***remains responsible for collecting the*** clinical ***outcome monitoring data and shall be in a position to make these data available upon request from the SoHO competent authority***.

5. SoHO entities shall not make any ***significant*** change ***within steps of the processing applied or in the*** activities performed for an ***authorized*** SoHO preparation, without the prior written ***authorisation*** of their ***SoHO*** competent authorities. ***Significant changes for which an application for an updated authorisation*** shall ***be required are those having an impact on the intended clinical indication or on the quality, safety or effectiveness of the SoHO preparation***.

6. The SoHO ***entity authorised*** for the SoHO preparation ▌ shall be ***based in the Member State where the application is submitted***.

Article 41a

SoHO clinical studies

1. When conducting SoHO clinical studies, with SoHO preparations that are not yet authorised, in the context of approved clinical outcome monitoring plans as referred to in Article 41(2), points (b) and (c), SoHO entities shall comply with the requirements set out in this Regulation and in particular the standards laid down in chapters VI and VII.

2. Before commencing a clinical study for the risk level referred to in Article 41(2) point (c), SoHO entities shall:

(a) apply for a favourable opinion from a relevant ethics committee and shall communicate such opinion to their SoHO competent authority. The opinion shall address the ethical, legal and methodological aspects of the clinical study, to determine the capacity of the study design to draw robust conclusions;

(b) await approval by the SoHO Competent Authority of the clinical outcome monitoring plan, as referred to in Articles 21, (2), (c) and 22a.

3. When applying SoHO to SoHO recipients in the context of a SoHO Clinical study, SoHO entities shall ensure that the intended SoHO recipients, or persons granting consent on their behalf, are informed that the SoHO preparation in question has not yet been authorised according to the provisions of the Regulation and that the SoHO preparation is being applied in the context of a clinical study that forms part of the authorisation process.

4. The person responsible for the SoHO clinical study shall be adequately qualified and trained.

5. SoHO entities shall detect, investigate and report serious adverse reactions and serious adverse events that occur in the course of a clinical study, in accordance with Article 47(1).

(Articles 42 and 43 moved to after Article 49)

Article 44

Activity data collection and reporting

1. SoHO entities shall collect ***and report*** data relating to ***any of the following SoHO*** activities ▌:

(a) ▌ donor ***registration***;

(b) collection;

(c) distribution;

(d) import;

(e) export;

(f) human application.

2. The data collected pursuant to paragraph 1 shall comprise the ***data set indicated*** in the EU SoHO Platform ▌.

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 ***of the annual activity data reports, extraction, submission and publication***.

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*** of the data collected pursuant to this Article ***before 30 June*** of the ***subsequent year***.

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 ▌ and to all ***the*** documents, samples, SoHO preparations and SoHO entities that are associated with that SoHO ***at any*** point***.*** Importing SoHO ***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 equipment coming into contact with those SoHO that might pose a risk to their quality or safety.

2. SoHO entities distributing ***SoHO*** shall ***apply*** a code that contains the information included in the ***requirements of the*** traceability system referred to in paragraph 1. 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 ▌ applied to the SoHO ▌ , or on the documents accompanying the distributed SoHO***,*** where it can be guaranteed that such documents will not be separated from the SoHO 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 distribution date, or disposal where applicable. They may store the data in electronic form. In case a SoHO entity ceases its activity, the traceability data shall be transferred to a contracted SoHO entity for the completion of the traceability period, with the prior information to the corresponding SoHO competent authorities.

4b. The Commission shall adopt implementing acts concerning the minimum SoHO donor and SoHO recipient data 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 system

1. SoHO entities shall apply a Single European Code ('SEC') to SoHO ▌ distributed for human application. In cases where ***SoHO*** are transferred for further processing in another SoHO entity or released for manufacture of products regulated by other Union legislation ***as provided for in Article 2(3) or exported to third countries***, SoHO entities shall, at least, apply the ***elements*** of the SEC that ***allow the*** identification of the donation. The SEC shall ***also*** appear on the ***primary*** packaging or on a label attached thereto, or on the documents referring to the SoHO where it can be ***ensured*** that such documents accompany the SoHO concerned.

2. Paragraph 1 shall not apply to:

   (a) reproductive ***SoHO*** for within ***relationship*** use;

   (b) blood or blood components for transfusion or for the manufacture of medicinal products;

   (c) ***SoHO*** applied to a ***SoHO*** recipient without being stored;

   (d) ***SoHO*** imported into the Union ***by derogation and*** authorised directly by ***SoHO*** competent authorities pursuant to Article 28(9);

   (e) ***SoHO*** 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*** at the point of distribution ▌ .

   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 and*** adverse ***events, including those*** detected during clinical outcome monitoring as part of a SoHO preparation authorisation application as referred to in Article 41.

2. ▌SoHO entities shall make all reasonable efforts to encourage prospective parents of children born from third party donation to ▌communicate information concerning ***serious*** genetic conditions ***as soon as they emerge in the children***, to the SoHO entity where they were treated. ***The SoHO*** entity shall communicate, without undue delay, ***that*** information to the SoHO ***establishment that released*** the reproductive ***SoHO for application or distribution*** with a view to ***investigating the suspected SAR and*** preventing further distribution of SoHO from the implicated SoHO donor***, in accordance with national legislation on the storage and use of reproductive SoHO***.

