Council of the European Union

Brussels, 21 September 2023
(OR. en)

12955/23

Interinstitutional File:
2022/0216(COD)

LIMITE

SAN 518
CODEC 1593

WORKING DOCUMENT

From:	Presidency
To:	Delegations
No. prev. doc.:	14066/22 REV 1, 11061/23, 10846/23, 11432/23, 11823/23, 12116/23, 12118/23
Subject:	Proposal for a Regulation on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC *- Examination of the Presidency compromise text*

Delegations will find in Annex a compromise text prepared by the Presidency on the above-mentioned subject to be examined in the Working Party on Public Health on 27 and 29 September 2023.

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

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

The Presidency is presenting the text of the following Chapters together with related definitions.

In comparison to former Presidency compromise texts, some definitions have been moved and will be presented in different chapters/sections. Moreover, Article 50 has been moved to section I and is presented, with adaptations, as Article 37b.

CHAPTERS III, IV & V and related definitions organised by sections as follows:

- Section I – Registration of SoHO Entities: Recital 31, Art. 3(16), 3(24), 3(34), 3(56a), 18, 19, 37, 37a, 37b.
- Section V – Activity Data: Art. 3(60), 33, 44.
- Section VI – Traceability: Art. 3 (47), 3(48), 34, 45, 46.
- Section VIII – Vigilance: Articles 3(26), 3(27), 3(27a), 3(28), 3(28a), 3(29), 3(49), 3(50), 3(51), 3(52), 3(53), 3(54), 35, 47, 36.

ANNEX

Section I – Registration of SoHO Entities: Recital 31, Art. 3(16), 3(24), 3(34), 3(56a), 18, 19, 37, 37a, 37b.

Recital

(31) A broad range of public and private organisations influence the safety, quality and effic**tivenessacy** of SoHOs, even if they do not maintain banks of those SoHOs. Many organisations carry out a single SoHO activity, such as collection or donor testing on behalf of one or many organisations that maintain banks of SoHOs. The SoHO entity concept includes this broad range of organisations, from donor registries to physicians that apply SoHOs to recipients or use SoHO processing devices at the recipient's bedside. The registration of all such SoHO entities should ensure that **SoHO** competent authorities have a clear overview of the field and its scale and can take enforcement action when deemed necessary. A SoHO entity registration should refer to the legal entity, regardless of the number of physical sites associated with the entity.

Article 3

Definitions

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

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

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

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

CHAPTER III

SoHO SUPERVISORY ACTIVITIES

Article 18

Register of SoHO entities

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

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

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

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

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

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

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

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

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

5. The Commission may adopt implementing acts concerning the compatibility and comparability of the registers of SoHO entities for facilitating the submission to the EU SoHO Platform.

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

Article 19

Registration of SoHO entities

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAPTER IV

GENERAL OBLIGATIONS ON SOHO ENTITIES

Article 37

SoHO entity registration

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

1a. SoHO activities shall not be carried out by individuals that are not operating within a registered SoHO entity. ~~Where a natural person carries out SoHO activities within an organisation, such organisation shall be the SoHO entity.~~

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

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

(b) name and contact details of the person responsible for communication with the relevant SoHO competent authority;

(c) a declaration that the SoHO entity ~~complies with the obligations and requirements on SoHO entities set out in this Regulation and that it~~ will maintain a quality management system appropriate to its activities;

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

(e) a list of the SoHOs and its activities, as listed in Article 2(1a), that the SoHO entity is carrying out;

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

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

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

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

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

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

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

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

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

Article 37a

~~SoHO Entity~~ Responsible Person

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

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

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

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

*Article ~~50~~ **37b**[1]*

Quality management system

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

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

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

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

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

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

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

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

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

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

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

(f) internal audits;

(g) management of contracted third parties;

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

(ha) complaints;

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

(hc) continuity planning.

