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INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
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 - Outcome of the European Parliament's first reading (Strasbourg, 22 to 25 April 2024)

I. INTRODUCTION

In accordance with the provisions of Article 294 of the TFEU and the Joint declaration on practical arrangements for the codecision procedure[1], a number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this file at first reading.

In this context, the Chair of the Committee on the Environment, Public Health and Food Safety (ENVI) Pascal CANFIN (RE, FR) presented on behalf of ENVI a compromise amendment (amendment number 244) to the abovementioned proposal for a Regulation, for which the rapporteur, Nathalie COLIN-OESTERLÉ (EPP, FR), had prepared a draft report. This amendment had been agreed during the informal contacts referred to above. No other amendments were tabled.

[1] OJ C 145, 30.6.2007, p. 5.

II. VOTE

When it voted on 24 April 2024, the plenary adopted the compromise amendment (amendment number 244) to the abovementioned proposal for a Regulation. The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto[2].

The Parliament's position reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the Parliament's position.

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[2] The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in ***bold and italics.*** The symbol "▌" indicates deleted text.

ANNEX
(24.4.2024)

P9_TA(2024)0353

Standards of quality and safety for substances of human origin intended for human application

European Parliament legislative resolution of 24 April 2024 on the 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 (COM(2022)0338 – C9-0226/2022 – 2022/0216(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2022)0338),

– having regard to Article 294(2) and Article 168(4), point (a), of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0226/2022),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 27 October 2022[1],

– after consulting the Committee of the Regions,

– having regard to the provisional agreement approved by the committee responsible under Rule 74(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 30 January 2024 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0250/2023),

[1] OJ C 75, 28.2.2023, p. 154.

1. Adopts its position at first reading hereinafter set out[2];

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

[2] This position replaces the amendments adopted on 12 September 2023 (Texts adopted, P9_TA(2023)0299).

P9_TC1-COD(2022)0216

Position of the European Parliament adopted at first reading on 24 April 2024 with a view to the adoption of Regulation (EU) 2024/… of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee[5],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[6],

[5] OJ C 75, 28.2.2023, p. 154.
[6] Position of the European Parliament of 24 April 2024.

Whereas:

(1) According to 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 (the 'Charter'), 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 is to adopt measures setting high standards of quality and safety for organs and substances of human origin (***SoHO***), blood and blood derivatives. Furthermore, Member States are not to be prevented from maintaining or introducing more stringent protective measures. ▌

(3) According to Article 168(7) TFEU, Union action is to 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), TFEU are not to affect national provisions on the donation or medical use of organs and blood.

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

(5) Directives 2002/98/EC[7] and 2004/23/EC[8] of the European Parliament and of the Council constitute the Union's regulatory framework for blood and blood components and for tissues and cells, respectively. Although those Directives have harmonised to a certain degree the rules of Member States in the area of quality and safety 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 such substances. A fundamental revision of those Directives is needed for a robust, transparent, up-to-date and sustainable regulatory framework for such substances, which achieves quality and safety ***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.

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7 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).

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

(6) Directives 2002/98/EC and 2004/23/EC are highly interconnected and contain very similar provisions on oversight and equivalent principles on ***quality*** and ***safety*** in the ▌ sectors they regulate. In addition, many authorities and operators work across those sectors. As this Regulation aims to define high level standards that will be common to ▌ blood**,** tissues and cells ▌ , it would be appropriate that it replaces those 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***.

(7) 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 stem cells from peripheral blood, from umbilical-cord blood or from bone marrow, reproductive cells ***and tissues, 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 prevent a situation in which certain groups of SoHO donors or SoHO recipients and offspring from medically assisted reproduction*** are not protected by an appropriate Union level quality and safety framework. This will, for example, ensure the protection of ***SoHO*** donors and ***SoHO*** recipients of human breast milk, intestinal microbiota, blood preparations that are not used for transfusion, and any other SoHO that might be applied to humans in the future.

(8) Ensuring the quality and safety of ***SoHO*** is crucial ***when*** such substances biologically interact with the body of the ***SoHO*** recipient ***or of recipients receiving products manufactured from SoHO regulated by other Union legislation***. However, 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 processed and stored in a variety of ways, becoming SoHO preparations, which can be applied to ***SoHO*** recipients. In those circumstances, this Regulation should apply to all activities from ***SoHO*** donor ***registration*** to human application and ***clinical***-outcome ***registration. SoHO*** can also be used to manufacture products regulated by other Union legislation, ▌namely medical devices, regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council[9], medicinal products, regulated by Directive 2001/83/EC of the European Parliament and of the Council[10]***,*** advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007 of the European Parliament and of the Council[11], ***and investigational medicinal*** products***,*** regulated by ▌Regulation ***(EU) No 536/2014 of the European Parliament and of the Council[12].*** This Regulation should apply without prejudice to Union legislation on genetically modified organisms.

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9 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).

10 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).

11 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).

12 ***Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).***

(10) ***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 a person for human application to themselves or from persons as part of their own current or future medically assisted reproduction treatment or as part of such treatment in the context of within-relationship use, have an impact on the safety, quality or effectiveness of SoHO or the safety of SoHO donors.***

(11) Entities ***that register prospective living SoHO donors, recording the information needed to identify a match with prospective SoHO recipients in the same Member State or internationally, should be considered as SoHO entities. The registering of persons 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 the meaning of this Regulation and should not, therefore, require the entity carrying out that activity to register as a SoHO entity.***

(12) ***The review of SoHO donor history, together with the 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 as a SoHO activity.***

(13) Testing for communicable disease status, or for the purpose of matching a SoHO donor with a specific SoHO recipient, is an activity with a high degree of impact on the safety of SoHO and, as such, it should be considered as a SoHO activity. Laboratories that carry out such testing should therefore be registered as SoHO entities. While such testing is generally for the purpose of protecting the SoHO recipient, communicable disease testing of persons prior to the storage of SoHO collected from them, for the purpose of subsequent re-application to them, is important to prevent cross-contamination between such SoHO while in storage. Therefore, such testing should include the allogeneic, autologous and within-relationship use contexts.

(14) Collection of SoHO involves risks both to SoHO donors and to persons from whom SoHO are being collected for subsequent re-application to those same persons as well as to persons from whom SoHO are collected as part of their own current or future medically assisted reproduction treatment or as part of such treatment in the context of within-relationship use. As such, collection of SoHO should be considered as a SoHO activity. For the purposes of this Regulation and to ensure comprehensive SoHO donor protection, that activity should be understood to include the pre-treatment of persons with hormones, growth factors or other medicinal products that is required to make the collection possible.

(15) ***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 blood 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,*** processing of SoHO ***should be considered as a SoHO activity and any entity performing SoHO processing should be subject to appropriate oversight, including an obligation to obtain an authorisation for any SoHO preparation they distribute or apply. In cases where a surgical team prepares distributed SoHO for human application, without removal from the surgical field and immediately prior to the human application, such preparatory handling should not be considered as 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 allogeneic or autologous use. In addition, in the autologous context, the preparation of SoHO during and for the purpose of human 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 SoHO 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.***

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

(17) SoHO are stored in SoHO establishments prior to their release. For the purposes of this Regulation, storage refers to maintaining SoHO under 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 as a SoHO activity.

(18) ***As the release of SoHO is a critical step that allows SoHO to be moved from a 'quarantined' to an 'available for use' status, it should be considered as 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 release step. In cases where the receiving SoHO 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 release step prior to the re-application of the SoHO preparation to the SoHO recipient. In such cases, quality control tests 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 those circumstances.***

(19) ***SoHO distributed for human application might be intended for an individual SoHO recipient on the basis of a medical prescription. Alternatively, SoHO might be distributed in batches to be stored as a local stock to be used, as required, in a SoHO entity carrying out human 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.***

(20) 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 as a SoHO activity with a significant impact on the quality and safety of SoHO and entities performing import should be authorised as importing 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 with 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 it should be possible for the authorised registry to delegate the steps of physical checking of the imported SoHO and their documentation to the SoHO entity receiving and applying the SoHO to the SoHO recipient.

(21) All SoHO being exported from the Union should first require a release to confirm compliance with the quality and safety provisions of this Regulation. Export, which should be considered as a SoHO activity, can have an impact on SoHO supply within the Union. Therefore, entities exporting SoHO should be authorised as SoHO establishments.

(22) In the context of this Regulation, any reference to effectiveness should be considered to include an expected response in a SoHO recipient that is measurable in terms of degree, such as an engraftment of bone marrow cells after transplant, or if an expected result in a SoHO recipient that is successful or not, but cannot be measured in terms of degree, such as the success or failure of a cornea or bone transplant, and which is evaluated in accordance with a previously approved clinical-outcome monitoring plan, when such a plan is required.

(23) Human application of SoHO is a SoHO activity that falls within the scope of this Regulation, but that activity is only subject to a limited number of provisions. Entities applying SoHO to SoHO recipients are subject to provisions concerning traceability, reporting activity data and notifying adverse reactions or events, where relevant, and provisions concerning monitoring clinical outcomes when applying SoHO in the context of a plan for SoHO preparation authorisation. There are also obligations not to apply SoHO unnecessarily and to obtain SoHO recipient consent. However, the clinical decisions and the clinical procedures relating to human application of SoHO fall outside the scope of this Regulation and are governed by national legislation on the organisation of the healthcare systems of Member States.

(24) 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 human 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 as a SoHO activity, as it ensures that data quality and data management procedures are robust and allow for the data to be used for the purpose 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 SoHO preparation authorisations and access to SoHO therapies.

(25) Persons from whom SoHO are collected for subsequent human application as part of their own treatment, or persons from whom SoHO are collected as part of their own current or future medically assisted reproduction treatment or as part of such treatment in the context of within-relationship use, should not be considered as SoHO donors in the context of this Regulation. The protection of the health of such persons being treated in autologous or within-relationship context is the responsibility of the national healthcare systems and applying provisions targeted at the protection of SoHO donors, for example monitoring such persons on SoHO donor registries, would be disproportionate. However, when SoHO collected from such persons 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, persons from whom SoHO are collected in the autologous context or in the medically assisted reproduction context are not covered by the SoHO donor protection provisions of this Regulation, but are deemed duly protected under the SoHO recipient provisions.

(26) Solid organs are excluded from the definition of ***SoHO*** for the purposes of this Regulation and, thus, from the scope of this Regulation. 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 of the European Parliament and of the Council[13]. ***Composite vascular allografts, such as hands or faces, should be considered as falling within 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.

(27) While the donation and banking of human breast milk should be regulated to prevent disease transmission and ensure quality and safety, the feeding of one's own child with one's own breast milk should not fall within the scope of this Regulation. This includes also personal situations where such 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 this Regulation to those settings. However, if such breast milk is processed by a specialised SoHO entity, in particular if it is pasteurised, this Regulation should apply.

[13] 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).

(28) This Regulation should not interfere with national legislation in the health area having objectives other than quality and safety of ***SoHO, where such legislation*** is compatible with Union law, in particular legislation concerning the organisation of ***health-care systems 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.*** 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 with a view to ensuring quality and safety and to protecting human health. ***However, this Regulation does not require a specific use distribution or import of SoHO where such use, distribution or import is prohibited under national legislation concerning ethical aspects.***

(29) A derogation from compliance with certain provisions of this Regulation should be envisaged for specific circumstances. In many Member States, military organisations are active in carrying out SoHO activities, in particular in the collection, testing, processing, storage and distribution of blood and blood components. Those organisations and their SoHO activities should be regulated by this framework to ensure levels of SoHO donor and SoHO recipient protection equivalent to those provided by civil services. However, making public the locations and activities of those organisations is likely to compromise national security or defence. Therefore, the reporting and oversight provisions of this Regulation should apply to those organisations, but the publication of associated information should not be obligatory. Derogations from compliance with this Regulation, in particular regarding the obligation to authorise SoHO preparations, should also be envisaged 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.

(30) When ***SoHO*** are used in the autologous context 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 context. ***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 the autologous context. Where such a closed-system medical device has been CE marked for a specific purpose, and has therefore been demonstrated to achieve the intended result, and where the process carried out within that 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 demonstrated as part of the CE marking process for that specific purpose***.

(31) When SoHO for autologous use are collected and processed before being applied again in the same person and without storage, risks associated with the processing of that SoHO 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 tests and checks to be performed during the process, and therefore, no release step should be required before human application to the SoHO recipient. Similarly, in the case of intra-uterine insemination for within-relationship use, where SoHO are collected and processed from one of the partners before being applied to the other partner without storage, such SoHO should not be subject to a SoHO release step but the SoHO preparation authorisation should specify the required quality control tests and checks to be performed during collection, processing and human application. Where SoHO for autologous use, or SoHO for within-relationship use, 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. Therefore, the requirements for SoHO release and for SoHO establishment authorisation should apply in those circumstances.

(32) Where ***SoHO are collected for 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 adopted in those other frameworks to ensure a high level of protection of recipients of those products manufactured from SoHO. Therefore, without prejudice*** to Directive 2001/83/EC ***and Regulations (EC) No 1394/2007, (EU) No 536/2014 and (EU) 2017/745,*** this Regulation should ***always*** apply to the ***registration, evaluation and testing of SoHO donors,*** as well as to ***SoHO collection and release. This Regulation should also apply*** to the ***storage, import and export of SoHO up to and including 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.

(33) ***SoHO can*** be combined with other regulated products***, in particular with medical devices,*** before human application. Close interaction between this regulatory framework and the medical device framework is ▌ necessary to ensure a high level of human health protection for all cases where such SoHO combined with medical devices are ***intended for human application. Where the 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, 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. Therefore, the demineralised bone in those examples should be subject to the SoHO preparation authorisation provisions of this Regulation, to ensure the property of inducing bone formation is 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.***

(34) This Regulation does not prevent Member States from maintaining or introducing more stringent protective measures***. If they do so,*** Member States should ***make details of such measures publicly available for reasons of transparency***. More stringent protective measures put in place by Member States should be ***compatible with Union law,*** and be proportionate to the risk to human health ▌. Such measures should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation, unless those measures or their application are objectively justified by a legitimate aim, and the means of achieving that aim are appropriate and necessary. ***They could include, for instance, the presence of, or the access to, qualified medical professionals where SoHO collection takes place.***

(35) The verification of compliance with this Regulation through SoHO supervisory activities is of fundamental importance to ensure that, across the Union, the objectives of this 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.

(36) ***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***, and that carries out 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 prevent Member States from assigning certain tasks to other SoHO competent authorities of that Member State, in particular where there is a need to ensure an efficient or agile communication with the Commission or other Member States. Furthermore, the list of all SoHO national authorities should be made publicly available on the EU SoHO Platform provided for in this Regulation.***

(37) 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 political influence and from ***interference by*** industry ***or other actors*** that might affect their operational impartiality. 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 ***anyone*** that has infringed this Regulation.

(38) 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 provided 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 communicable disease testing, should be considered as posing a serious risk to human health, and such information should be made publicly available.

(39) 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.