3. In cases where SoHO entities detect or suspect that an adverse ***reaction or adverse event*** meets the definition of a ***SAR or a SAE***, they shall submit a ▌notification to their ***SoHO*** competent authorities ***without undue delay and*** shall include the following ***information***:

   (a) a ▌description of the suspected ***SAR or SAE***;

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

   ▌

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

   (e) a preliminary assessment of the seriousness of the consequences of the ***suspected SAR or SAE***.

3a. SoHO entities other than SoHO establishments shall communicate adverse reactions or adverse events to the SoHO establishment for which they carry out SoHO activities in the context of an agreement or to the SoHO establishment that distributed the SoHO to them, as appropriate. In such cases, the SoHO establishments receiving the communication shall be responsible for the investigation and shall report to their SoHO competent authorities when the adverse reaction or adverse event concerned is deemed a SAR or a SAE. All other SoHO entities shall investigate and report SAR or SAE directly to their SoHO competent authorities.

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 receiving 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*** affected by adverse ***reactions or adverse events*** referred to in paragraph ***3***, 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 ***SAR or SAE*** detected ***or communicated to them according to paragraph 3a***. On completion of ***that*** investigation ▌, SoHO entities shall provide ***an*** 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 ▌ to the donation or application of the SoHO***, if applicable***;

   (b) the final assessment of the seriousness of the consequences ▌ 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*** information concerning a ***SAR or a SAE*** to other SoHO entities engaged in the collection, processing, testing, storage and distribution of SoHO collected from the same ***SoHO*** donor, or otherwise possibly affected ▌. They shall only ***communicate*** information necessary and appropriate in order to facilitate traceability and ensure quality and safety in such cases, and shall, in particular, limit the information to details necessary to take mitigating actions. ***A risk assessment of the seriousness and likelihood of recurrence shall be included in the communication.*** SoHO entities***, where relevant,*** shall also ***communicate*** such information to organ procurement organisations in cases where ***the SoHO*** donor who is implicated in the ***SAR or SAE*** has also donated

organs ***or to manufacturers in cases where SoHO collected from that SoHO donor have been distributed to manufacture products regulated by other Union legislation, as referred to in Article 2(3)***.

CHAPTER V

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*** be audited by the ***contracting SoHO establishment 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***.

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 ***submit*** the application for authorisations as SoHO establishments to ***the SoHO*** competent authorities ***of their territories***.

2. The applicant SoHO establishment shall provide the name and contact details of the ***responsible person for*** carrying out the SoHO activities subject to the authorisation***,*** ***pursuant*** to Article ***37a.*** The ▌ SoHO establishment shall not make any ***significant*** changes ***with regards to SoHO or*** SoHO activities subject to the authorisation without the prior written ***authorisation*** of the ***SoHO*** competent authority. ▌

2a. Significant changes for which an application for an updated authorisation shall be required pursuant to paragraph 2 are those relating to the types of SoHO concerned, to the types 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*** shall be based in the ***Member State where the SoHO establishment is authorised***.

Article 42

Importing SoHO ***establishment*** authorisation

1. SoHO ***establishments*** shall not import ***SoHO*** without a prior importing SoHO ***establishment*** authorisation.

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

2a. SoHO entities responsible for human application to a specific SoHO recipient may request to their SoHO competent authorities a derogation from the requirement for an importing SoHO establishment authorisation in the circumstances referred to in Article 28(9).

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

Article 43

Application for importing SoHO ***establishment*** authorisations

1. ***Article 49*** shall ***apply mutatis mutandis to the applications for*** importing SoHO ***establishments authorisation***.

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*** shall ***also provide:***

(-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 shall include, at least:

(i) details of the third country supplier contracted;

(ii) the requirements to be met to ensure the equivalency of the quality, safety 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 SoHO will be equivalent, in terms of quality, safety and effectiveness, to SoHO authorised according to the provisions of this Regulation.

▌

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

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

5a. The releasing officer of an importing SoHO establishment shall release imported SoHO for distribution only when they have verified compliance with the quality, safety and effectiveness requirements specified in the agreement referred to in paragraph 2 of this Article and when the physical and documentation controls referred to in paragraph 4 are satisfactory. In the case of national or international donor 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 ***SoHO*** 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 49a

Releasing officer

1. In cases where a SoHO establishment releases SoHO, it shall designate one or more releasing officers.

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

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

Article 49b

Physician

1. SoHO establishments shall designate a physician who carries out its tasks in the same Member State and who shall at least fulfil the following conditions and have the following qualifications:

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

(b) at least two years' practical experience in the relevant field.

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

(a) development, review and approval of procedures for establishing and applying SoHO donor eligibility criteria, procedures for SoHO collection and criteria for the allocation of SoHO;

(aa) supervision of the implementation of 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 in SoHO donors, SoHO 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 evidence gathering to support applications for SoHO preparation authorisations pursuant to Article 41;

(d) other tasks of relevance to the health of SoHO donors, SoHO recipients and offspring from medically assisted reproductionof 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, SoHO recipients and, where relevant, offspring from medically assisted reproduction.