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

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

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

Section V – Activity Data: Article 3(60), 33, 44[2]

Article 3

Definitions

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

CHAPTER III

SoHO SUPERVISORY ACTIVITIES

Article 33

Activity data extraction, submission and publication

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

[2] Definition 31 will be presented in Chapter XI

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

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

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

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

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

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

CHAPTER IV

GENERAL OBLIGATIONS ON SOHO ENTITIES

Article 44

Activity data collection and reporting

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

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

   (b) collection;

   (c) distribution;

   (d) import;

   (e) export;

   (f) human application.

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

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

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

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

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

Section VI – Traceability: Art. 3(47), 3(48), 34, 45, 46[3]

Article 3

Definitions

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

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

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

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

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

[3] Definition (63) will be presented in Chapter VII.

CHAPTER III

SoHO SUPERVISORY ACTIVITIES

Article 34

Traceability and coding

1. **SoHO C**competent authorities shall verify that SoHO entities have appropriate procedures in place to ensure traceability and coding of SoHOs as referred to in Article 45**, including SoHOs that are released for manufacture of products regulated by other Union legislation**.

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

CHAPTER IV

GENERAL OBLIGATIONS ON SoHO ENTITIES

Article 45

Traceability and coding

1. SoHO entities shall implement a traceability system**.** in order to unmistakably link each SoHO donor to their SoHO ~~donation~~ and to all **the documents, samples, SoHO preparations and SoHO entities that are associated with that SoHO at any point.** ~~**the activities related to such SoHOs from**~~ ~~documents, samples, SoHO preparations and SoHO entities that are associated with that SoHO from the point of~~ **donor recruitment** ~~collection to human application and outcome monitoring~~ ~~**or other destinations such as manufacturing or disposal, and vice versa.**~~ ~~With regard to imported SoHOs,~~ **I**~~i~~mporting SoHO ~~entities~~ **establishments** shall ensure an equivalent level of traceability**,** ~~**with regard to imported SoHOs**~~.

2. SoHO entities ~~**or SoHO establishments collecting, importing, releasing, or**~~ distributing SoHO~~**s, as applicable,**~~ shall generate a code that contains the information included in the **requirements of the** traceability system referred to in paragraph 1. ~~**Such SoHO entities or SoHO establishments**~~ ~~They~~ **They** shall ensure that the code **generated**:

   (a) is unique within the Union;

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

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

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

3. SoHO entities shall include the codes referred to in paragraph 2**, prior to distribution,** on the labels ~~to be~~ applied to the SoHO**,** ~~or SoHO preparations prior to distribution~~, or on the documents accompanying the distributed SoHO**,** ~~or SoHO preparations~~ where it can be guaranteed that such documents will not be separated from the SoHO ~~or SoHO preparation~~ **or will be kept digitally linked to the SoHO** concerned.

4. SoHO entities ~~**or establishments, as it applies,**~~ shall use a labelling system that meets the labelling requirements set out in the relevant technical guidelines referred to in Articles 56(4) and 59(4).

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

Article 46

European coding systems

1. SoHO entities shall apply a Single European Code ('SEC') to ~~all donated~~ SoHO**s** ~~preparations~~ distributed for human application. In cases where SoHOs ~~or SoHO preparations~~ are transferred for further processing in another SoHO **entity**~~establishment entity~~ or released for manufacture of products regulated by other Union legislation **as provided for in Article 2(3)**~~, or as the starting and raw material thereof~~, **or exported to third countries**, SoHO **entities**~~establishments entities~~ shall, at least, apply **the elements of the SEC that allow the identification of** ~~the part of the SEC that allows identification of~~ the donation[4] ~~identification sequence of the SEC~~. The SEC shall **also** appear ~~also~~ on the **primary** packaging or on a label attached thereto, or on the documents referring to the SoHO where it can be ~~guaranteed~~ **ensured** that such documents accompany the SoHO concerned.

2. Paragraph 1 shall not apply to:

   (a) reproductive ~~cells~~ **SoHO** for within couple use;

   (b) blood or blood components for transfusion or for the manufacture of medicinal products~~, within each Member State~~;

   (c) SoHOs applied to a **SoHO** recipient without being stored**, when donation and application of their own SoHO are carried out in the same ~~surgical~~ procedure, without any processing. However, in the case where these SoHOs are finally stored, paragraph 1 shall apply;~~.