(40) Where there is doubt about the regulatory status of a particular substance, product or activity under this Regulation, SoHO competent authorities should consult ▌ the relevant authorities responsible for other relevant regulatory frameworks, namely medicinal products, ***advanced therapy medicinal products,*** medical devices or organs, ***and the SoHO Coordination Board (SCB) established by this Regulation,*** with the aim of ensuring coherent procedures for the application of this Regulation ***and other relevant Union legislation***. SoHO competent authorities should inform the ***SCB*** of the outcome of their consultations ***and submit a request to the SCB for its opinion on the regulatory status of the substance, product or activity.*** When ***SoHO*** or SoHO preparations are used to manufacture products regulated by other Union legislation, SoHO competent authorities should cooperate with the relevant authorities responsible for the products regulated by other Union legislation on their territory. That cooperation should aim to reach an agreed approach for any subsequent communications between the SoHO competent authorities and those relevant authorities responsible 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, ***where SoHO competent authorities decide not to follow the SCB's opinions, they*** should ***justify their decisions, and the Commission should upon a*** duly substantiated request of a Member State***, or should be able, on its own initiative***, to decide on the regulatory status of a particular substance, product or activity under this Regulation.

(41) In order to comply with the principle that the human body and its parts as such are not to give rise to financial gain and thereby to support a donation system that SoHO donors and SoHO recipients can trust, Member States should be able to take appropriate measures which aim to ensure that SoHO entities are transparent in the calculation of fees in respect of their technical services and in the financial management of their services. In that respect, it should be possible to refer, inter alia, to the cost of testing, processing, storage, distribution, personnel and transportation, infrastructure and administration, and to the need to invest in state-of-the-art processes and equipment to ensure the long-term sustainability of the services offered.

(42) ***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 ***in which 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 different situations, including the possible violations of this Regulation perpetrated through fraudulent or other illegal practices and based on previous compliance history. Accordingly, the likelihood of non-compliance with any provisions of this Regulation should be taken into account when scheduling ***SoHO*** supervisory activities.

(43) A broad range of public and private entities influence the ***quality, safety*** and ***effectiveness*** of SoHO, even if they do not ***store*** those SoHO. Many entities carry out a single SoHO activity, such as collection or ***SoHO*** donor testing on behalf of one or more entities that ***store SoHO***. The SoHO entity concept includes this broad range of entities, from ***SoHO*** donor registries to ***hospitals and clinics where SoHO are applied to SoHO*** recipients or ▌SoHO processing devices ***are used*** at the SoHO 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 child of a friend or relative, while respecting the principle 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 persons, or for many families, they should be considered as SoHO activities and should fall under the scope of this Regulation.***

(44) Since SoHO preparations can be subjected to a series of SoHO activities, performed in accordance with the processing method chosen, 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 as a result of that specific series of activities, performed in that specific manner. When SoHO are prepared with newly developed and validated collection, testing or processing methods, safety and ***effectiveness*** in ***SoHO*** recipients should be demonstrated by means of clinical-outcome data collection and review. The extent of such required clinical-outcome ***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 from medically assisted reproduction or there is a high degree of certainty that benefit outweighs risk, based on the evidence provided, the vigilance requirements provided for in this Regulation should be adequate to ***verify quality and safety and effectiveness***. This should apply for well-established SoHO preparations that are introduced in a new SoHO entity but have been robustly demonstrated as being safe and effective by their use in other entities.

(45) With regard to SoHO preparations that pose a ▌risk ***that is more than negligible, and the benefit is expected to outweigh that risk***, the applicant should propose a plan for clinical-outcome monitoring that should fulfil different requirements appropriate to the risk in question. The most up-to-date guidance of the European Directorate for the Quality of Medicines & HealthCare (EDQM), which is 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 a SoHO clinical study with monitoring of pre-defined clinical end-points. In the case of high risk ***and a positive benefit-risk assessment, and cases where the risk or the benefit are not evaluable due to a lack of scientific and clinical data or knowledge***, SoHO clinical studies 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 SoHO clinical study should be designed in a way that leads to reliable and robust data and conclusions.***

(46) For the sake of efficiency, it should be permitted***, without changing the regulatory status of the SoHO concerned,*** to implement clinical-outcome ***monitoring plans*** using the established framework in the pharmaceutical sector for clinical trials, as set out in Regulation (EU) No 536/2014 ▌, when ***SoHO entities*** wish to do so. While applicants can choose to record the clinical data generated during the implementation of 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 SoHO clinical studies, to boost multi-centre studies and to foster collaboration to generate more robust results and conclusions, and to make the knowledge generated available to other researchers, healthcare professionals, participants themselves and the general public.***

(47) In order to facilitate innovation and reduce administrative burden, ***SoHO*** competent authorities should share with each other information on newly authorised SoHO preparations together with 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 human 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.***

(48) ***SoHO*** competent authorities should ***periodically*** review the SoHO entities registered in their territory and ensure that those entities that carry out 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 fall within 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.***

(49) With regard 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 purposes of this Regulation, reconstructive surgery should not be considered as 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. SoHO national authorities are involved in the process of establishing those guidelines through their participation in the governance bodies of both the ECDC and the EDQM. Member States should be able to adopt*** other guidelines, ***as a reference for SoHO entities located in their territory. When adopting such other guidelines, Member States should verify and document*** that those 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.

(50) 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[14], 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 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 that context, the work of the EDQM on developing and updating technical guidelines on ***quality*** and ***safety*** of blood, tissues and cells, should be considered an important contribution to the field of ***SoHO*** in the Union***.***

[14] 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).

Those technical 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 quality and safety of SoHO. The Commission should be able 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.***

(51) The ECDC, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council[15], is a Union agency with the mission of strengthening Europe's defences against communicable diseases. The work of the ECDC on developing and updating guidelines on quality and safety of ***SoHO*** from a communicable disease threat perspective, should be considered an important contribution in the field of SoHO 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.

[15] 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).

(52) 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 on the EU 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 States should decide if SoHO entities should be able to delegate the submission of the activity data to such registries.

(53) When a ***serious*** genetic ***disorder that might result in a life-threatening, disabling or incapacitating*** condition is detected in the offspring 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 therefore important that relevant information in such cases is effectively communicated between SoHO entities and acted upon appropriately.

(54) This Regulation respects the fundamental rights and observes the principles recognised ▌by the Charter***,*** in particular human dignity, the integrity of the person ***and the prohibition on making the human body and its parts as such 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 those 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, inter alia, by ensuring that consent for donation is freely given and ***SoHO*** donors or their representatives are informed with regard 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, and 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 SoHO recipients and offspring from medically assisted reproduction is not compromised by SoHO allocation actions that do not respect their dignity***. This Regulation should therefore apply accordingly.

(55) Given the special nature of ***SoHO***, due to their human origin, and the increasing demands for such 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 persons whose health status is such that no detrimental effects will ensue as a result of the donation. This Regulation should therefore include standards 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 SoHO, 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 the SoHO donor's health*** should be ***proportionate to those levels of*** risk.

(56) Due to the high sensitivity of the protection of SoHO 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 SoHO donation by a person that is unrelated to the intended SoHO recipient, 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.

(57) ***Article 3 of the Charter prohibits making 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 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, SoHO donation*** **should be** ***voluntary and unpaid, and be founded on the principles of altruism of the SoHO 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, and spreading the responsibility for donation evenly across the Union population to the extent possible. Voluntary and unpaid SoHO donation contributes to the respect for human dignity*** **and to** ***protecting 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*****.**

(58) It is recognised, including by the Council of Europe Committee on Bioethics in its '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' from March 2018, that while financial gain should be avoided, compensation should be able to be acceptable to prevent SoHO donors being financially disadvantaged by their donation. Therefore, 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 SoHO donor or constitute an incentive that would cause a SoHO 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. It should be possible for compensation to consist of the reimbursement of expenses incurred in connection with SoHO donation or of 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-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 national level and the application of compensation that is financially neutral for the SoHO donor have the effect of removing any incentive for SoHO 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. It should be possible for Member States to 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, 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 SoHO donor recruitment campaigns, for example using advertising billboards or posters, on television, newspaper, magazine or social media advertisements or similar.

(59) SoHO entities should not offer financial incentives or inducements to potential SoHO donors or to those giving consent on their behalf as such an action would be contrary to the principle of voluntary and unpaid donation. Refreshments and small gifts, such as pens or badges, should not be considered as inducements and the practice of offering them to SoHO donors is acceptable as a recognition of their efforts. On the other hand, rewards or benefits, such as payment of funeral expenses, or payment of health insurance unrelated to the SoHO collection, should be considered as inducements, and as such contrary to the principle of voluntary and unpaid donation and should not be permitted.

(60) This Regulation is not meant to cover research using ***SoHO*** when that research does not involve human application, 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 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 SoHO 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 concerning voluntary and unpaid donation set out in this Regulation.***

(61) In order to maintain public trust in SoHO donation and the use of SoHO, 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. ▌

(62) 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 the scope of this Regulation as such testing is associated with particular ethical concerns that fall outside the scope of this Regulation.

(63) Where evidence demonstrates that specific ***procedures*** reduce or eliminate the risk of transmission of specific ***communicable*** or non-***communicable*** 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. ▌

(64) 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 those campaigns should be to ***ensure the broadest possible SoHO donor base, with a view to a more resilient supply of 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***.

(65) The COVID-19 pandemic can be considered as having been 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 that 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[16] 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.

[16] ***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).***

(66) In the development of national SoHO emergency plans, Member States should cooperate with relevant stakeholders and should take into account the opinions of the Health Security Committee established by Article 4 of Regulation (EU) 2022/2371 and the Health Crisis Board referred to in Article 5 of Council Regulation (EU) 2022/2372[17], where 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 the ECDC and the guidelines of the EDQM in the establishment and operation of national SoHO emergency plans. National SoHO emergency plans might include, among preparedness and response measures, stockpiling of certain SoHO where possible and appropriate.

[17] ***Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (OJ L 314, 6.12.2022, p. 64).***

(67) In order to ensure self-sufficiency and sustainability of supply of critical SoHO, Member States should establish national SoHO emergency 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, SoHO donor recruitment and retainment strategies and arrangements for cooperation between SoHO competent authorities, experts and relevant stakeholders. National SoHO emergency plans contribute to European self-sufficiency in terms of supply of critical SoHO. Providing training and better information for prescribers would reduce the risk of unnecessary human application of SoHO. Furthermore, it is important that Member States improve patients' safety by minimising the risks associated with human application of SoHO, and improve patient outcomes, while at the same time ensuring sufficiency of SoHO supplies and reducing financial pressure on healthcare systems of Member States. Some Member States do so, inter alia, via the Patient Blood Management (PBM) approach as endorsed by the World Health Organization.

(68) 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 SoHO, SoHO donors and recipients. There could even be situations in which some products with low profitability are no longer produced, thereby hampering their accessibility for patients. Therefore, 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.

(69) 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***.

(70) In order to promote a coordinated application of this Regulation, a SoHO Coordination Board (SCB) should be set up. The Commission ***and the Member 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 appointed 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***.

(71) 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 are able to 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 issuing an opinion 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.*** Those measures should promote a coherent cross-sectoral approach and facilitate SoHO innovation.

(72) ***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 ***set out in this Regulation. The controls could be organised in different ways, such as audits, visits or surveys, and in collaboration with the Member States so as to limit the administrative burden***. They should also serve to investigate and collect information on enforcement practices or problems, emergencies and new developments in Member States. They should be performed by personnel who are independent, free from any conflict of interests 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.

(73) 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 improving 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 SoHO Platform should be further used for the sharing of best practices documented and published by the SCB on SoHO*** supervisory activities.

(74) 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.

(75) 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 Regulations (EU) 2016/679[18] and (EU) 2018/1725[19] of the European Parliament and of the Council***.***

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18 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

19 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

(76) ***SoHO***, by definition, relate to persons, and there are circumstances where the processing of personal data ▌could 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 quality, 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 therefore 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.

(77) 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.

(78) 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 to take into account ***the*** technical and scientific developments in the field of ***SoHO, and with*** additional rules on the authorisation of importing SoHO ***establishments***, on obligations and procedures for importing SoHO ***establishments***, and on data protection, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission ▌. It is of particular importance that the Commission carry 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[20]. 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.

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

(79) In order to ensure uniform conditions for the implementation of this Regulation regarding the ▌application for an 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. In order to ensure uniform conditions for the implementation of this Regulation, including the determination of the regulatory status of a substance, product or activity, ***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 regard to the frequency of donations when such frequency implies a risk, SoHO*** recipients and offspring from medically assisted reproduction, the ▌management and tasks of the ***SCB***, and the transitional provisions concerning SoHO preparations, implementing powers should also 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[21]. ***In addition to the 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, this Regulation provides for implementing acts that relate to consultation and communication tools, supervisory functions, traceability and import rules and monitoring, for example of activity volumes. Those implementing acts will have significant impact on the Member States' public services in the field of health and on 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 established by this Regulation to assist the Commission, delivers no opinion, in accordance with Article 5(4), second subparagraph, point (b), of Regulation (EU) No 182/2011.***

[21] 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).

(80) Since the objective of this Regulation, namely to ensure quality and safety of ***SoHO*** and a high level of protection of ***SoHO*** donors 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, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale or effects, be better achieved at Union level, 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.***

(81) 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 and the changes in the rules on SoHO entities, SoHO establishments and SoHO preparations, as well as to avoid that donated ***SoHO*** are discarded unnecessarily. A transitional regime for establishments already designated, authorised, accredited or licensed before the general date of application of this Regulation should be introduced to ensure legal certainty and clarity. In particular, there should be clarity for the establishments concerned as regards their registration and authorisation status as well as their tasks and responsibilities under this Regulation, whilst allowing ***SoHO*** competent authorities additional time to transfer the relevant information to the systems introduced by this Regulation. To allow for a smooth transition, it is also appropriate that those preparation processes already authorised and lawfully used under the former regimes are still valid, and that ***SoHO*** already collected and stored before that date are able to be used for a certain period of time.

(82) 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***[22]***,***

HAVE ADOPTED THIS REGULATION:

[22] OJ C ***450, 28.11.2022, p. 7***.

CHAPTER I
GENERAL PROVISIONS

Article 1
Subject matter

This Regulation establishes measures that set high standards of quality and safety for all substances of human origin (SoHO) 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 applies to ▌:

(a) SoHO ***intended for human application and SoHO used to manufacture products regulated by other Union legislation, as referred to in paragraph 6, 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 quality, safety or effectiveness of SoHO, as follows:***

(i) SoHO ***donor registration;***

(ii) SoHO ***donor history review and medical examination;***

(iii) testing of SoHO donors or of persons from whom SoHO are collected for autologous or within-relationship 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.

2. This Regulation does not apply to:

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

(b) breast milk when used exclusively for feeding one's own child, without any processing carried out by a SoHO entity.

3. This Regulation shall be 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.

4. By way of derogation from paragraph 1 of this Article, the provisions of this Regulation concerning the publication or communication of information, in particular the obligations in that respect set out in Article 4(2), Article 7, Article 19(3), Articles 29, 31, 41, 63, 64 and 67 and Article 81(3), point (b), shall not apply when such publication or communication might imply a risk to national security and defence.