Article 49c

Export

1. SoHO establishments shall ensure that SoHO released for export comply with the requirements of this Regulation.

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

I

CHAPTER VI

SoHO DONOR PROTECTION

Article 52

Objectives regarding SoHO donor protection

1. SoHO entities shall ensure ***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, by identifying and minimising such risks*** before, during and after the ***SoHO collection***.

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

Article 53

Standards concerning SoHO donor protection

1. In case of collection of ***SoHO from*** donors, regardless of whether or not the ***SoHO*** donor is ▌ 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,*** any persons granting ***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;

▌

(d) safeguard the rights of the ***living SoHO*** donor to physical and mental integrity***, to non-discrimination***, to privacy and to the protection of the personal data***, including health data,*** concerning them in accordance with Regulation (EU) 2016/679;

(e) ensure that donation is voluntary and unpaid, pursuant to Article 54;

(f) verify the eligibility of the ***living SoHO*** donor on the basis of a donor health evaluation that aims to ***identify and*** minimise any risk that the ***SoHO collection*** might pose to the ***SoHO*** donor's health;

(g) document the results of the ***living SoHO*** donor health evaluation ▌;

(h) communicate and clearly explain the results of the ***living SoHO*** donor health evaluation to the ***living SoHO*** donor or***, where applicable,*** any persons granting ***consent on their*** behalf, in accordance with national legislation;

(i) identify and minimise any risks to the health of the ***living SoHO*** donor during the ***collection*** procedure, including exposure to reagents or solutions that might be ***harmful to health***;

(j) ***in cases where SoHO can be donated repeatedly, and frequent donation might negatively influence the living SoHO donor's health,*** verify, by means of ***registries, as referred to in paragraph 3, that living SoHO*** donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article ***56(4) and monitor relevant health indicators to evaluate*** that their health is not compromised;

(k) ▌ in cases where ***SoHO donation implies*** a significant risk to a ***living SoHO*** donor***,*** as referred to in paragraph ***4, develop and implement a plan for monitoring the SoHO donor's health after the donation***;

(l) in the case of an ▌ unrelated donation, refrain from revealing the ***SoHO*** donor's identity to the ***SoHO*** recipient ***or to the offspring***, apart from ▌ circumstances where such information exchange is permitted in the Member State ***concerned***.

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 ***physical, and, where appropriate, mental*** health and their health histories to assure the safety of the donation process for those donors. SoHO entities may perform ***additional*** tests as part of the ***SoHO*** donor health evaluations. They shall perform such tests in cases where evaluations indicate that ***such*** tests are necessary to establish the eligibility of those ***SoHO*** donors from the perspective of their own protection. The physician, ▌ referred to in Article ***49b***, shall approve the procedure and criteria for ***SoHO*** donor health evaluations.

3. SoHO entities that collect ***SoHO from living SoHO*** donors ***as referred to in paragraph 1 point (j) shall register such SoHO donors in a SoHO entity registry or, where available,***

in national or recognised international registries, to verify donation ***frequency. Entity-level and national registries shall have the possibility for interconnectivity with other such registries. In cases where a SoHO entity level registry or a national*** registry ***is used, and where the circumstances imply a risk that a SoHO donor is donating too frequently, in more than one SoHO entity, in one or more Member States, SoHO entities shall verify that this is not the case by consulting with interconnected donor registries on a case-by-case basis***. SoHO entities ***shall be in a position to demonstrate to their SoHO competent authorities, on request, an appropriate procedure that mitigates this risk. Such procedures*** shall ***take into account the technical guidelines referred to in Article 56(4)***.

4. ***SoHO entities that collect SoHO from living SoHO donors that are subjected to a surgical procedure in order to donate, or that are treated with prescribed medication to facilitate donation*** shall ensure that the plan for monitoring ***the SoHO*** donor health after 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.

▌

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 ***living 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 ▌any persons granting ***consent*** on their behalf▌.

2. ***Where*** Member States ▌allow for the compensation ***of living SoHO donors, in accordance with the principle of voluntary and unpaid donation and based on transparent criteria, including*** through fixed ▌allowances***, or through non-financial forms of compensation,*** the conditions for such ***compensation shall be established*** in

national legislation, including ***by*** setting ▌ an upper limit ***for compensation thatshall endeavour to guarantee financial neutrality,*** consistent with the standards laid down in this Article. ***Member States*** may delegate the setting of conditions for such ***compensation*** to independent bodies that are established in accordance with national legislation. ***The setting of compensation conditions shall be based on criteria that take into account the best practices documented and published by the SCB as referred to in Article 68(1), point (db). SoHO donors may choose not to be compensated.***

2a. When Member States allow for the compensation of SoHO donors as referred to in paragraph 2, the conditions for such compensation applied by each Member State shall be made available to the SCB for sharing with the SoHO national authorities of the other Member States via the SoHO platform and the information shall be updated without undue delay if modified.

2b. Member States shall ensure that any promotion and publicity activities in support of the donation of SoHO do not refer to compensation, without prejudice to the right of donors to be informed of their rights, in accordance with national law.

3. SoHO entities may compensate ***living SoHO*** donors as provided for by their ***Member States*** pursuant to paragraph 2. ***At the request of their SoHO competent authority, SoHO entities shall provide information in a transparent manner on the details of how they have implemented the conditions laid down national legislation.***

3b. Member States shall ensure compliance with standards of VUD, equivalent to those laid down in this Article, also when SoHO are donated exclusively for use in research without any human application.

Article 55

Standards concerning information to be provided prior to consent ▌

1. SoHO entities shall provide ***living*** SoHO donors ***or, if applicable,*** any persons granting ***consent*** on their behalf, ▌ with all appropriate information relating to the donation ▌ process***,*** in accordance with national legislation ▌ .

2. SoHO entities shall provide the information referred to in paragraph 1 before the consent ***to donate*** is granted ▌ . SoHO entities shall provide the information in an accurate and clear manner, using terms that are easily understood by the ***SoHO*** donors or***, if applicable, any***

persons ***granting*** consent ***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 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 ***revoke*** consent and any restrictions on ***that*** right ***after the collection***;

▌

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

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

(g) the recording and protection of ***SoHO*** donor***'s*** personal ***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) ***other*** applicable safeguards ▌ to protect the ***SoHO*** donor***.***

▌

3a. ***In case of deceased SoHO donors, SoHO entities shall provide any persons granting consent to donation, and in accordance with national legislation, with the information referred to in paragraphs 3(a), (aa), and (c).***

Article 56

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 ▌ or 55, in order to ensure convergent and high levels of ***SoHO*** donor ***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. ***The implementing 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 referred to in Articles 53 and 55***.

4. For those standards concerning ***SoHO*** donor protection or elements thereof for which no implementing act has been adopted, ▌ SoHO entities shall ***take into account***:

   (a) the most recent technical guidelines, as indicated on the EU SoHO Platform ▌, as follows:

      (i) published by the ECDC concerning the prevention of communicable disease transmission ▌;

      (ii) published by the EDQM concerning ***SoHO*** donor protection other than from transmission of communicable ***diseases***;

(b) other guidelines***, adopted by Member States, as*** referred to in ***Article 29(7a)*** point ***(b)***;

(c) ***other*** guidelines ***or*** technical ***methods, applied in specific circumstances, as referred to in Article 29 (7a) point (c)***.

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 ▌ 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 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 ***provide a justification to their SoHO competent authorities during inspection, for each specific standard, or element thereof, that the other guidelines are adequate to achieve the level of safety and quality defined in that standard of this Regulation. This justification may be based on a documented demonstration of equivalence with the technical guidelines published by the ECDC and by the EDQM referred to in paragraph 4, point (a). Where other technical methods are applied, SoHO entities shall*** perform a risk assessment to demonstrate that the technical methods applied achieve a high level of ***protection of SoHO donors***, 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 ***and their application, 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 ***that achieve*** high levels of safety and quality ***of SoHO. Such procedures shall ensure that*** benefits for SoHO recipients and offspring from medically assisted reproduction ▌ outweigh ***residual*** risks. They shall, in particular, achieve a high level of assurance that pathogens, toxins or genetic conditions ***that are potentially life-threatening, disabling or incapacitating and originate from a third party donor,*** are not transmitted to ***SoHO*** recipients or offspring from medically assisted reproduction. ***Procedures to prevent the transmission of serious genetic conditions shall include genetic testing to the extent that national legislation allows for such testing.***

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 ***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 ***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*** 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 ***potentially life-threatening, disabling or incapacitating genetic conditions with a significant prevalence in the SoHO donor population; or***

(ii) testing ***SoHO*** recipients to identify ***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 ***resulting from*** cross-contamination ***between SoHO*** during collection, processing, storage and distribution***. Such*** measures ***shall*** ensure that physical contact between ***SoHO*** from different ***SoHO*** donors***, SoHO collected from different individuals for future autologous or within relationship use,*** is avoided or, in cases where ***pooling SoHO*** is necessary for ***effectiveness or feasibility*** of the SoHO preparation, is ***limited to the justifiable level***.

5. In the procedures referred to in paragraph 1, SoHO entities shall mitigate risks arising from microbial contamination of ***SoHO*** from the environment, the personnel, the equipment ***and the materials*** coming into contact with ***SoHO*** 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 ***that come into contact with SoHO during collection, processing, storage or distribution,*** such that their sterility***, where necessary,*** is ensured***;***

(ca) performing quality control testing of SoHO to detect microbial contamination and using methods of inactivation or elimination of microorganisms, where feasible and appropriate.

6. In the procedures referred to in paragraph 1, SoHO entities shall mitigate the risks that any reagents and solutions added to ***SoHO*** or coming ***into*** contact with ***SoHO*** during collection, processing, storage and distribution might be ***transferred to SoHO*** recipients and have a ***harmful*** 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 ***SoHO***, necessary for clinical ***effectiveness***, have been changed by any SoHO activity performed, in a manner that renders ***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 ***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*** cause an ***unexpected*** immune reaction in ***SoHO*** recipients by combining, at least, the following measures:

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

(aa) including procedures to reduce, when feasible, those elements of SoHO that stimulate an unintended immune response, as applicable;

(b) correctly distributing ***and applying SoHO*** 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***, including where related to the protection of dignity, in accordance with national law,*** of SoHO recipients or of offspring from medically assisted reproduction arising from ***SoHO applied*** and not addressed in paragraphs 2 to 8by 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 distributing SoHO entity shall respect the limits imposed by the receiving Member State. This article does not affect Member States's rules concerning limits on the cross-border distribution of reproductive SoHO.