▌

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

(a) ***SoHO*** are processed ***or*** stored before human application, this Regulation applies;

▌

(b) ***SoHO are neither*** processed ***nor*** stored before human application, this Regulation does not apply.

6. ***In the case of SoHO collected for the purposes of manufacturing*** medical devices, 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, regulated by*** Regulation (***EU***) ***No 536/2014***, the provisions of this Regulation applicable to the ***SoHO activities referred to in paragraph 1, points (c)(i) to (iv) and (viii), of this Article apply***. Insofar as the SoHO activities ***referred to in paragraph 1, points (c)(vii), (ix), (x) and (xi),*** of this Article are carried out on ***SoHO up to and including*** their distribution to ***a manufacturer*** regulated by ▌ other Union legislation, as referred to in this paragraph, this Regulation also applies.

▌

7. By way of derogation from paragraph 6, where SoHO are used to manufacture products regulated by other Union legislation and those products are exclusively for therapeutic use on the person from whom the SoHO were collected, the provisions of this Regulation relating to the SoHO activities referred to in paragraph 1, points (c)(iii) and (iv), apply.

8. Where non-viable ***SoHO*** or their derivatives, within the meaning of Article 2, points (***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 medical device, ***this Regulation applies to*** the non-viable ***SoHO*** or their derivatives ***and the final combination*** shall be ***subject to*** this Regulation. Where the action of the non-viable ***SoHO*** or their derivatives is ancillary to that of the medical device***, this Regulation applies to all SoHO activities to which the non-viable SoHO or their derivatives are subjected up to and including their distribution for integration into the medical device, and the final combination shall be subject to Regulation (EU) 2017/745***.

Article 3

Definitions

For the purposes of this Regulation, the following definitions apply:

▌

(1) ‘substance of human origin’ or ‘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 such substance***;

(2) ‘critical SoHO’ means a SoHO for which an insufficient supply will result in serious harm or risk of serious harm to ***recipients’ health or in a serious interruption in the manufacture of products regulated by other Union legislation, as referred to in Article 2(6), where an insufficient supply of such products will result in serious harm or risk of*** serious ***harm to human health;***

(3) ‘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 definition, embryos are considered reproductive SoHO even though they are not collected from the human body***;

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

▌

(5) ***'SoHO donation' means a process by which a person voluntarily and altruistically gives SoHO from their own body for persons in need, or authorises the use of such SoHO 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, where applicable, the consent given by an authorised person in accordance with national legislation;***

(6) 'SoHO donor' means ***a living or deceased SoHO donor***;

(7) ***'living SoHO donor' means a living person who has volunteered to a SoHO entity, or has been presented by a person granting consent on their behalf, in accordance with national legislation, with a view to making a donation of SoHO, for the purpose of use in a person other than themselves, and other than in situations of within-relationship use;***

(8) ***'deceased SoHO donor' means a deceased person who has been referred to a SoHO entity with a view to SoHO collection, and from whom consent had been granted in that respect or from whom SoHO collection is permitted, in accordance with national legislation;***

(9) 'SoHO recipient' means the person to whom ***SoHO*** are applied ***or the human application of SoHO is envisaged, whether by allogeneic, autologous or within-relationship use***;

(10) ***'recipient' means a SoHO recipient or any person receiving a product manufactured from SoHO, regulated by other Union legislation, as referred to in Article 2(6);***

(11) 'consent' means:

(a) the permission given freely without coercion by a living SoHO donor or a SoHO recipient for an action affecting them to proceed;

(b) the permission given freely without coercion by any person granting consent on behalf of a living SoHO donor or a SoHO recipient who has no capacity to consent, or the authorisation granted under national legislation, for an action to proceed in relation to the living SoHO donor or the SoHO recipient; or

(c) the permission given freely without coercion by any person granting consent, or the authorisation granted under national legislation, for an action to proceed in the case of a deceased SoHO donor in accordance with national legislation;

(12) 'allogeneic use' means the human ***application*** of SoHO ***collected*** from ***a person other than the SoHO recipient***;

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

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

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

(16) ‘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***;

(17) ‘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;

(18) ‘offspring from medically assisted reproduction’ means ▌children ▌born following medically assisted reproduction;

(19) ‘human application’ means being 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;

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

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

(22) ‘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***;

(23) ‘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 human application during a surgical intervention, without the SoHO being removed from the surgical field before they are applied***;

(24) ‘quality control’ means performing ***a pre-defined test or set of*** tests or checks to confirm that ▌ pre-defined quality criteria ***are met***;

(25) ‘storage’ means the maintenance of ***SoHO*** under appropriate controlled conditions ▌ ;

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

(27) ‘distribution’ means ***providing***, within the Union, ▌ released ***SoHO:***

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

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

(c) ***intended*** for the manufacture of products regulated by other Union legislation, ▌ as referred to ***in Article 2(6), to a manufacturer of such products;***

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

(29) ***‘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;***

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

(31) ‘clinical-outcome ***registration***’ means ***the management of a clinical registry where information on the results from the implementation of a clinical-outcome*** monitoring plan ***are recorded, including transferring such information to other registries***;

(32) 'clinical-outcome monitoring plan’ means a programme for evaluating the safety and effectiveness of a SoHO preparation following human application;

(33) ‘SoHO entity’ means an entity legally established in the Union that carries out one or more of the SoHO activities referred to in Article ***2(1), point (c);***

(34) ‘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 SoHO entities or alternative substances or products for ***recipients***;

(35) ‘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;

(36) ‘responsible person’ means an appointed person in a SoHO entity who has the responsibility of ensuring compliance with this Regulation;

(37) ‘SoHO preparation’ means a ▌type of SoHO that:

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

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

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

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

(39) ‘effectiveness of SoHO’ means the extent to which the human application of SoHO achieves the intended biological or clinical outcome in the SoHO recipient;

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

(41) ‘***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;

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

(43) ‘adverse ***reaction***’ means any incident ***which could be reasonably associated with the quality or safety of SoHO, or their collection from a SoHO donor or human application to a SoHO recipient,*** that caused harm to a living SoHO donor, ▌ to a SoHO recipient or to offspring from medically assisted reproduction ▌ ;

(44) ‘adverse event’ means any incident or error associated with SoHO activities that can 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;

(45) ‘serious adverse ***reaction***’ or ‘***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 of a toxic substance*** that might cause such condition;

(c) transmission of a genetic ***disorder that:***

(i) in the case of medically assisted reproduction with third-party donation, resulted in pregnancy loss or might result in a life-threatening, disabling or incapacitating condition in the offspring from medically assisted reproduction***; or***

(ii) in the case of medically assisted reproduction in the context of within-relationship use, resulted in pregnancy loss or might result in a life-threatening, disabling or incapacitating condition in the offspring from medically assisted reproduction***, due to 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 results referred to in points (a) to (d);

▌

(f) prolonged sub-optimal health of a SoHO donor following single or multiple SoHO donations;

(46) 'serious adverse event' or 'SAE' means an adverse event that poses a risk of any of the following:

(a) inappropriate SoHO distribution;

(b) a defect posing a 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 SoHO or SoHO for autologous use;

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

(f) loss of the traceability of SoHO;

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

(48) ‘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*** the degree of severity of ***an adverse event involving a risk of such harm***;

(49) ‘quality management system’ means a formalised system that documents the processes, procedures, and responsibilities to support achieving defined quality standards in a consistent manner;

(50) ‘delegated body’ means a legal body to which the SoHO competent authority has delegated certain SoHO supervisory activities in accordance with Article ***9(1)***;

(51) ‘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 such arrangements are applied effectively and are suitable to achieve the objectives;

(52) ‘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 ▌;

(53) ‘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 referred to in Article 2(6);***

(54) ‘Single European Code’ means the unique identifier applied to certain SoHO distributed in the Union;

(55) ‘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 & HealthCare of the Council of Europe (EDQM);

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

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

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

(59) ‘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 national measures that are more stringent than those provided for in this Regulation on condition that those measures ▌ are compatible with Union law, and are proportionate to the risk to human health***, including in light of relevant scientific knowledge***.

2. Member States shall make publicly available details of ***the more stringent*** measures ***adopted*** in accordance with paragraph 1 without undue delay, including via 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 they ▌confer responsibility for SoHO supervisory activities***. The SoHO competent 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 ***under 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 an 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 of this Article, that SoHO competent authority*** shall ***also be considered as the SoHO national authority. When a Member State designates more than one SoHO competent authority in accordance with that paragraph, it shall designate a single*** SoHO national authority ***among them, in accordance with national law. The SoHO national authority shall be*** responsible for the tasks ***referred to in Article 8(2). The designation of a single SoHO national authority shall not prevent the*** Member ***State from assigning certain tasks to other SoHO competent*** authorities***, in particular the management of SoHO rapid alerts, in order 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***:

▌

(a) the ***name*** and contact details of ***the*** SoHO national authority referred to in paragraph 4***;***

(b) the names and contact details of any SoHO competent authority designated in accordance with paragraph 1, when such SoHO competent authority is different from the SoHO national authority referred to in paragraph 4.

▌

Article 6

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 placed in a situation that may, directly or indirectly, affect the impartiality of their professional conduct. ***Personnel performing SoHO supervisory activities shall provide a declaration of their interests and regularly update that declaration. On that basis, SoHO competent authorities shall take the relevant measures to mitigate the risk of conflict of interests.***

▌

Article 7

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 pursuant to Article 19(7), (8) and (9), Article 25(3), (4) and (5), or Article 27(8), point (h), and the reasons for it, accessible and clear to the public in cases where:

      (i) a SoHO entity does not comply with this Regulation; or

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

2. Paragraph 1 of this Article 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 8

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 by***:***

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

   (b) SoHO preparations with their corresponding authorisation.

2. The SoHO national authority designated 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 for carrying out other tasks, provided for in Article 4(2), Article 12(4), Article 13(2), (3) and (4), Article 16(1), Article 31(4), Article 33(13) and (14), Article 34(2), Article 62, Article 64(3), Article 65(3) and (4), and Article 68(2) and (5). The SoHO national authority may also be responsible for the task provided for in Article 12(1).

3. ***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***;

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

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

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

(e) ***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 the case of ***crisis situations that impede the normal performance of their tasks;***

(f) 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;

(g) provide opportunities for their personnel to participate in the Union training referred to in Article 70 where such training is available and relevant.

Article 9

Delegation of certain SoHO supervisory activities to ***other*** bodies

1. Member States may empower a SoHO competent authority responsible for any of the SoHO supervisory activities referred to in Articles 20, 22, 27, 28 and 29, Article 31(1), Article 32(1), Article 33(2) and (3), Article 33(4), point (a), and Article 33(5), (6) and (8) to (12), to delegate that SoHO supervisory activity to one or more other bodies ('delegated bodies').

2. Member States ***shall ensure that the delegated bodies have the powers needed to effectively perform the SoHO supervisory activities delegated to them and fulfil the obligations set out in Article 10. SoHO*** competent authorities that delegate ▌SoHO supervisory activities ***in accordance with paragraph 1 of this Article to a delegated body*** shall ***have in place*** a written agreement ***with that delegated body***.

3. ***The delegating SoHO*** competent authorities shall ensure that the ***written*** agreement referred to in paragraph 2 of this Article ***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 ▌ set out in Articles 10 and 11***;***

(e) provisions on its termination in the case of withdrawal of the delegation pursuant to Article 11.

4. ***SoHO competent authorities that have delegated SoHO supervisory activities pursuant to paragraph 1 shall submit the names and contact details of the delegated bodies, together with the details concerning the delegated SoHO supervisory activities, to the EU SoHO Platform.***

Article 10

Obligations of the delegated bodies

1. Delegated bodies to which ▌SoHO supervisory activities ***are*** delegated in accordance with Article ***9*** shall:

(a) ***meet the obligations set out in Article 8(3);***

(b) ***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;

(c) 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

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

2. Articles 6 and 75 and, where relevant, Articles 23 and 30 shall apply to delegated bodies.

Article 11

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

SoHO competent authorities that have delegated certain SoHO supervisory activities to delegated bodies in accordance with Article ***9*** shall:

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

(b) fully or partly withdraw the delegation without delay, ***where 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 SoHO supervisory activities; or***

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

The interval between the audits referred to in the first paragraph, point (a), of this Article 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 ***9(3)***, point (b)***, as well as the scope and the impact of the delegated SoHO supervisory activities on the quality and safety of SoHO***.

Article 12

Communication and coordination between SoHO competent authorities

1. Where more than one SoHO competent authority is responsible for performing 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 ***and of the tasks of the SoHO national authority, as referred to in Article 8(2).***

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 the opinion issued***, which, in turn, shall notify the ***SCB, for publication of that opinion 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 compliance with the confidentiality obligations 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 the SoHO supervisory activities*** referred to in Articles 27 and 28.

Article 13

Consultation and cooperation with authorities of other regulatory sectors

1. Member States shall ensure that their SoHO national authority has appropriate mechanisms in place 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(6) of this Regulation within the Member State concerned.

2. 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 the obligation set out in Article 12(2),*** consult***, via the SoHO national authority, with the competent authorities*** referred to in ***paragraph 1 of this Article, as appropriate, with a view to reaching a decision on the regulatory status of that substance, product or activity***. In such cases, the ***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***.

3. In the course of the consultation referred to in paragraph 2, the ***SoHO*** competent authorities ***involved in such consultation*** may also***, via their 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 ***consultation referred to in paragraph 2 has not lead to a decision on the regulatory status of such a substance, product or activity in the Member State concerned.***

The ***SoHO*** competent authorities ***involved in the consultation referred to in paragraph 2 of this Article*** 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 69(1), point (c), with the ***relevant*** equivalent advisory bodies established under other relevant Union legislation referred to in Article 2(6).

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

4. ***When a consultation referred to in paragraph 2 and, where relevant, paragraph 3 of this Article leads to a regulatory status decision, the SoHO*** competent authorities shall***, via their SoHO national authority,*** inform the SCB of the ▌decision taken in the Member State ***concerned with a view to the publication thereof by the SCB in the SoHO compendium, pursuant to Article 69(1), point (e). The SoHO competent authorities shall include a description of the reasons for the decision, and where the decision taken differs from*** the SCB ***opinion, provide a justification***.

5. The Commission ***shall***, upon a duly substantiated request ***from*** a Member State following the consultation referred to in paragraph 2 of this Article, or ***may*** on its own initiative, by means of implementing acts, determine the regulatory status of a substance, product or activity under this Regulation, where such a determination ***is needed to avoid risks to the safety of SoHO donors, recipients or offspring from medically assisted reproduction, or risks of a compromised access of recipients to safe and effective treatment. Such a request from a Member State shall be considered duly substantiated where*** questions arise in ***respect of the regulatory status of a substance, product or activity under this Regulation***, in particular where such questions cannot be resolved at Member State level, or in ***consultations conducted in accordance with Article 69(1), point (c),*** between the SCB and the advisory bodies established ***under*** other relevant Union legislation ***referred to in Article 2(6)***.

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

6. ***In the case of SoHO*** referred to in Article 2(6) ***or*** (8), the ***SoHO*** competent authorities shall cooperate with the competent authorities responsible for the supervisory activities under ***other*** relevant Union legislation ***referred to in Article 2(6)***, 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 the regulatory status of SoHO changes***.

7. The consultation and cooperation referred to in paragraphs 2, 3 and 6 may also be initiated on the basis of a request ▌ from a SoHO entity ***for an opinion***.

8. Where a SoHO competent authority takes an enforcement decision concerning a SoHO entity that performs SoHO activities and activities regulated by other Union legislation and overseen by competent authorities as referred to in paragraph 1, the SoHO competent authority shall, without undue delay, via the SoHO national authority, inform the relevant competent authority designated under that other Union legislation of its decision.

▌

Article 14

Obligations as regards Commission controls

SoHO competent authorities and delegated bodies shall cooperate with the Commission in respect of the performance of the Commission controls referred to in Article 71. In particular, they shall:

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

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

▌

Article 15

Transparency regarding fees for technical services required for making SoHO available

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

CHAPTER III

SoHO SUPERVISORY ACTIVITIES

Article 16

Register of SoHO entities

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

2. 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 registered pursuant to ▌Article 17 in the register of SoHO entities and on the EU SoHO Platform is consistent, and shall submit any changes in that information to the EU SoHO Platform without undue delay.

3. 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 17

Registration of SoHO entities

1. ***SoHO*** competent authorities shall have procedures in place for the registration of SoHO entities in accordance with Article 35.

2. SoHO competent authorities shall verify that each SoHO entity registered in a national registry or the EU SoHO Platform has provided the information pursuant to Article 35(3) before publication of the registration on the EU SoHO Platform. Where national registries are in place, the SoHO competent authority shall submit the information on the registration to the EU SoHO Platform after carrying out that verification.

3. SoHO competent authorities shall verify whether an authorisation is required under Article 19, 25 or 26 for a registered SoHO entity, taking into account the declaration referred to in Article 35(4).

4. SoHO competent authorities shall identify whether the SoHO entity is a critical SoHO entity, in accordance with the criteria agreed by the SCB, taking into account the self-assessment carried out by the SoHO entity, where applicable, as referred to in Article 35(4). SoHO competent authorities shall update the registration information accordingly.

5. Where, on the basis of the information provided, an entity does not fall within the definition of a SoHO entity as set out in Article 3, point (33), the SoHO competent authority shall remove the registration from the EU SoHO Platform and, where applicable, from the national registry, and inform the entity without undue delay.

6. ***SoHO*** competent authorities shall:

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

(b) request the SoHO entity to provide supplementary details on the information provided ***in accordance with Article 35(3),*** if needed;

(c) ***provide instructions on the procedures to be followed to apply for*** an authorisation***, where relevant***;

(d) where applicable, ***inform the SoHO*** entity of its status as a critical SoHO entity ***and of the related obligations pursuant to Articles 64 and 67***;

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

7. In the case of changes in the information registered by the SoHO entity in accordance with Article 35(6), SoHO competent authorities shall verify those changes and publish the updated registration on the EU SoHO Platform without undue delay, including in the case of cessation of SoHO activities of the SoHO entity concerned.

▌

Article 18

SoHO preparation authorisation system

1. ***SoHO*** competent authorities shall establish and maintain a system for ***granting SoHO preparation authorisations to SoHO entities located in their territory. Such a system shall include the reception*** and processing ***of*** applications ***and the approval of clinical-outcome monitoring plans to generate the evidence required for authorisation, where necessary, and*** shall allow for the suspension or withdrawal of authorisations.

2. ***SoHO*** competent authorities shall authorise SoHO preparations in accordance with Articles 19, 20 ***and 21*** and, where applicable, Article 22.

3. The requirement of SoHO preparation authorisation shall be 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(6).

4. SoHO preparation authorisations shall be valid throughout the Union for the period set out in the ▌ authorisation granted ***pursuant to Article 19(2), point (e),*** 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 that SoHO preparation has demonstrated to that Member State compliance with that*** more stringent measure ▌ .

▌

Article 19

Authorisation of SoHO preparations

1. ***SoHO*** competent authorities shall ***provide guidelines and templates*** for the ***submission of applications for SoHO preparation authorisations*** in accordance with Article 39***, and*** for the ***design of the clinical-outcome monitoring plans referred to in Article 21***. When developing those guidelines and templates, ***SoHO*** competent authorities shall ***use the templates and take into account*** the relevant best practices documented and published by the SCB, as referred to in Article 69(1), point (d). ***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 for authorisation of SoHO preparations.***

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

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

(b) assess the SoHO preparation pursuant to Article 20 and examine agreements between the applicant ▌SoHO entity and any SoHO entity or third party contracted by that applicant SoHO entity ***to perform*** activities ***or relevant steps of the processing in relation to the SoHO preparation***, where applicable;

(c) request the applicant SoHO entity ***to provide supplementary information, if needed;***

(d) grant ***or refuse the approval for*** clinical-outcome ***monitoring plans, as appropriate***, in accordance with Article 20(4), points (c) and (d), ***and indicate a time limit for the applicant SoHO entity to submit the results of the approved clinical-outcome monitoring;***

(e) ***on the basis of the assessment under point (b) of this paragraph, and of the results of the clinical-outcome monitoring referred to in point (d) of this paragraph, where applicable,*** grant or refuse the authorisation for the SoHO preparation ***and, indicate which conditions apply, if any***.

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

4. ***SoHO*** competent authorities shall conclude the SoHO preparation authorisation steps ▌referred to in paragraph 2 of this Article, within ***the time limit set out for the authorisation taking into account best practices documented and published by the SCB, as referred to in Article 69(1), point (d). Such time limit may be extended for:***

   (a) the duration of the consultations referred to in Article 13(2) and (3);

   (b) the time needed to prepare and submit a response to a request for additional information to the SoHO entity;

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

   (d) the time needed to perform additional validation or to generate additional quality and safety data as requested by the SoHO competent authority.

5. For SoHO preparations that incorporate a medical device, as defined in Article 2, point (1), of Regulation (EU) 2017/745, as an integral part, and where that 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 Regulation.

6. Where a SoHO competent authority receives in the course of the conformity assessment procedure pursuant to Article 52 of Regulation (EU) 2017/745 a request for an opinion in relation to ***a medical device that incorporates a SoHO preparation as an integral part, and where that medical device has an action that is principal to that of the SoHO preparation, it*** shall ***provide an opinion regarding compliance of the SoHO preparation part with this*** Regulation***, in accordance with Section 5.3.1 of Annex IX to that Regulation***, and inform the SCB of the opinion provided.

7. ***SoHO*** competent authorities may, in accordance with national legislation, suspend the SoHO preparation authorisation ***where*** SoHO supervisory activities demonstrate, or give reasonable ground for suspecting, that ***such SoHO preparation, or any activities performed in respect of that preparation, do not comply with the conditions of its authorisation or with this Regulation. SoHO competent authorities shall,*** in accordance with national legislation, suspend the SoHO preparation authorisation ***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.

8. Where SoHO ***competent authorities have*** confirmed cases of non-compliance as referred to in paragraph 7***, 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 SoHO preparation authorisation ***from the SoHO entities*** concerned.

9. ***SoHO*** competent authorities may, in accordance with national legislation, withdraw the SoHO preparation authorisation if ***a suspension, as referred to in paragraph 7, is not sufficient to resolve the identified shortcomings***.

10. In cases of suspension or withdrawal of a SoHO preparation authorisation, as referred to in paragraphs 7, 8 and 9, ***SoHO*** competent authorities shall, without undue delay, amend accordingly the authorisation ***information*** for the SoHO entity concerned on the EU SoHO Platform***.***

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

(a) the specific SoHO recipient has no therapeutic alternative, the treatment cannot be postponed or the specific 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 concerned has not been authorised under this Regulation.

SoHO competent authorities may require that the SoHO entity concerned 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.

▌

12. 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 20

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 that SoHO preparation.

2. ***SoHO preparation*** assessors who meet the requirements set out in Article 23 shall carry out the assessment of SoHO preparations.

3. Where a SoHO preparation that is subject to an application for SoHO preparation authorisation pursuant to Article 19 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 the SoHO entities concerned,*** that the SoHO activities performed ***and the steps of the processing applied*** for that SoHO preparation are carried out by the applicant ▌SoHO entity in such a manner 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. Where a SoHO preparation that is subject to an application for SoHO preparation authorisation pursuant to Article 19 has not been ▌ authorised in another SoHO entity, ***or where the SoHO competent authority chooses not to take a SoHO preparation authorisation in another Member State into account, the SoHO*** competent authority ***shall***:

(a) ▌ assess ***the adequacy of*** the information provided by the applicant SoHO entity pursuant to Article ***39(2), point (b)***;

▌

(b) ▌ initiate the consultation provided for in Article ***13***, if, during the assessment of the ***information*** referred to in point ***(a) of this paragraph***, 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;

(c) ▌ evaluate the ***benefit-risk*** assessment ***carried out*** by the applicant SoHO entity pursuant to Article 39(2), point (c), ***including the scientific evidence and clinical data provided regarding the expected benefit and risk***;

(d) ***in cases where the evidence provided in accordance with point (c) of this paragraph is not sufficient to provide certainty that the benefit outweighs the 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 the plan's proportionality to the level of risk ***and expected benefit*** of the SoHO preparation in accordance with Article ***21;***

(e) ▌consult the SCB, pursuant to Article 69(1) on the evidence necessary and sufficient for the authorisation of a particular SoHO preparation ***where the best practices referred to in paragraph 7 of this Article are not sufficient***;

(f) ▌assess, in the case of a ***clinical-outcome monitoring plan previously approved*** pursuant to Article 19(2), point (d), the results of the clinical-outcome monitoring ***upon its completion and submission of the results by the applicant***.

5. When assessing the SoHO preparation pursuant to paragraph 4, points (d) and (f), ***SoHO*** competent authorities shall ***verify***, in the cases where the applicant SoHO entity has proposed to record, and recorded, the results of the clinical-outcome monitoring in an existing clinical registry, whether that ▌clinical 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 27, 28 and 29. ***Pursuant to Article 12, Member States shall ensure communication and cooperation between SoHO preparation assessors and inspectors.***

7. When conducting the assessment steps referred to in paragraph 4 of this Article, ***SoHO*** competent authorities shall ***take into account*** the best practices documented and published by the SCB, as referred to in Article 69(1), point (d).

Article 21

Clinical-outcome monitoring plans

1. In cases where the scientific evidence and clinical data provided as part of the benefit-risk assessment carried out by the applicant SoHO entity, as referred to in Article 20(4), point (c), is not sufficient, or where the risk is more than negligible, the SoHO competent authority shall approve a clinical-outcome monitoring plan submitted by the applicant SoHO entity. The approved clinical-outcome monitoring plan shall be the basis for the gathering of further evidence to allow for the assessment and authorisation of the new SoHO preparation or a new indication for the SoHO preparation.

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

3. 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 pre-defined number of SoHO recipients;

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

4. In the cases referred to in paragraph 3, 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 SoHO clinical study;

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

(c) a summary of the processing methodology;

(d) a summary of the study design;

(e) the planned date of commencement and completion of the SoHO clinical study.

5. In cases 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 EU SoHO Platform shall be modified without undue delay.

Article 22

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 referred to in Article 20 may be carried out by ***SoHO preparation assessors assigned by*** more than one Member State, as a joint SoHO preparation assessment.

2. ***With the prior 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 a request, taking into account its available resources***.

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

   (a) the scope of the joint SoHO preparation assessment;

   (b) the roles of the participating SoHO preparation assessors during and following the joint SoHO preparation assessment ▌ ;

   (c) the powers and responsibilities of each participating ***SoHO competent*** authority.

The SoHO competent authorities participating in the joint SoHO preparation assessment shall commit themselves in the agreement referred to in the first subparagraph to jointly accept the results of that assessment. That 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 SoHO preparation assessments. ***Member States may operate such programmes under*** a single written agreement ***as referred to*** in paragraph 3.

5. For the purpose of coordinating and performing joint SoHO preparation assessments, SoHO competent authorities shall take into account the relevant best practices documented and published by the SCB, as referred to in Article 69(1), point (d).

Article 23

Specific requirements concerning SoHO preparation assessors

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

(a) ***possess*** 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 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 referred to in Article 20 may be done jointly by a team of persons which collectively have the qualifications and experience set out in paragraph 1 of this Article.

3. In exceptional cases, ***SoHO*** competent authorities may consider that a person's considerable and relevant experience exempts that 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 Articles 20 ***and 21***.

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, as well as 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 participating in joint ***SoHO preparation*** assessments have completed the relevant Union training referred to in Article 70(1) and are included in the list referred to in Article 70(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 those set out in Articles 6***, 75*** and 76.

Article 24

SoHO establishment authorisation system

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

2. In accordance with Article 25, ***SoHO*** competent authorities shall authorise as SoHO establishments the SoHO entities that ***fall within the definition of a SoHO establishment as set out in Article 3, point (35)***.

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

4. ***SoHO*** competent authorities may decide that certain SoHO entities that do not ***fall within the definition of a SoHO establishment as set out in Article 3, point (35),*** also need to be authorised as SoHO establishments, in particular SoHO entities that:

(a) have significant influence on the quality and safety of SoHO 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 a decision and of the resulting obligation to comply with all provisions of this Regulation relating to 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 set out 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 until the SoHO 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*** that more stringent measure ▌.

▌

Article 25

Authorisation of SoHO establishments

1. ***SoHO*** competent authorities shall provide guidelines and templates to allow that applications ***for*** SoHO establishment authorisations are submitted in accordance with Article 46. When developing those guidelines and templates, ***SoHO*** competent authorities shall ***take into account*** the relevant best practices documented and published by the SCB, as referred to in Article 69(1), point (d). ***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 a SoHO establishment authorisation.***

2. Upon receipt of an application for a SoHO establishment authorisation, ***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 the applicant SoHO establishment to provide supplementary information, if needed;

(e) carry out an on-site ▌ inspection of the applicant SoHO establishment ***pursuant to Article 27,*** and, where applicable, ***of SoHO entities or*** third parties contracted by the SoHO establishment ▌ pursuant to Article ***28***;

(f) inform the applicant SoHO establishment, without undue delay, of the outcome of the assessment and inspections referred to in points (b), (c) and (e), and in point (d), where relevant ▌ ;

(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 subject to the authorisation and which conditions apply, if any;

▌

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

(i) assess and, as appropriate, authorise any significant changes made by the SoHO establishment to the information provided in the application and communicated to them pursuant to Article 46(2), and update that information on the EU SoHO Platform.

3. ***SoHO*** competent authorities may***, in accordance with national legislation,*** suspend the SoHO establishment authorisation, or the authorisation of certain SoHO activities which the SoHO establishment is authorised to perform, where SoHO supervisory activities demonstrate, or give reasonable grounds for suspecting that the SoHO establishment concerned ***does not comply with the conditions of its authorisation or with this Regulation. SoHO*** competent authorities ***shall, in accordance with national legislation,*** suspend the SoHO establishment authorisation ***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 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 cases of non-compliance as 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 those SoHO establishments.