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 ***an approved clinical outcome monitoring plan of a SoHO preparation***

by their SoHO competent authority pursuant to Article 41(4) or, in the context of ***use pursuant to Article 21(9a), an individual treatment attempt with respect to the clinician's decisions on therapy and in health emergency situations*** pursuant to Article ***64***;

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

(c) advertise or promote particular SoHO ▌ 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, including reconstructive surgery, 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, in case of donation from a living SoHO donor 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 donation from a living SoHO donor, the interview may also include any part of the interview conducted as part of the evaluation referred to in Article 53(1), point (f). For living SoHO donors that donate repeatedly, the interviews referred to in the ***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).***

▌

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, ▌ any persons granting ***consent*** on their behalf, in accordance with national legislation.

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

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

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 personal data, including health data,*** of the ***SoHO recipients, and where relevant of the offspring from*** medically assisted reproduction;

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

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***, 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 ▌ 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 apply the standards or elements concerning SoHO recipient and offspring protection as referred to in*** Article ***58***.

4. For those standards or elements of standards concerning ***SoHO*** recipient and offspring protection for which no implementing act has been adopted, ▌ SoHO entities shall ***take into account***:

   (a) the most recent technical guidelines, as indicated on the EU SoHO Platform ▌ , as follows:

      (i) published by the ECDC concerning the prevention of communicable disease transmission ▌ ;

      (ii) published by the EDQM concerning ***SoHO*** recipient and offspring protection other than from transmission of communicable disease ▌ ;

   (b) other guidelines***, adopted by Member States, as*** referred to in ***Article 29(7a)*** point ***(b)***;

(c) ***other*** guidelines ***or*** technical ***methods, applied in specific circumstances, as referred to in article 29(7a) point (c)***.

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 ▌ 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 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 ***provide a justification to their SoHO competent authorities during inspection, for each specific standard, or element thereof, that the other guidelines are adequate to achieve the level of safety and quality defined in that standard of this Regulation. This justification may be based on a documented demonstration of equivalence with the technical guidelines published by the ECDC and by the EDQM referred to in paragraph 4, point (a). Where other technical methods are applied, SoHO entities shall*** perform a risk assessment to demonstrate that the technical methods applied achieve a high level of protection of ***SoHO donors,*** 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*** that releases ***SoHO for distribution or export***, shall have a procedure in place, under the control of the ***releasing officer,*** as referred to in Article ***49a, for SoHO release***, to ensure that the standards or elements of a standard referred to in ***Articles*** 58 and ▌ 59 ***and their implementation***, have been verified and documented prior to release and that all conditions included in any applicable authorisations in accordance with this Regulation have been complied with.

SoHO processed for autologous or within relationship use, without SoHO storage, shall not require release before application. In such cases, the SoHO preparation authorisation shall include a definition of the quality control parameters to be monitored during the processing.

Article 61

Exceptional release

1. The physician referred to in Article ***49b*** may authorise ***a releasing officer in a SoHO establishment*** pursuant to Article ***49a***, to release ***for distribution*** a certain SoHO preparation ***and*** for application to ***an intended SoHO*** recipient in cases where that SoHO preparation does not meet all of the relevant standards ▌ referred to in ***Articles 58 and 59, or does not fully comply with its SoHO preparation authorisation, or has been imported under the derogation referred to in Article 28(9),*** when the ***potential benefit for the SoHO recipient outweighs the risks and no alternative is available. The exceptional release condition*** shall be ***explicitly indicated on the label or in the accompanying documentation associated with the released SoHO preparation***.

2. ***Exceptional release, as referred to in paragraph 1, shall only be authorised in the case of release for distribution, on the basis of a documented request from the physician treating the intended SoHO recipient, where such a request includes a confirmation of full knowledge and agreement of any deviation from the provisions of this Regulation. The physician referred to in Article 49b shall document the decision process in a risk-benefit assessment. In such 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 with that SoHO entity, shall lay down a time period during which the monitoring shall continue.

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.

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 preparation does 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, within their territories, in collaboration with SoHO National Authorities, SoHO competent authorities and SoHO entities, each within their respective tasks, shall consider all reasonable efforts for a sufficient, adequate and resilient supply of critical SoHO aimed to appropriately meet recipients' needs, and to contribute to European self-sufficiency.

2. Member States shall make all reasonable efforts to:

(a) facilitate public participation in SoHO donation activities for critical SoHO, with a view to ensure a broad and resilient SoHO donor base built on voluntary unpaid donations in accordance with Article 54;

(b) ensure that critical SoHO donor recruitment and retention strategies are put in place, including communication campaigns and education programmes;

(c) carry out the activities referred to in paragraph 1 through preparedness and response measures, with due regard to Article 54;

(d) ensure optimal use of critical SoHO, taking account of therapeutic alternatives.