5. ***SoHO*** competent authorities may, in accordance with national legislation, withdraw the SoHO establishment authorisation if ***a suspension, as referred to in paragraph 3, is not sufficient to resolve the identified shortcomings***.

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

Article 26

Authorisation of importing SoHO ***establishments***

1. ***SoHO*** competent authorities shall ***authorise as importing SoHO establishments those*** SoHO entities ***that import SoHO,*** as referred to in Article ***24(2)***.

2. ***Article 24(1), (3) and (5) and Article 25 shall apply, mutatis mutandis, to the authorisation of importing SoHO establishments.***

3. Upon receipt of an application for ***an importing SoHO establishment authorisation, SoHO competent authorities shall act in accordance with Article 25(2). SoHO*** competent authorities shall ***also assess the procedures in place at the applicant importing SoHO establishment to ensure that the imported SoHO are equivalent, in terms of quality, safety and effectiveness, to SoHO preparations authorised in accordance with this Regulation.***

▌

4. ***With regard to Article 25(2), point (e), and in cases where the imported SoHO are not physically received by the importing SoHO establishment but are sent directly to the SoHO entity for human application to a specific SoHO recipient or to an operator for manufacturing a product regulated by other Union legislation, as referred to in Article 2(6), SoHO competent authorities may choose to carry out an inspection by means of remote document review.***

▌

5. ***SoHO*** competent authorities may require to inspect any ▌third-country ***supplier*** to the applicant importing SoHO establishment 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***.

▌

6. By ***way of*** derogation from paragraph 1, ***SoHO*** competent authorities may authorise imports of ***SoHO*** for immediate ***human*** application to a specific ***SoHO*** recipient***, when requested by the SoHO entity responsible for that human 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 of SoHO.***

7. The Commission is empowered to adopt delegated acts in accordance with Article 77 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***.

8. Where, in the case of risk to quality and safety of imported 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 27

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.***

2. SoHO competent authorities shall carry out the following inspections of 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 indicates possible non-compliance with ▌ this Regulation;

(c) ***announced or unannounced*** inspections ***targeted at a specific activity or topic as provided for in Article 20(6)***, ***Article 26(5), Article*** 29 and ▌ Article 33(6).

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

▌

4. ***SoHO competent authorities shall carry out on-site inspections. However, 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 modes do not pose a risk to the quality and safety of ***SoHO***;

(b) such inspection ***modes*** do not prejudice the effectiveness of inspections; ▌

(c) protection of SoHO donors, SoHO recipients or offspring from medically assisted reproduction is respected; and

(d) the maximum interval between two on-site inspections pursuant to paragraph ***9*** is not exceeded.

5. ***SoHO*** competent authorities shall ensure that inspections are carried out by inspectors who meet the requirements set out in Article 30.

▌

6. The inspections shall include the verification that SoHO establishments comply with the standards, or elements thereof, set out in Chapters VI and VII.

In cases where the SoHO establishments follow:

(a) the technical guidelines published by the ECDC and by the EDQM referred to in Article 56(4), point (a), and Article 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 such guidelines;

(b) other guidelines as referred to in Article 56(4), point (b), and Article 59(4), point (b), ***adopted by the Member State in accordance with paragraph 7 of this Article, 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 referred to in point (a) or (b) of this paragraph, or*** other technical methods that are ***not addressed in guidelines, applied in specific circumstances,*** as referred to in Article 56(4), point (c), and Article 59(4), point (c), the inspectors shall evaluate the ***steps taken by the SoHO establishments to ensure the adequacy of such guidelines or technical methods, and their compliance with the standards set out in this Regulation; for that evaluation, the SoHO establishments shall provide the inspectors with all the necessary information, pursuant to Article 56(7) and Article 59(7)***.

7. ***When adopting the guidelines referred to in paragraph 6***, point (b)***, of this Article, the Member State shall***, prior to the inspection, ***verify and document that those guidelines are adequate to achieve compliance with the standards set out in Chapters VI and VII and shall make those guidelines available on the EU SoHO Platform. Those 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 6, point (a), of this Article***.

8. 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) where ***applicable,*** evaluate the design and implementation of the quality management system in place pursuant to Article 37;

(e) evaluate compliance with the vigilance and the traceability systems;

(f) take samples for analysis***,*** copies of documents***, and photographs or videos,*** if required;

(g) evaluate the SoHO entity emergency plan in place in accordance with Article 67, where applicable;

(h) 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.***

9. ***Following the inspection referred to in Article 25(2), point (e), SoHO*** competent authorities shall carry out ***periodic*** inspections pursuant to paragraph ***2***, point (a), of this Article, ***so that the interval between two on-site inspections shall not exceed, in any event, 4 years. The frequency of inspections shall take*** account of:

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

▌

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

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

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

▌

10. 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. ***Where 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.

▌

11. 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*** documented and published by the SCB, as referred to in Article 69(1), point (d).

12. The Commission may adopt implementing acts concerning ***technical elements of*** the procedures to be followed for inspections of SoHO establishments.

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

Article 28

Inspections of ***SoHO entities,*** other ***than SoHO establishments, and of third parties***

1. ***SoHO*** competent authorities may carry out, pursuant to Article 27(1), inspections ***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 to the SoHO entity's past ▌ compliance ***records***.

2. In the cases referred to in paragraph 1 of this Article, Article 27 shall apply, ***mutatis mutandis***, to the inspection of SoHO entities other than SoHO establishments ***and of the third parties contracted***.

▌

Article 29

Joint inspections

1. At the request of one or more ***SoHO*** competent authorities, ***via their SoHO national authority to another SoHO national authority***, inspections pursuant to Article 27(1) and Article 28(1) may be carried out ***with the participation of*** inspectors ***sent for that purpose by another*** Member State as a joint inspection.

2. ***With the prior 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 a request, ***taking into account its 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) the ***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 ***State*** receiving the request ***agree*** that there are other reasonable grounds for conducting a joint inspection.

3. Where the SoHO competent authority receives a request for joint inspection of a SoHO entity, it may decline that request, in particular if:

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

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

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

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

5. The SoHO competent 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 the national legislation of that Member State***.

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

▌

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 4.

7. For the purpose of coordinating and performing joint inspections, SoHO competent authorities shall take into account the relevant best practices documented and published by the SCB, as referred to in Article 69(1), point (d).

Article 30

Specific requirements 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 exempts that person from the requirements set out in the first subparagraph.

2. Before inspectors take up their duties, ***SoHO*** competent authorities shall provide inspectors with a specific induction training. For the specific induction training, ***SoHO*** competent authorities shall ***take into account*** the relevant best practices documented and published by the SCB, as referred to in Article 69(1), point (d).

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 documented and published by the SCB, as referred to in Article 69(1), point (d);

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

(d) the legal framework applicable to 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 healthcare 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 SoHO establishments and by continuous training, as appropriate***. SoHO*** competent authorities shall ***make all reasonable efforts*** to ensure that inspectors participating in joint inspections have completed the relevant Union training referred to in Article 70(1) and are included in the list referred to in Article 70(5).

5. Inspectors may be assisted by technical experts provided that the ***SoHO*** competent authorities ensure that those experts comply with the relevant requirements of this Regulation ▌.

▌

Article 31

Extraction***, submission*** and publication of activity data

1. ***SoHO*** competent authorities shall verify that SoHO entities that have activity data collection and reporting obligations pursuant to Article 41 submit ***to their SoHO competent authorities, via the EU SoHO Platform, an*** annual ***report*** with those activity data***.*** The EU SoHO Platform ***shall allow for the compilation of the annual reports submitted by the SoHO entities and provide the SoHO competent authorities with an annual aggregated report with the activity data from their SoHO entities***.

2. By way of derogation from paragraph 1 of this Article, Member States may decide that SoHO entities shall submit the activity data referred to in Article 41(1) to SoHO competent authorities through national or international registries, in cases where such registries collect activity data matching the data sets indicated on the EU SoHO Platform. In such case, the SoHO competent authorities shall submit those activity data in accordance with the implementing acts adopted pursuant to Article 41(3).

3. ***SoHO*** competent authorities shall ***ensure that the*** annual ***aggregated*** report of activity data for their SoHO entities ***is made publicly available in their Member States, including via the internet. The annual aggregated*** report ***of activity data may also be published*** on the ***EU SoHO Platform after review and approval by SoHO national authorities***.

4. The Commission shall compile the annual aggregated reports from the SoHO competent authorities and prepare an annual Union SoHO activity report. After having shared that report with the SoHO national authorities for their review and approval, the Commission shall publish the annual Union SoHO activity report and make it available on the EU SoHO Platform.

Article 32

Traceability

1. ***SoHO*** competent authorities shall verify that SoHO entities have appropriate procedures in place to ensure traceability and coding of SoHO as referred to in Article 42.

2. ***SoHO*** competent authorities shall establish procedures for the unique identification of SoHO establishments that are to apply the Single European Code pursuant to Article 43. ***SoHO*** competent authorities shall ensure that such identification complies with the technical standards established for that coding system. For that purpose, ***SoHO*** competent authorities may use a SoHO establishment identification code generated by the EU SoHO Platform.

Article 33

Vigilance

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

2. SoHO competent authorities shall provide guidance and templates for the submission of SAR or SAE notifications and investigation reports as referred to in Article 44. The guidance and templates provided shall take into account the best practices documented and published by the SCB as referred to in Article 69(1), point (d). SoHO competent authorities shall also establish procedures for the receipt of SAR or SAE notifications pursuant to Article 44.

3. Upon receipt of a ***SAR or SAE*** notification ***pursuant to Article 44(3)***, ***SoHO*** competent authorities shall:

▌

(a) verify that the ▌ notification includes the information referred to in Article ***44(3)***;

▌

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

4. ***Upon receipt of a SAR or SAE notification*** pursuant to Article ***44(3), SoHO*** competent authorities ***may:***

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

(b) request advice from the SCB pursuant to Article 69(1).

Where 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.

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

▌

(a) verify that the ▌ investigation report includes the information required pursuant to Article 44(7);

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

(c) request additional documentation from the submitting SoHO entity, if required;

(d) inform the submitting SoHO entity of the conclusion of the ***assessment, if corrections are required***.

6. ***SoHO*** competent authorities may carry out inspections, pursuant to Article 27 or 28, 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 they may carry out inspections to verify an accurate implementation of the corrective and preventive actions planned, ***or when they consider that a particular serious adverse reaction or serious adverse event might constitute a public health threat***.

7. Where a SAR or SAE notification concerns a risk to public health, SoHO competent authorities shall, without delay, communicate essential information to other SoHO competent authorities via the SoHO rapid alert procedure referred to in Article 34. SoHO competent authorities receiving that information shall in turn communicate it to the general public, where relevant.

8. Upon receipt of a ***SAR or SAE*** notification with implications for ***quality, safety,*** or supply of a product manufactured ***from a SoHO*** and regulated by other Union legislation, as referred to in Article 2(6)***, SoHO*** competent authorities shall inform, without undue delay ***and via their SoHO national authority***, the relevant authorities competent for that product, pursuant to Article 13(6).

9. Upon receipt of information regarding a serious incident within the meaning of Article 2, point (65), of Regulation (EU) 2017/745, or information regarding a serious adverse reaction within the meaning of Article 1, point (12), of Directive 2001/83/EC, associated with a product manufactured from or with SoHO, where that information indicates 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.

10. Upon receipt of information regarding a serious incident and field safety corrective action ***within the meaning of Article 2, points (65) and (68), of*** Regulation (EU) 2017/745, ***as well as within the meaning of Article 2, points (68) and (71), of Regulation (EU) 2017/746 of the European Parliament and of the Council***[23]***, the SoHO*** competent authorities receiving such information shall ***communicate it to*** the SoHO entities ***that may be using the medical 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 falls within the definition of a ***serious adverse reaction as set out in Article 3, point (45), of this Regulation or the definition of a serious adverse event as set out in Article 3, point (46), of this Regulation***.

▌

11. ***SoHO*** competent authorities ***or Member States*** shall ensure that the procedures referred to in paragraphs 1 to 6 of this Article provide for an adequate interconnection between the SAR and SAE▌ notifications pursuant to this Article and the reporting system established in accordance with Article 11 of Directive 2010/53/EU, for instance where a ***SAR or SAE*** notification relates to SoHO donations▌ by SoHO donors that also donated organs.

[23] ***Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).***

12. ***SoHO*** competent authorities shall submit to their SoHO national authority an annual summary of the ***SAR and SAE*** notifications and ***the investigation reports of confirmed serious adverse reactions and serious adverse events. That summary shall, where necessary, include recommendations arising from an analysis of the serious adverse reactions and serious adverse events*** reported.

13. SoHO national authorities shall submit an annual summary of confirmed SAR or SAE notifications and of the related investigation reports to the EU SoHO Platform before 30 June of the subsequent year and shall make an aggregated version of that summary publicly available in their Member State, including via the internet. SoHO national authorities shall include in the annual summary the numbers and types of SAR or SAE notifications reported to them that meet the thresholds of seriousness and imputability as set out in the best practices documented and published by the SCB, as referred to in Article 69(1), point (d).

14. The Commission shall aggregate the annual summaries of the SoHO national authorities, and prepare and publish an annual ***Union*** SoHO vigilance report***,*** after having shared ***it*** with the SoHO national authorities for review and approval. ***That report shall include overall pattern analysis and recommendations.***

15. The Commission may adopt implementing acts concerning the procedures to be followed for consultation and coordination between SoHO 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 34

SoHO rapid alerts

1. ***SoHO*** competent authorities shall, upon receipt of a SAR or SAE notification or other information with implications for ▌ quality***, safety*** or supply of ***SoHO in more than one*** Member ***State, inform their SoHO national authority, 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 SoHO 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 a SoHO rapid alert on the EU SoHO Platform when surveillance of communicable diseases indicates a new risk to the safety of SoHO. The ECDC may indicate in such a SoHO rapid 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 SoHO rapid alert with further information such as details of relevant risk mitigating actions taken in their Member State.

5. ***SoHO national authorities*** and the ECDC shall ***take into account*** the relevant best practices documented and published by the SCB, as referred to in Article 69(1), point (d), when launching and handling a SoHO rapid alert.

CHAPTER IV

GENERAL OBLIGATIONS ON SoHO ENTITIES

Article 35

SoHO entity registration

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

Entities may request from a SoHO competent authority within their territory an opinion on whether the activities they are carrying out are subject to the registration requirements set out in this Chapter.

2. SoHO activities shall only be carried out by persons who operate within a registered SoHO entity.

3. In order to register as a SoHO entity, the SoHO entity shall provide the following information:

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

(b) name and contact details of the responsible person as referred to in Article 36;

(c) acknowledgment from the SoHO entity that it may be inspected pursuant to Article 28 and that it will cooperate with the relevant SoHO competent authority in any matter relating to the conduct of SoHO supervisory activities in accordance with this Regulation;

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

(e) where applicable, a list of SoHO establishments 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 13(1).

4. SoHO entities shall declare, when registering, whether they need an authorisation pursuant to Article 19, 25 or 26. They shall also carry out a self-assessment of whether they meet the criteria for being a critical SoHO entity and communicate the result.

5. In Member States where the EU SoHO Platform is used for registration of SoHO entities, as referred to in Article ***16(1)***, entities falling within the definition of a SoHO entity as set out in Article 3, point (33), shall register directly on the EU SoHO Platform in accordance with the instructions from their ***SoHO*** competent authorities.

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

7. ***Where 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 42, where applicable.***

8. ***Where the SoHO stored is intended for autologous or within-relationship use, or is a highly matched SoHO for a specific SoHO recipient, and the SoHO entity ceases SoHO 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 such SoHO.***

Article 36

Responsible person

1. ***SoHO entities shall appoint a person responsible, within their entity, for ensuring that SoHO activities carried out by the SoHO entity comply with the requirements of this Regulation applicable to those SoHO activities.***

2. 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 recognised as equivalent by the Member State concerned and shall have at least 2 years of experience in the relevant field.

3. 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, SoHO entities shall without undue delay inform their SoHO competent authorities of the name and contact details of the new responsible person and the date on which the responsibility of that person is assumed.

4. The responsible person may fulfil the role of releasing officer, as referred to in Article 49, or the role of physician, as referred to in Article 50, provided that that person is in possession of the required qualifications or experience as laid down in those Articles.

Article 37

Quality management system

1. ***SoHO entities shall establish, maintain and update a quality management system that is appropriate, taking into account their SoHO activities and that achieves a high level of quality of SoHO.***

2. ***SoHO entities shall design the quality management system in a way that ensures that SoHO activities are carried out in a consistent manner, by personnel that have documented and periodically assessed competence to perform the tasks allocated to them and that SoHO activities are carried out in facilities that are designed and maintained in a manner that prevents SoHO contamination, or cross-contamination between SoHO, or loss of traceability. In that respect, 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 on 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, where applicable to their SoHO activities, the following:

(a) documentation of roles, responsibilities of personnel and organisation;

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

(c) the procurement qualification, validation and monitoring of premises, materials and equipment, including IT systems;

(d) other documentation relevant for the quality management system put in place;

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

(f) quarantine and release;

(g) withdrawal of SoHO from the inventory of released SoHO and recalls;

(h) internal audits;

(i) management of contracted third parties;

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

(k) complaints;

(l) management of traceability and vigilance, pursuant to Articles 42, 43 and 44;

(m) continuity planning.

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

5. The Commission may adopt implementing acts regarding selected elements 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 38

SoHO preparation authorisation

1. SoHO entities shall not release or, in the context of autologous or within-relationship use, shall not prepare and immediately apply ▌ to a ***SoHO*** recipient, SoHO preparations without prior SoHO preparation authorisation***, other than in the context of the implementation of an approved clinical-outcome monitoring plan as part of*** a 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 from their ***SoHO*** competent authorities a derogation from the requirement for a SoHO preparation authorisation in health ***emergency situations referred to in Article 65, or for a specific SoHO recipient when justified by the clinical*** circumstances ***as*** referred to in Article ***19(11)***.

Article 39

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

1. SoHO entities shall ***submit*** applications for ▌ SoHO preparation authorisation ***to the SoHO competent authority in 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;

   (b) ▌ 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;

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

      (iii) ***a summary of*** SoHO collection procedures ***and any specific quality control tests and checks carried out on the collected SoHO prior to processing***;

(iv) 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***;

(v) 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***, where applicable, and, in the case of the use of in-house developed equipment, reagents or materials, evidence of the validation of their quality***;

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

(vii) ***a specification of the SoHO preparation, including*** quality control and release parameters;

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

(ix) details of any ***SoHO entities or*** third parties contracted ***to perform activities or relevant steps of the processing applied*** to the SoHO preparation;

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

(xi) where relevant, non-clinical data on the effectiveness and toxicity of the SoHO preparation;

(c) the results of a ***benefit-risk*** assessment conducted in respect of the combination of SoHO activities performed for the SoHO preparation, together with the intended clinical indication for which ***the application for SoHO preparation 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 the other guidelines referred to in Article 59(4), point (b) or (c)***;

(ii) whether the SoHO preparation meets the quality criteria defined in ***a monograph or specification as*** referred to in point (i) of this point and whether it is intended to be used for the indication and with the mode of human application to which that monograph ***or specification*** refers, where such details are provided in that monograph, ***or whether it meets the requirements set out in the other guidelines 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 on 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 SoHO entity 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 the EDQM for the performance of such risk assessments, as referred to in Article 56(4), point (a), and Article 59(4), point (a)***;

(d) 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 the purpose of providing further evidence, where necessary,*** for the SoHO preparation authorisation, in line with the results of the ***benefit-risk*** assessment ***and pursuant to point (c)***;

(e) an indication of the data which is to be regarded as proprietary and which is to be accompanied, where appropriate, by a verifiable justification.

3. ***If the application for SoHO preparation authorisation includes clinical-outcome registration, in accordance with Article 20(5)***, the applicant shall ***provide details of the clinical registry to the SoHO competent authority and request approval for its use.***

4. ***Where applicable, in accordance with Article 20(4), point (d), and Article 21,*** SoHO entities shall ***prepare and distribute the SoHO preparation concerned solely for the implementation and within the limitations, of a*** clinical-outcome monitoring ***plan that has been approved by the SoHO competent authority,*** pursuant to Article 19(2), point (d), and submit the results ***and*** their ***analysis to their SoHO*** competent ***authority in accordance with the time limit set in the approval.***

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

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

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

Article 40

SoHO clinical studies

1. Where SoHO entities carry out, in the context of approved clinical-outcome monitoring plans, SoHO clinical studies as referred to in Article 21(3), points (b) and (c), with SoHO preparations that are not yet authorised the SoHO entities shall comply with the requirements set out in this Regulation and in particular with the standards laid down in Chapters VI and VII.

2. Before commencing a SoHO clinical study for the risk level referred to in Article 21(3), point (c), SoHO entities shall:

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

(b) await approval by the SoHO competent authority of the clinical-outcome monitoring plan, as referred to in Article 19(2), point (d), and Article 21.

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 concerned has not yet been authorised in accordance with this Regulation and that the SoHO preparation is being applied in the context of a SoHO clinical study that forms part of the authorisation process for that SoHO preparation.***

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

5. ***In the course of a SoHO clinical study, SoHO entities shall comply with the vigilance and reporting requirements set out in Article 44.***

Article 41

Activity data collection and reporting

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

   (a) ▌SoHO 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*** on 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, and for extraction, submission and publication of activity data***.

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***.

5. By way of derogation from paragraph 4 of this Article, where Member States require SoHO entities to report activity data as referred to in Article 31(2), the SoHO entities shall submit their annual report of activity data to the indicated registries before 30 June of the subsequent year.

Article 42

Traceability and coding

1. SoHO entities shall implement a traceability system***,*** in order to unambiguously link each SoHO donor ***or the person from whom SoHO are collected for autologous or within-relationship 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***.

2. The traceability system referred to in paragraph 1 of this Article shall be able to:

(a) identify the SoHO donor or the person from whom SoHO are collected for autologous or within-relationship use and the SoHO 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 referred to in Article 2(6);

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

3. SoHO entities distributing ***SoHO*** shall ***apply*** a code that contains the information ***required by the*** traceability system referred to in paragraph 1 of this Article. SoHO entities 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 collected in the case of autologous use***;

(d) complies with technical rules for the Single European Code referred to in Article 43, where applicable as indicated in that Article.

The first subparagraph shall not apply in the context of autologous or within-relationship use of SoHO collected in the same SoHO entity where they are applied.

4. SoHO entities shall include the codes referred to in paragraph 3***,*** on the labels ▌applied to the SoHO ▌, ***prior to its distribution,*** 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.

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

6. 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, where applicable, from the date of disposal or export. They may store the data in electronic form. Where a SoHO entity ceases its activity, the traceability data shall be transferred to a contracted SoHO entity for the remaining part of the traceability period, after informing the SoHO competent authority.

7. 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 43

European coding system

1. SoHO entities shall apply a Single European Code 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 referred to in Article 2(6), or exported to third countries***, SoHO entities shall, at least, apply the ***elements*** of the Single European Code that ***allow for the*** identification of the donation. The Single European Code shall ***also*** appear on the ***primary*** packaging of the SoHO concerned or on a label attached thereto, or on the documents referring to that SoHO where it can be ***ensured*** that such documents accompany the SoHO concerned.

2. Paragraph 1 of this Article 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 way of derogation and*** authorised directly by ***SoHO*** competent authorities pursuant to Article 26(6);

(e) ***SoHO*** that are imported to or collected 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 entities 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 44

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 39.

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 human application*** with a view to ***investigating the suspected serious adverse reaction 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*** falls within the definition of a serious adverse reaction as set out in Article 3, point (45), ***or the definition of a serious adverse event as set out in Article 3, point (46)***, 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 ***serious adverse reaction or serious adverse event***;

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

▌

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

(d) a preliminary assessment of the seriousness of the consequences of the ***suspected serious adverse reaction or serious adverse event***.

4. ***SoHO entities other than SoHO establishments shall communicate adverse reactions or adverse events to the SoHO establishment for which they carry out SoHO activities on the basis of an agreement or to the SoHO establishment that distributed the SoHO to them, as appropriate. In such cases, the SoHO establishments which receive 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 to be a serious adverse reaction or serious adverse event.***

SoHO entities other than those referred to in the first subparagraph shall investigate and report serious adverse reactions or serious adverse events directly to their SoHO competent authorities.

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

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

7. SoHO entities shall conduct an investigation of each serious adverse reaction ***or serious adverse event*** detected by, ***or communicated to, them in accordance with paragraph 4***. On completion of ***that*** investigation ▌, SoHO entities shall provide ***an*** investigation report to their ***SoHO*** competent authorities. The SoHO entities shall include in the report:

   (a) a full description of the investigation of the serious adverse reaction or serious adverse event ▌ ***and the final assessment of the imputability of the serious adverse reaction*** to the collection process or to the human application of the SoHO, ***where applicable***;

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

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

8. SoHO entities shall ***communicate*** information concerning a serious adverse reaction ***or serious adverse event*** 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 of SoHO in such cases, and shall, in particular, limit the information to details necessary to take risk mitigating actions. ***A risk assessment of the seriousness and likelihood of recurrence shall be included in the communication.*** SoHO entities shall***, where relevant,*** also ***communicate*** such information to organ procurement organisations in cases where ***the SoHO*** donor who is implicated in the ***serious adverse reaction or serious adverse event*** 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(6)***.

CHAPTER V

GENERAL OBLIGATIONS ON SoHO ESTABLISHMENTS

Article 45

SoHO establishment authorisation

1. SoHO establishments shall not carry out any ***of the SoHO*** activities ***that would qualify them as a SoHO establishment as defined in Article 3, point (35), without prior SoHO establishment authorisation.*** This shall apply regardless of whether all SoHO activities are carried out by the ***SoHO*** establishment itself or whether one or more are contracted to another SoHO entity.

In the case of a decision on the need for a SoHO establishment authorisation under Article 24(4), the SoHO entity shall not carry out the SoHO activity requiring SoHO establishment authorisation as communicated by the SoHO competent authority, without prior SoHO establishment authorisation.

2. In cases where SoHO establishments contract other SoHO entities to perform a part or all of certain SoHO activities, the SoHO establishments shall ensure that those contracted SoHO entities carry out those contracted SoHO activities in compliance with 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 SoHO ***entity has not been accredited, certified or authorised, as part of a national programme, for the specific contracted SoHO activities***.

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

Article 46

Application for SoHO establishment authorisation

1. SoHO entities shall ***submit*** the application for authorisation as SoHO establishment to ***the SoHO*** competent authorities ***of their territories***.

2. The applicant SoHO establishment shall provide the name and contact details of the ***responsible person*** as referred to in Article ***36.***

   The ▌SoHO establishment shall not make any ***significant*** changes ***with regard to the SoHO or*** the SoHO activities subject to the authorisation without the prior written ***authorisation*** of the ***SoHO*** competent authority. ▌

3. Significant changes for the purposes of paragraph 2 means changes 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.

4. 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 permanent or temporary replacement of the responsible person.

5. ***The legal entity that holds the SoHO establishment authorisation*** shall be based in the ***Member State where the SoHO establishment is authorised***.

Article 47

Importing SoHO ***establishment*** authorisation

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

2. In the case of import of ▌ human plasma that is intended to be used for the manufacture of medicinal products regulated by other Union legislation and which is included in a plasma master file (PMF) as referred to in Directive 2001/83/EC, paragraph 1 of this Article shall not apply ***as the importers are to be authorised by other Union legislation. In those cases, the importers shall be registered as SoHO entities***.

3. SoHO entities responsible for human application to a specific SoHO recipient may submit a request to their SoHO competent authorities for a derogation from the requirement for an importing SoHO establishment authorisation in the circumstances referred to in Article 26(6).

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

Article 48

Application for importing SoHO ***establishment*** authorisation

1. ***Article 46*** shall ***apply mutatis mutandis to the applications for*** importing SoHO ***establishment authorisations***.

2. Prior to applying for an 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 set out in in paragraph 3, point (b).

3. The applicant ***SoHO establishment*** shall ***provide:***

(a) documentation of the accreditation, designation, authorisation or licence granted by a competent authority or authorities to the third-country supplier for carrying out the activities related to the SoHO to be imported;

(b) a written agreement as referred to in paragraph 2 that shall include, at least:

(i) details of the third-country supplier contracted;

(ii) the requirements to be met to ensure the equivalence of the quality, safety and effectiveness 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 entity sub-contracted by that supplier, contracted by the importing SoHO establishment;

(c) documentation describing the imported SoHO and demonstrating 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 in accordance with 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. ***The releasing officer of an importing SoHO establishment shall release imported SoHO for distribution only after that officer has verified compliance with the quality, safety and effectiveness requirements specified in the agreement referred to in paragraph 3, point (b), and when the physical and documentation controls referred to in paragraph 4 are satisfactory.***

6. 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 a ***SoHO*** recipient in cases where the import of SoHO is organised for a ***specific SoHO*** recipient.

In the case of national or international donor registries that are authorised as importing SoHO establishments, the physical and documentation controls referred to in paragraph 5 may be delegated to the SoHO entity that receives the imported SoHO for human application and the release step may be completed remotely.

7. The Commission shall adopt implementing acts specifying the information to be provided in an application for an importing ***SoHO establishment authorisation*** 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 49

Releasing officer

1. In cases where a SoHO establishment releases SoHO, it shall appoint 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 recognised as equivalent by the Member State concerned and shall have at least 2 years of experience in the relevant field.

3. The releasing officer may delegate the task of releasing SoHO as referred to in paragraph 1 to other persons who shall be qualified by training and experience to perform such a task. In such cases, those persons shall perform that task under the responsibility of the releasing officer who will always be responsible for the release.

The responsibility for releasing SoHO may be delegated to an alternate in the event of short-term absence of the releasing officer, provided that the alternate meets the requirements set out in paragraph 2.