In so doing, Member States 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, in case of shortages or upon request, to communicate this information to their SoHO competent authorities, that shall establish appropriate mechanisms to receive this information. SoHO competent authorities shall be in a position to get an overview of the availability of critical SoHO in their territories, when needed.

5. In cases where the availability of critical SoHOs depends on commercial interests, each Member State shall seek that those SoHO entities, within the limit of their responsibilities, provide an appropriate and continuous supply of critical SoHO to SoHO recipients in their territory.

Article 62

▌National SoHO emergency plans

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

1a. 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.

▌

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

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

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

(ba) a consolidated national overview of critical SoHO entities emergency plans, as laid down in Article 66;

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

(d) ▌procedures for sharing information***, where appropriate, via the EU SoHO platform, as well as elements of information to be exchanged between SoHO National*** Authorities of other Member States and other parties concerned, as appropriate***, including in cases of shortages of critical SoHO with cross-border impact***;

(e) ***preparedness and response measures*** for specific identified risks, in particular those concerning communicable disease outbreaks***, war or terrorist attacks and environmental disasters***;

(f) a procedure for the assessment and authorisation, ***in the context of an emergency situation and in accordance with Article 64***, of requests from SoHO entities***,*** for derogations***from the obligation to have a SoHO preparation authorisation pursuant to Article 40(1);***

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

▌

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 ***involve relevant stakeholders in the elaboration of*** their national ***SOHO*** emergency plans***, in particular by cooperating with their critical SoHO entities, as well as with the EDQM and the ECDC. Member States shall review at least every four***

years such plans in order to take into account changes in the ***designation of critical SoHO entities, the*** organisation of ***SoHO*** competent authorities and ***the*** experience gained from implementing the plans and simulation exercises.

6a. Member States shall present a summary of their national emergency plans, and major reviews of these plans, within the SCB.

6b. 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.

Article 63

Supply alerts for critical SoHOs

1. Critical SoHO entities shall***,*** without undue delay***, send*** a SoHO supply alert to their ***SoHO*** competent authorities in case of significant ***shortages of supply of critical SoHO***, indicating the underlying ***reasons***, the expected impact on ***recipients*** and any mitigating actions taken***,*** including possible alternative supply channels if appropriate. ***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 there is a significant risk of being cancelled or postponed, due to unavailability; and

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

2. ***SoHO*** competent 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, to the extent possible; and

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

3. The SoHO National Authorities ***shall*** submit***, without undue delay,*** to the EU SoHO Platform the SoHO supply alert received in cases where the supply interruption might affect other Member States ***and may do so*** where such interruption might be addressed through cooperation***, including through exchange of SoHO,*** 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***, as referred to in Article 40(3) and*** 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 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 SoHO 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*** competent authorities shall***:***

(a) indicate the period of time for which the ***permit referred to in paragraph 1*** is granted ***and if such SoHO preparations may be distributed to other Member States;***

(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. 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**.**

2a. 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

Emergency ***derogations in man-made or natural disasters***

1. Insofar as necessary to ensure supply of critical SoHO, Member States may ***allow for derogations from certain standards and obligations*** set out in ***this Regulation when large scale life-threatening situations in the context of man-made or natural disasters, notably in the context of armed conflicts, pose a risk to human life, and such derogations are the only measure available to mitigate the risk. Derogations shall not be granted from the provisions of this Regulation that concern voluntary unpaid donation and SoHO donor consent. The derogations shall be applied in a manner that ensures the protection of SoHO donors and SoHO recipients to the maximum extent possible in the circumstances of the crisis.***

2. Member States ***granting such derogations*** 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

Each ***critical SoHO entity*** shall ***draw up*** a SoHO entity emergency plan that ***implements*** the national SoHO emergency plan as referred to in Article 62.

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 may*** invite experts and observers to attend its meetings, and may cooperate with other external experts***,*** as appropriate.***The SCB may also invite, where relevant,*** other Union institutions, bodies, offices and agencies***. In such cases, they*** shall have an observer ***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. The Commission shall make publicly available*** 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***.

3a. The Commission shall make the Rules of procedures of the SCB, the agenda and the summary minutes of each meeting, and the best practices agreed and documented by the

SCB, as provided in Art 74 (2a) (d), publicly available on the EU SoHO Platform, unless such publication undermines the protection of a public or private interest, as defined in Article 4 of Regulation (EC) No 1049/2001.

4. The Commission shall ***co-chair*** the meetings of the SCB ***together with a representative of the SoHO National Authority of a Member State, elected by and from among the representatives*** of the ***Member States in the SCB, and in accordance with the Rules of Procedure.***

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;

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

(b) ***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*** for advice to the SCB, and for other communications ***to*** the SCB;

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

(f) the delegation of ▌ 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 ***SCB members, alternates, observers and*** invited experts;

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

7. The Commission ***may***, by means of implementing acts, adopt the necessary measures for the ▌ management ▌ 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 ***SoHO*** competent authorities regarding ***the coordinated*** implementation of this Regulation and the implementing and delegated acts adopted pursuant to it, by:

(a) preparing opinions***,*** at the request of ***SoHO*** competent authorities***, via their SoHO National Authorities,*** in accordance with Article 14(2) first sub-paragraph, on the regulatory status under this Regulation of a substance, product or activity and ***including such*** opinions ***in the SoHO*** compendium;

(aa) by … [one year after the date of entry into force of this Regulation], drawing 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 and made publicly available on the SoHO platform;

(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) ***documenting and publishing*** 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) defining indicative criteria of 'critical SoHO' and indicative criteria of "critical SoHO entity", providing and updating a list of what is considered a 'critical SoHO' by Member States, and making such information available to the SoHO National Authorities on the EU SoHO Platform;

(db) documenting practices among Member States for establishing the conditions for 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 SoHO 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 ***within their respective areas of expertise***, and with the EMA on authorisations and supervisory activities concerning the implementation of the PMF certification pursuant to Directive 2003/63/EC, to support the harmonised implementation of standards and technical guidelines;

(f) collaborating for the effective organisation of joint inspections and joint SoHO preparation ***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, and where appropriate with the Advisory Committee on Public Health Emergencies as established in Regulation (EU) 2022/2371, supporting a coordinated approach to ensure the implementation of emergency plans in cases where an emergency affects more than one Member State 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***.

2. The Commission may adopt implementing acts describing criteria and procedures for the consultation of advisory ***bodies*** established under other relevant Union legislation ***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 competent authorities' personnel

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

▌

2. The Commission may provide Union training to personnel of ***SoHO*** competent authorities of EEA Member States***,*** 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*** competent authorities shall ensure that the knowledge ***and materials*** acquired through the Union training activities referred to in paragraph 1 of this Article ***are*** disseminated as necessary and appropriately used in the personnel training activities referred to in Article ***9***.

4. The Commission may support, in cooperation with the ***SoHO National Authorities*** , the organisation of programmes for the exchange of ***SoHO*** competent authorities' personnel between two or more Member States and for the temporary secondment of personnel from one Member State to the other as part of personnel training.

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 ***70***.The Commission shall make this list available to the ***SoHO National Authorities***.

▌

Article 70

Commission controls ▌

1. The Commission shall perform controls ***to confirm whether*** Member States ***effectively apply*** the requirements relating to:

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

   (b) the SoHO supervisory activities ▌ 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 referred to in paragraph 1 in cooperation with the ***SoHO National Authorities***, and shall carry them out in a manner that avoids unnecessary administrative burden.

3. When performing the controls referred to in paragraph 1, the Commission ▌ shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c), on ▌ SoHO supervisory activities ▌ .

4. ▌ The Commission***,*** in carrying out the controls referred to in paragraph 1***, may be supported by*** experts from the ***SoHO competent authorities selected***, whenever possible***,*** from the list referred to in Article 69(5)***. Experts from the SoHO competent authorities*** shall ***be given*** the same rights of access as the Commission ▌ .

5. Following each control, the Commission shall:

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

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

(c) take the comments ▌ 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***.

▌

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 controls in Member States, including the costs of Member State experts assisting the Commission ▌ ;

(c) providing funding from the relevant Union ***programmes*** 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 ***of facilitating*** effective and efficient implementation of this Regulation, ***and notably of collaborating on initiatives to achieve sufficiency of supply,*** including ***actions to promote donation and optimal use of critical SoHO, and on*** 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 development and updating of technical guidelines ***with a view to contributing to the*** implementation of this Regulation***, including through cooperation, as provided for in Union law, with the EDQM on the guidelines published by them;***

(ca) 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) and aiming at a common approach to the assessment of the regulatory status of substances, products and activities, taking into account the specificities and the scope of each legal framework;

(cb) establishing, managing and maintaining the EU SoHO Platform.

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 ▌, reimbursement and special allowances for ***participants*** in those meetings ▌.

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[16], for the reform of national or regional SoHO supply supervision, provided those reforms aim to achieve compliance with this Regulation.

16 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).

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 controls***, 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 ***a digital*** platformto facilitate effective and efficient exchange of information concerning SoHO activities in the Union, as provided for in this Regulation ***("EU SoHO Platform")***.

▌

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 ***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.

▌

5. The Commission shall provide instructions***, materials and training on the correct use of the EU SoHO Platform*** for SoHO ***competent authorities via their SoHO National Authority. The Commission, where appropriate and in cooperation with their SoHO National Authority, shall provide instructions and training for SoHO entities*** on the correct use of the EU SoHO Platform. ***Those training materials shall be available on EU SoHO Platform.***

Article 74

General functionalities of the EU SoHO Platform

1. The EU SoHO Platform shall enable SoHO entities, ***SoHO*** competent authorities, Member States and the Commission to process information, data and documents concerning ***SoHO,***

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 Platform shall ▌ provide a secure ***channel for restricted*** 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 Authorities and the Commission, in particular in relation to activity data concerning SoHO activities of SoHO entities, the summaries of notifications and investigation reports of confirmed SAR or SAE, SoHO rapid alerts and SoHO supply alerts;

(d) between SoHO National Authorities and the SCB;

(e) between SoHO National Authorities and the ECDC, in relation to alerts related to communicable diseases, where applicable; and

(f) between SoHO entities and their respective SoHO competent authorities, when the SoHO competent authorities choose to use the EU SoHO Platform for such exchanges.