Article 50

Physician

1. Each SoHO establishment shall appoint a physician who carries out their 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 2 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;

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

(c) 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;

(d) design and supervision, in collaboration with treating physicians, of clinical-outcome monitoring plans to generate evidence required to support applications for SoHO preparation authorisations pursuant to Article 39;

(e) other tasks of relevance to the health of SoHO donors, SoHO recipients and offspring from medically assisted reproduction in relation to SoHO collected or supplied by the SoHO establishment.

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

4. By way of derogation from paragraph 2 of this Article, where SoHO entities are authorised as SoHO establishments in accordance with Article 24(4), 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 51

Export

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

2. By way of derogation from paragraph 1 of this Article, SoHO that do not comply with all the relevant standards and guidelines referred to in Articles 58 and 59 may be released for export in the case of exceptional release pursuant to Article 61(3). Nevertheless, SoHO establishments shall even in those circumstances comply with the standards referred to in Chapter VI, as well as the obligations related to vigilance and traceability.

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 SoHO donation, by identifying and minimising such risks*** before, during and after the ***SoHO collection***.

3. SoHO competent authorities shall verify the compliance with this Chapter as well as with national legislation on consent and voluntary and unpaid donation.

Article 53

Standards concerning SoHO donor protection

1. Where ***SoHO are collected from*** SoHO 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 in a way that is adequate in view of their capacity to understand it;

(ii) the contact details of the SoHO entity responsible for collection from which they can request further information, if needed;

▌

(c) 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;

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

(e) verify the eligibility of the ***living SoHO*** donor on the basis of a donor health evaluation that aims to ***identify, with a view to*** minimising, any risk that the ***SoHO collection*** might pose to the ***SoHO*** donor's health;

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

(g) 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;

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

(i) ***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 of this Article, that living SoHO*** donors are not donating more frequently than indicated as safe in technical guidelines referred to in Article ***56(4) and monitor relevant health indicators to evaluate*** whether their health is not compromised;

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

(k) in the case of an ▌ unrelated SoHO donation, refrain from revealing the ***SoHO*** donor's identity to the recipient ***or to the offspring from medically assisted reproduction***, apart from ▌in 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 (e), of this Article, 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 SoHO donation process for those SoHO 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 ***additional*** tests are necessary to establish the eligibility of those ***SoHO*** donors from the perspective of their own protection. The physician ▌referred to in Article ***50*** 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 (i), of this Article shall register such SoHO donors in a SoHO entity registry or, where available, in national or recognised international registries, to verify*** donation ***frequency. SoHO entity-level and national registries shall have the possibility of interconnectivity with other such registries. Where a SoHO entity-level registry or a national*** registry ***is used, and where the circumstances point to a risk that a SoHO donor is donating too frequently in more than one SoHO entity located in one or more Member States, SoHO entities shall verify whether this is the case by consulting with interconnected SoHO donor registries on a case-by-case basis***. SoHO entities ***shall be in a position to demonstrate to their SoHO competent authorities, on request, that an appropriate procedure that mitigates such risk is in place. 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 SoHO donation,*** shall ensure that the plan for monitoring ***the SoHO*** donor's health after SoHO donation, as referred to in paragraph 1, point (j), is proportionate to the risks associated with the SoHO donation. SoHO entities shall include in the plan the time period during which the monitoring shall continue.

▌

5. The Commission is empowered to adopt delegated acts in accordance with Article 77 to supplement this Regulation in cases where additional standards are needed in order to ensure the protection of SoHO donors.

6. 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 that shall 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 conditions for such compensation shall be based on criteria that take into account the practices documented by the SCB, as referred to in Article 69(1), point (g). SoHO donors may choose not to be compensated.***

3. 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 EU SoHO Platform and the information shall be updated without undue delay if it has been modified.

4. 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 SoHO donors to be informed of their rights, in accordance with national law.

5. 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 in national legislation.***

6. Member States shall ensure compliance with standards concerning voluntary and unpaid donation, 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, where applicable,*** any persons granting ***consent*** on behalf of a SoHO donor, ▌ with all appropriate information relating to the SoHO 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 for future recipients of the SoHO concerned.

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

(a) the purpose and nature of the SoHO donation;

(b) 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 referred to in Article 2(6), to which specific consent shall be granted;

(c) the consequences and risks of the SoHO donation;

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

(e) the right to ***revoke*** consent and any restrictions on ***that*** right ***after the collection***;

▌

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

(g) the right of the ***SoHO*** donor ***or, where 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***;

(h) 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***;

(i) the possibility that the SoHO donor identity may be revealed to the offspring from medically assisted reproduction that is born as a result of their SoHO donation in cases where national legislation grants that right to such offspring;

(j) ***other*** applicable safeguards ▌ to protect the ***SoHO*** donor***.***

▌

4. In the case of deceased SoHO donors, SoHO entities shall provide any persons granting consent to collection on their behalf in accordance with national legislation, with the information referred to in paragraph 3, points (a), (b), (d) and (e).

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 Article 53 ▌ or 55, in order to ensure convergent and high levels of ***SoHO*** donor ***protection***, the Commission may adopt implementing acts setting out 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 concerning SoHO donors protection, or elements thereof, 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 27(6),*** point ***(b)***;

(c) ***other*** guidelines ***or*** technical ***methods, applied in specific circumstances, as referred to in Article 27(6), point (c)***.

5. In the cases referred to in paragraph 4, point (a), of this Article, for the purposes of Article 28 in conjunction with Article 27, 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), of this Article.

6. In the cases referred to in paragraph 4, point (b), of this Article, for the purposes of Article 28 in conjunction with Article 27, 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 guidelines referred to in paragraph 4, point ***(b), of this Article***.

7. In the cases referred to in paragraph 4, point (c), of this Article, for the purposes of Article 28 in conjunction with Article 27, SoHO entities shall ***provide during inspection a justification to their SoHO competent authorities for each specific standard or element thereof, that the other guidelines are adequate to achieve the level of quality and safety set out in that standard. That 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), of this Article.***

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 they shall record the practice followed to establish such 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

PROTECTION OF SoHO RECIPIENTS AND OFFSPRING FROM MEDICALLY ASSISTED REPRODUCTION

Article 57

Objectives regarding protection of SoHO recipients and offspring from medically assisted reproduction

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

Article 58

Standards concerning protection of SoHO recipients and offspring from medically assisted reproduction

1. SoHO entities shall establish procedures ***that achieve*** high levels of quality and safety ***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 for the application of temporary or permanent deferrals of SoHO donors 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 are relevant to the SoHO concerned,*** including the transmission of ***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 for the application of 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 human application of SoHO;

(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 any of the following 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 such conditions occurring in the offspring from medically assisted reproduction.

4. ***In*** the procedures referred to in paragraph 1, SoHO entities shall take measures to 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***, as well as SoHO collected from different persons for future autologous or within-relationship use,*** is avoided or, in cases where ***pooling of SoHO*** is necessary for the ***effectiveness or feasibility*** of the SoHO preparation, such contact is ***limited to a 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 combining 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;

(b) 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***;

(c) ***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;

(d) 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***;***

(e) 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 of this Article, SoHO entities shall mitigate the risks that inherent properties of ***SoHO***, necessary for clinical ***effectiveness***, might be 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 39(2), point (b)(viii);

(b) gathering evidence of ***effectiveness*** as referred to in Article 39(2), point (d), when needed.

8. In the procedures referred to in paragraph 1 of this Article, 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;

(b) putting in place procedures to reduce, when feasible, those elements of SoHO that stimulate an unintended immune response, as applicable;

(c) correctly distributing ***and applying SoHO*** to the correct ***SoHO*** recipients pursuant to Article 42.

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 8, by applying procedures that SoHO entities have validated as safely and effectively mitigating the risk concerned or that are demonstrated by published scientific evidence as mitigating the risk.

10. SoHO entities that distribute reproductive SoHO from third-party donation shall comply with rules established in national legislation regarding the limits to the number of offspring from medically assisted reproduction or of human applications with reproductive SoHO from a single SoHO donor, where applicable. SoHO entities shall monitor compliance with such rules via registries for reproductive SoHO donors, in accordance with the national legislation. Without prejudice to such rules, 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 shall not affect Member States' rules concerning limits on the cross-border distribution of reproductive SoHO.

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

12. SoHO entities shall not:

(a) apply SoHO preparations to ***SoHO*** recipients without proven benefit, except in the context of:

(i) ***a clinical-outcome monitoring plan approved by their SoHO competent authority pursuant to Article 19(2), point (d);***

(ii) ***an individual treatment attempt with respect to the treating physician's therapeutic decision pursuant to Article 19(11); or***

(iii) a health emergency situation pursuant to Article ***65***;

(b) apply SoHO preparations to SoHO recipients unnecessarily; ***SoHO entities shall make optimal use of SoHO, taking into account therapeutic alternatives, and following the most up-to-date 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***;***

(d) distribute or apply allogeneic SoHO for purposes other than the prevention or treatment of a medical condition, including through reconstructive surgery, or for medically assisted reproduction.

13. 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 the SoHO donor, in the case of donation from a living SoHO donor or, where applicable, with any persons granting consent on their behalf; or

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

In the case of donation from a living SoHO donor, the interview referred to in the first subparagraph, point (a), of this paragraph may also include any part of the interview conducted as part of the evaluation referred to in Article 53(1), point (e). For living SoHO donors that donate repeatedly, the interviews referred to in the first sub***paragraph, point (a), of this paragraph*** 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 Article 53(1), points (d) and (e), and Article 53(2).***

▌

14. SoHO entities shall document the results of ***SoHO*** donor eligibility verification as 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.

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

15. 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 human 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 human application of ***SoHO*** or any ***serious*** genetic conditions in offspring ***from*** medically assisted reproduction with third-party donation, ***as referred to in*** Article 44(2).

16. The Commission is empowered to adopt delegated acts in accordance with Article 77 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***.

17. Where, in the case of risk to SoHO recipients and offspring from medically assisted reproduction arising from inadequate levels of quality and safety 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 protection of ***SoHO*** recipients and offspring from medically assisted reproduction

1. When the Commission ▌ deems it necessary to establish binding rules on the implementation of a particular standard, or elements thereof, 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 setting out particular procedures to be 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 the health of the ***SoHO*** recipient or of the offspring from medically assisted reproduction, 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 thereof, concerning protection of SoHO recipients and offspring from medically assisted reproduction as referred to in*** Article ***58***.

4. For those standards, or elements thereof, concerning protection of ***SoHO*** recipients and offspring from medically assisted reproduction 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 protection of ***SoHO*** recipients and offspring from medically assisted reproduction other than from transmission of communicable disease ▌;

(b) other guidelines***, adopted by Member States, as*** referred to in ***Article 27(6),*** point ***(b)***;

(c) ***other*** guidelines ***or*** technical ***methods, applied in specific circumstances, as referred to in Article 27(6), point (c)***.

5. In the cases referred to in paragraph 4, point (a), of this Article, for the purposes of Article 28 in conjunction with Article 27, 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), of this Article.

6. In the cases referred to in paragraph 4, point (b), of this Article, for the purposes of Article 28 in conjunction with Article 27, 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), of this Article***.

7. In the cases referred to in paragraph 4, point (c), of this Article, for the purposes of Article 28 in conjunction with Article 27, SoHO entities shall ***provide during inspection a justification to their SoHO competent authorities, for each specific standard, or element thereof, that the other guidelines are adequate to achieve the level of quality and safety set out in that standard. That 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), of this Article.***

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 ***49, for SoHO release*** to ensure that the standards, or elements thereof, 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 granted in accordance with this Regulation have been complied with.

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

Article 61

Exceptional release

1. The physician referred to in Article ***50*** may authorise ***a releasing officer in a SoHO establishment*** referred to in Article ***49***, to release a certain SoHO preparation ***for distribution and*** for human application to ***an intended SoHO*** recipient even 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 26(6),*** provided that the ***potential benefit for the SoHO recipient outweighs the risks and that no alternative is available. The exceptional release condition*** shall be ***explicitly indicated on the label or in the documentation accompanying the released SoHO preparation***.

2. Exceptional release referred to in paragraph 1 of this Article shall 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 of, and agreement to, any deviation from this Regulation. The physician referred to in Article 50 shall document the agreement together with a benefit-risk assessment. In such circumstances, the intended SoHO recipient, or person granting consent on their behalf, shall be informed of the exceptional release and shall be required to give consent in accordance with national legislation prior to the human application of SoHO.

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

3. ***Exceptional release, as referred to in paragraph 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, and agreement to, any deviation from this Regulation.***

4. ***Exceptional release, as referred to in paragraph 1 of this Article, may also be authorised in the case of certain SoHO to be used for the manufacture of a product regulated by 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 Article 58 or 59 and on the basis of a documented request from the manufacturer, where such a request includes a confirmation of full knowledge of, and agreement to, any deviation from this Regulation.***

CHAPTER VIII

SUPPLY CONTINUITY

Article 62

Critical SoHO supply sufficiency

1. Member States shall, within their territories and in collaboration with SoHO national authorities, SoHO competent authorities and SoHO entities, each within their respective competence, consider all reasonable efforts for achieving a sufficient, adequate and resilient supply of critical SoHO with a view 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 ensuring a broad SoHO donor-base and SoHO donor-base resilience built on the standards concerning voluntary and unpaid donation in accordance with Article 54;

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

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

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

Accordingly, 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 able, in the event of shortages or upon request, to communicate such information to their SoHO competent authorities.

SoHO competent authorities shall, in turn, establish appropriate mechanisms to receive such information referred to in the first subparagraph and shall be able to get an overview of the availability of critical SoHO in their territories, when needed.

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

Article 63

▌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 is*** likely to present, a serious risk to human health.

2. 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 with Directive (EU) 2022/2557 of the European Parliament and of the Council[24].

▌

[24] ***Directive (EU) 2022/2557 of the European Parliament and of the Council of 14 December 2022 on the resilience of critical entities and repealing Council Directive 2008/114/EC (OJ L 333, 27.12.2022, p. 164).***

3. Member States shall ***draw up*** the plans referred to in paragraph 1 of this Article, ***setting out 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***;

(c) a consolidated national overview of critical SoHO entity emergency plans referred to in Article 67;

(d) the powers and responsibilities of ***SoHO*** competent authorities ***in situations of emergency as referred to in paragraph 1 of this Article***;

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

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

(g) a procedure for the assessment and authorisation, ***in the context of a health emergency situation and in accordance with Article 65***, of requests from SoHO entities for derogations ***from the obligation to have a SoHO preparation authorisation pursuant to Article 38(1);***

(h) a mechanism to ensure that in a health emergency situation, critical SoHO are prioritised according to specific medical needs.

▌

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

5. 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 4 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.

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

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

Article 64

Supply alerts for critical SoHO

1. Critical SoHO entities shall***,*** without undue delay***, send*** a SoHO supply alert to their ***SoHO*** competent authorities in the event of ▌ significant ***shortages of supply of critical SoHO***, indicating the underlying ***reasons***, the expected impact on ***recipients*** and any mitigating actions taken***,*** including in relation to possible alternative supply channels if appropriate.