2a. The EU SoHO Platform shall 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 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;

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

(h) the SoHO compendium;

(i) the 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;

(k) the more stringent measures adopted by Member States, in accordance with Article 4;

(l) the rules of procedure of the SCB, the agenda and the summary minutes of each meeting unless such publication undermines the protection of a public or private interest, as defined in Article 4 of Regulation (EC) No 1049/2001;

(m) the list of SoHO National Authorities.

3. ***By 1 year of the entry into force of the Regulation,*** the Commission shall adopt implementing acts laying down technical specifications for the EU SoHO Platform, ***covering its management, maintenance, functions,*** including its ***minimal functionalities***, the roles and responsibilities of each of the parties listed in paragraph 1, the retention periods for personal data and the technical and organisational measures to ensure the safety and security of personal data processed***, including health data***.

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[17], 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 ***effective implementation of this Regulation, in particular for the purpose of authorisations, inspections, investigations or Commission controls.***

▌

2. Information ***and data*** may be exchanged on a confidential basis between ***SoHO*** competent authorities and between ***SoHO National*** Authorities and the Commission, ***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*** competent authorities may publish or make otherwise available to the public the outcome of SoHO supervisory activities regarding individual SoHO entities provided that the following conditions are met:

   (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

[17] 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).

the public, prior to its publication or release, taking into account the urgency of the situation;

(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 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.***

▌

Article 76

Data protection

1. Personal data required for the application of Articles 5(5) and ***10(2a)***, Articles 35 and 36, Article ***37(1b)*** points ***(a) and (b)***, Article ***37a(2)***, Article ***41(2)***(***-a***), ***Article 49(2),*** and Articles 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 ***73 and 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;

(b) to process relevant information on clinical outcome monitoring.

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***,*** SoHO entities ***and*** any third party contracted by a SoHO entity, as applicable, in such a way that the personal data of the subjects remain protected in accordance with the applicable legislation on personal data protection. ***They*** 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***,*** SoHO entities ***and*** any third party contracted by a SoHO entity, shall implement appropriate technical and organisational measures to protect information and personal data processed***, including health data,*** against unauthorised or 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, ▌ 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 ▌ .

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 ▌.

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), ▌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), ▌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 = ***5*** years after the date of entry into force of this Regulation], notify the Commission of those rules and of those measures and shall notify it, 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 ***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*** 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 ***37(1b)***, points (a) and (d), and information regarding the registration and authorisation status according to the verification referred to in point (a) of this paragraph to the EU SoHO Platform as referred to in Chapter XI.

4. For tissue establishments referred to in ***paragraphs 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 ▌;

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

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 = ▌ date of ***application*** of this Regulation], or that were otherwise designated, authorised, accredited or licensed under national legislation before the date of application

of this Regulation, shall be deemed to be authorised as the corresponding SoHO preparations in accordance with ▌ this Regulation.

3. ***SoHO*** competent authorities shall submit the information referred to in paragraphs 1 and 2 to the EU SoHO Platform, and link those ***SoHO preparations, authorised pursuant to transitional provisions,*** 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(1c), point(i), (iv), (v), (vi), (vii), (viii), (ix) and (xii) with SoHO not addressed expressly in Directives 2002/98/EC nor 2004/23/EC, before … [OP please insert the date = of application of this Regulation] shall be allowed to continue their activities regarding those SoHO until [OP please insert the date = one year after the date of application of this Regulation], without applying this Regulation, except for the following requirements:

(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) by … [OP please insert the date = three months after the date of application of this Regulation].

Article 83

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

1. ***SoHO*** already ***in storage*** before … [OP please insert the date = date of application of this Regulation] shall not be subject to the relevant obligations provided for under this Regulation, provided those ***SoHO are released and distributed before …*** [OP please insert the date = ***two years*** after the date of application of this Regulation] ▌ 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 ***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. ***SoHO*** 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*** are available, in particular because the ***SoHO*** are autologous, intended for within ***relationship*** 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].

▌

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 = ***three*** 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 evaluation report shall include an assessment of the implementation of Article 54. The Commission shall use aggregated and anonymised data and information gathered from SoHO competent authorities and from data and information submitted to the EU SoHO Platform for the purposes of the evaluation report. Member States shall provide the Commission with additional information as necessary and proportionate for the preparation of the evaluation report, including information on the conditions for compensation of SoHO donors, pursuant to Article 54. The evaluation report shall, where appropriate, be accompanied by a legislative proposal to amend this Regulation.***

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 = ***three*** years after the date of entry into force of this Regulation].

2. ***The Commission is empowered to adopt the delegated acts referred to in*** Article ***42(3), and the implementing acts referred to in Article 43(6), Article 44(3), Article 45(4b),***

Article 46(3), Article 74(3) as from … [OP please insert the date = one day after the date of entry into force of this Regulation].

Article 67 and Article 68(1)(aa) shall apply from … [OP please insert the date = one day after the date of entry into force of this Regulation].

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*