Shortages shall be considered significant when***:***

(a) the human application of critical SoHO or the distribution of critical SoHO for the manufacture of products regulated by other Union legislation, as referred to in Article 2(6), 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 a SoHO supply alert referred to in paragraph 1 of this Article shall:

(a) communicate that 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 the national SoHO emergency plans referred to in Article 63.

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 as referred to in Article 63(3), point (e).

Article 65

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

1. By way of derogation from Article 19, ***SoHO*** competent authorities may permit, at the request of a SoHO entity ***as referred to in Article 38(3) and*** duly justified by a health emergency situation, the distribution, or preparation for immediate human application, of SoHO preparations within their territory even if the procedures referred to in Article 19 have not been carried out, provided that***:***

   (a) the human application 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 considering the requirements of this Regulation or the available data indicate a positive benefit-risk assessment; and

   (c) the SoHO preparation is for immediate human application to a defined group of SoHO recipients, who have no therapeutic alternative, the treatment cannot be postponed, 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 human application of that SoHO preparation, in accordance with national legislation, prior to the human application itself.

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

(a) indicate the period of time for which the ***permission 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 39 and collect retrospectively data on the human application of the SoHO preparation during the health emergency situation;***

(c) inform the SoHO national authority of the ***permission referred to in paragraph 1, provided for the SoHO preparation concerned.***

3. ▌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 human application, of SoHO preparations in accordance with paragraph 1**.**

4. 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 permission within its territory before the distribution takes place.***

Article 66

▌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, in particular 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 and 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 provide reasons for the measures taken.

Article 67

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 63.

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

CHAPTER IX
SoHO COORDINATION BOARD

Article 68
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 of the delegated and implementing acts adopted pursuant thereto, and to support them in that coordination, as well as to facilitate cooperation with stakeholders in that regard.

2. Each Member State shall appoint two permanent members and two alternates representing the SoHO national authority and, where the Member State chooses so, he Ministry of Health ***or other relevant authorities***.

The SoHO national authority may nominate members from other ***SoHO*** competent authorities. Those members shall ensure that the views and suggestions they express 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 observer ***status***.

3. Member States shall submit the names and affiliation of their nominated members ***and alternates, together with the corresponding declaration of interests for any member and alternate, stating the absence of any financial or other interest, to the Commission. The Commission shall make publicly available*** on the EU SoHO Platform ***the membership list indicating the name, the institution of origin and the declaration of interests of each nominated member and alternate***.

4. The Commission shall make the rules of procedures of the SCB, the agenda and the summary minutes of each meeting, as well as the best practices documented and published by the SCB, as referred to in Article 74(3), point (d), of this Regulation, publicly available on the EU SoHO Platform, provided that such publication does not undermine the protection of any public or private interest, as referred to in Article 4 of Regulation (EC) No 1049/2001 of the European Parliament and of the Council[25].

5. The representative of 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 of the SCB.***

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

7. The SCB shall deliberate by seeking to achieve 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.

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[25] ***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).***

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

(a) scheduling of meetings;

(b) election of the SoHO national authority co-chairing the meetings of the SCB and the duration of this mandate;

(c) ***deliberation*** and voting***, as well as timeframes for issuing opinions, taking into account the complexity of the file, the available evidence or other relevant factors***;

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

(e) ***submission of requests*** for advice to the SCB, and for other communications ***to*** the SCB;

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

(g) delegation of ▌ tasks to working groups, including on vigilance, inspection, and traceability, and on the applicability of this Regulation;

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

(i) invitation of experts to take part in the work of the SCB working groups and 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;

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

(k) declarations regarding conflict of interests of ***SCB members, alternates, observers and*** invited experts;

(l) establishment of working groups, including their composition and rules of procedure, and the delegation of ad-hoc tasks.

9. 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 69

Tasks of the SoHO Coordination Board

1. The SCB shall assist ***SoHO*** competent authorities regarding ***the coordinated*** implementation of this Regulation and of the implementing and delegated acts adopted pursuant to it, by:

(a) preparing opinions***,*** at the request of ***SoHO*** competent authorities***, submitted via their SoHO national authority,*** in accordance with Article 13(3), first subparagraph, on the regulatory status under this Regulation of a substance, product or activity and ***including such*** opinions ***in the SoHO*** compendium;

(b) drawing up, by … [1 year from the date of entry into force of this Regulation], a list of the existing substances, products or activities for which an opinion on the regulatory status under this Regulation is not available but is needed to avoid risks to the safety of SoHO donors, recipients or offspring from medically assisted reproduction, or risks of a compromised access of recipients to safe and effective treatments, making it publicly available on the EU SoHO Platform, and subsequently updating that list at its discretion;

(c) initiating at Union level, when preparing the opinions referred to in point (a) of this paragraph, a consultation with equivalent advisory bodies established under other relevant Union legislation in accordance with Article 13(3), second subparagraph, and including in the SoHO compendium the opinions concerning the Union legislation to be applied in cases where there is agreement with the equivalent advisory bodies;

(d) ***documenting and publishing*** best practices on the implementation of ▌SoHO supervisory activities ▌on the EU SoHO Platform;

(e) recording information notified in accordance with Article 13(4), and including such information in the ***SoHO*** compendium;

(f) setting indicative criteria for 'critical SoHO' and for 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;

(g) documenting practices followed by Member States to establish the conditions for compensation as referred to in Article 54(2);

(h) providing assistance and advice for the cooperation between SoHO competent authorities and other competent authorities, with a view to ensuring coherent oversight where the regulatory status of SoHO changes, as provided for in Article 13(6);

(i) providing advice on the minimum evidence necessary for the authorisation of a particular SoHO preparation, as referred to in Article 20(4), point (e);

(j) 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***, as well as with the European Medicines Agency on authorisations and supervisory activities concerning the implementation of the PMF certification pursuant to Directive 2001/83/EC, to support the harmonised implementation of standards and technical guidelines;

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

(l) providing advice to the Commission on the functional specifications of the EU SoHO Platform;

(m) in cooperation with the Commission, and, where appropriate, with the Advisory Committee on public health emergencies established pursuant to Article 24 of Regulation (EU) 2022/2371, supporting a coordinated approach to ensure the implementation of the national SoHO 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 63(7) of this Regulation;

(n) providing assistance in other matters related to the coordination ***or the implementation of this Regulation***.

2. The Commission may adopt implementing acts setting out criteria and procedures for the consultation of advisory ***bodies*** established under other relevant Union legislation ***in relation to 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 70

Union training and exchange of SoHO competent authorities' personnel

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

▌

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 SoHO.

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 ***8***.

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 of this Article, with a view to facilitating joint activities, in particular those referred to in Articles 22, 29, and ***71***. The Commission shall make this list available to the ***SoHO national authorities***.

Article 71

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 of this Article, the Commission ▌ shall consult the relevant best practices documented and published by the SCB, as referred to in Article 69(1), point (d), on ▌ SoHO supervisory activities ▌ .

4. ▌The Commission***,*** in carrying out the controls referred to in paragraph 1 of this Article***, may be supported by*** experts from the ***SoHO competent authorities selected***, whenever possible***,*** from the list referred to in Article 70(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 ***SoHO national authority*** concerned 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*** efficient and effective implementation of this Regulation, ***and in particular 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 70(1) and programmes for the exchange of SoHO competent authorities' personnel referred to in Article 70(4)***;

(ii) where ***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;***

(d) facilitating the cooperation between the SCB and advisory bodies established by other Union legislation referred to in Article 2(6), in particular through the organisation of joint meetings on the experience acquired with the application of Article 69(1), point (c), and aiming for 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;

(e) 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[26], for the reform of national or regional SoHO supply supervision, provided those reforms aim to achieve compliance with this Regulation.

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

[26] 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).

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*** platform to facilitate efficient and effective exchange of information concerning SoHO activities in the Union, as provided for in this Regulation ***(the 'EU SoHO Platform')***.

▌

2. 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.

▌

3. 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 shall, where appropriate and in cooperation with their SoHO national authority, 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 serious adverse reaction or serious adverse event, 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 SoHO rapid alerts related to communicable diseases, where applicable;

(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.

3. 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) approved SoHO clinical studies and ***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 documented and published 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 protection of SoHO donors, SoHO recipients and offspring from medically assisted reproduction;

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

(h) the SoHO compendium;

(i) the list of the existing substances, products or activities for which an opinion on the regulatory status under this Regulation is not available and is needed as referred to in Article 69(1), point (b);

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

(k) 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 referred to in Article 4 of Regulation (EC) No 1049/2001;

(l) the list of SoHO national authorities.

4. ***By ... [1 year from the entry into force of this 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, 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 publicly available 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 publicly available, 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 publicly available 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***;***

(d) the information or data made publicly available does not unnecessarily undermine the protection of legal rights of the SoHO entity or any other natural or legal person;

(e) the information or data made publicly available 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 publicly available, ***without prejudice to national legislation,*** provided that the ***conditions laid down in paragraph 5, point (c), are met.***

Article 76

Data protection

1. Personal data required for the application of Article 5(5), Article ***9(4)***, Articles 33 and 34, Article ***35(3),*** points ***(a) and (b)***, Article ***36(3)***, Article ***39(2), point*** (***a***), ***Article 46(2),*** Article 64 and Article ***68(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 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 33, 34, 39***, 42*** and 44, Article 53(1), points (e) and (f), Article 53(3), and Article 58(13), (14) and (15), shall only be processed for the purpose of ensuring quality and safety of SoHO 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 of this Regulation and the processing of personal data***, including health data,*** that might result from that activity, the Commission shall be regarded as a 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 to supplement 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 of this Article.

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 Article 26(7), Article 47(4), Article 53(5), Article 58(16) ▌ and Article 76(8) shall be conferred on the Commission for an indeterminate period of time from … [date of entry into force of this Regulation].

3. The delegation of power referred to in Article 26(7), Article 47(4), Article 53(5), Article 58(16) ▌ and Article 76(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in 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 Article 26(7), Article 47(4), Article 53(5), Article 58(16) or Article 76(8) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of 2 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 2 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 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 Article 5(4), third subparagraph, 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 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 … [***5*** years from 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 in accordance with Article 5(1) of Directive 2002/98/EC and tissue establishments designated, authorised, accredited or licensed in accordance with Article 6(1) of Directive 2004/23/EC before ... [the date of application of this Regulation referred to in Article 87(1), second subparagraph, 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 in accordance with Article ***9(1)*** of Directive 2004/23/EC before ... [the date of application of this Regulation referred to in Article 87(1), second subparagraph, 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 of this Article, ***SoHO*** competent authorities shall:

   (a) verify whether those establishments fall within the definition of a SoHO establishment as set out in Article 3, point (35);

   (b) submit to the EU SoHO Platform the information referred to in Article ***35(3)***, points (a) and (d), and the information regarding the registration and authorisation status according to the verification referred to in point (a) of this paragraph.

4. For tissue establishments referred to in ***paragraphs 1 and 2 of this Article***, the Commission shall:

(a) verify whether those establishments fall within the definition of a SoHO establishment as set out in Article 3, point (35);

(b) transfer to the EU SoHO Platform the relevant information from the EU Tissue Establishment Compendium of the EU Coding Platform laid down in Commission Directive 2006/86/EC[27], including the information regarding the registration and authorisation status according to the verification referred to in point (a) of this paragraph ▌;

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

[27] Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (OJ L 294, 25.10.2006, p. 32).

5. ***SoHO*** competent authorities shall inform those establishments not falling within the definition of a 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 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 in accordance with Article 6(2) of Directive 2004/23/EC before ... [the date of application of this Regulation referred to in Article 87(1), second subparagraph, 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 in accordance with 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 … [▌ the date of ***application*** of this Regulation referred to in Article 87(1), second subparagraph, of this Regulation], or that were otherwise designated, authorised, accredited or licensed under national legislation before that date, shall be deemed to be authorised as the corresponding SoHO preparations in accordance with ▌ this Regulation.

3. ***SoHO*** competent authorities shall submit the information about the SoHO preparations referred to in paragraphs 1 and 2 to the EU SoHO Platform, and link those ***SoHO preparations, deemed to be authorised pursuant to those paragraphs,*** 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 83

Transitional provisions concerning SoHO not addressed explicitly in Directive 2002/98/EC or 2004/23/EC

Entities carrying out one or more of the SoHO activities referred to in Article 2(1), points (c)(i), (iv) to (ix) and (xii), of this Regulation, in respect of SoHO not addressed explicitly in Directive 2002/98/EC or 2004/23/EC, before … [the date of application of this Regulation referred to in Article 87(1), second subparagraph, of this Regulation***] shall be allowed to continue such activities until ... [1 year from the date of application of this Regulation*** referred to in Article 87(1), second subparagraph, of this Regulation***], without applying this Regulation, except for the following requirements:***

(a) registration as SoHO entities pursuant to Article 35 of this Regulation;

(b) application for any and all relevant SoHO preparation authorisations, where required pursuant to Article 38 of this Regulation;

(c) application for a SoHO establishment authorisation, where required pursuant to Article 45 of this Regulation;

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

Such SoHO entities shall comply with the requirements referred to in the first paragraph, points (b) and (c), by … [3 months from the date of application of this Regulation referred to in Article 87(1), second subparagraph***].***

Article 84

Status of SoHO in storage or distributed before the application of this Regulation

1. ***SoHO*** already ***in storage*** before … [the date of application of this Regulation referred to in Article 87(1), second subparagraph] shall not be subject to the relevant obligations provided for under this Regulation, provided that those ***SoHO are released and distributed before …*** [***2 years*** from the date of application of this Regulation referred to in Article 87(1), second subparagraph], ▌under the condition that those SoHO were fully compliant with the applicable Union legislation and national law in force at the time when those SoHO were ***collected***.

2. SoHO which have been distributed before … [the date of application of this Regulation referred to in Article 87(1), second subparagraph] 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 … [the date of application of this Regulation referred to in Article 87(1), second subparagraph], and ***not distributed as referred to in paragraph 1 of this Article, 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 SoHO shall be subject to that Article from that date.

CHAPTER XIV
FINAL PROVISIONS

Article 85
Repeals

Directives 2002/98/EC and 2004/23/EC are repealed with effect from … [3 years from the date of entry into force of this Regulation].

Article 86

Evaluation

The Commission shall, by … [5 years from the date of application of this Regulation referred to in Article 87(1), second subparagraph], assess the application of this Regulation, produce an evaluation report on the progress towards achievement of the objectives of this Regulation and present its 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. For the purpose of the evaluation report, 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. 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.***

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 … [***3*** years from the date of entry into force of this Regulation].

2. ***The Commission is empowered to adopt the delegated acts referred to in*** Article ***47(4), and the implementing acts referred to in Article 41(3), Article 42(7), Article 43(3), Article 48(7) and Article 74(4) from … [the date of entry into force of this Regulation].***

   Article 68 and Article 69(1), point (b), shall apply from … [1 day from the date of entry into force of this Regulation].

   Article 80, Article 81(3), (4) and (5) and Article 82(3) shall apply from … [***4*** years from 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 ..., ...

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