   (d) **SoHOs imported into the Union by derogation and authorised directly by SoHO competent authorities pursuant to Article 28(9);**~~SoHOs imported into the Union in case of emergency authorised directly by competent authorities pursuant to Article 28(9);~~

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

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

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

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

Section VIII – Vigilance: Articles 3(26), 3(27), 3(27a), 3(28), 3(28a), 3(29), 3(49), 3(50), 3(51), 3(53), 3(54), 35, 47, 36.

CHAPTER I

GENERAL PROVISIONS

Article 3

Definitions

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

(27) 'adverse **reaction**~~occurrence~~' means any incident **~~linked to any SoHO activity as listed in Article 2(1)~~ which could be reasonably associated with the quality or safety of SoHO, or its collection or application ~~of SoHO or with the quality or safety of SoHO, applied~~ to a SoHO recipient,** that caused harm to a living SoHO donor, ~~harm~~ to a SoHO recipient or to offspring from medically assisted reproduction ~~or that implied a risk of such harm~~.

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

(28) 'serious adverse **reaction**~~occurrence~~' (SA**R**~~O~~) means an adverse **reaction** ~~occurrence~~ that result**s**~~ed~~ in~~, or implied a risk of,~~ any of the following**: as described in Article [35]/[47]:**

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

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

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

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

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

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

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

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

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

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

(a) inappropriate SoHO distributioned

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

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

(d) loss of highly matched or autologous SoHOs;

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

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

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

~~[(49) 'SA**R or SAE**O notification' means the communication from a SoHO entity, a SoHO establishment or a SoHO donor or recipient to a **SoHO** competent authority, of a **confirmed or suspected** serious adverse occurrence **reaction or event** or a suspected serious adverse occurrence associated with a SoHO donation or human application;]~~

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

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

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

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

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

CHAPTER III

SoHO SUPERVISORY ACTIVITIES

Article 35

Vigilance

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAPTER IV

GENERAL OBLIGATIONS ON SOHO ENTITIES

Article 47

Vigilance and reporting

1. SoHO entities shall maintain a system for detecting, investigating and recording information concerning adverse **reactions** ~~occurrences~~ **and adverse events**, including ~~adverse~~ **those reactions** ~~occurrences~~ detected during clinical outcome monitoring ~~plans~~ **plans** as part of a SoHO preparation authorisation application as referred to in Article 41.

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

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

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

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

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

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

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

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

In such cases, the SoHO establishments receiving the communication shall be responsible for the investigation and shall report to their SoHO competent authorities when the adverse reaction or event concerned is serious. All other SoHO entities shall investigate and report serious adverse reactions or events directly to their SoHO competent authorities.

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

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

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

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

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

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

6. SoHO entities shall **communicate** ~~report~~ information concerning a SA**R or SAE** to other SoHO entities engaged in the collection, processing, testing, storage and distribution of SoHO collected from the same **SoHO** donor, or otherwise possibly affected ~~by the SAO concerned~~. They shall only report information necessary and appropriate in order to facilitate traceability and ensure quality and safety in such cases, and shall, in particular, limit the information to details necessary to take mitigating actions. **A risk assessment of the seriousness and likelihood of recurrence shall be included in the communication.** SoHO entities**, where relevant,** shall also **communicate** ~~report~~ such information to organ procurement organisations in cases where **the SoHO** ~~a~~ donor who is implicated in the SA~~O~~**R or SAE** has also donated organs **or SoHOs ~~and~~ to manufacturers ~~of~~ in cases where SoHO collected from that SoHO donor have been distributed to manufacture products regulated by other Union legislation, as referred to in Article 2(3)** ~~**from distributed SoHOs from the implicated SoHO donor**~~.

CHAPTER III

SoHO SUPERVISORY ACTIVITIES

Article 36

SoHO rapid alerts

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

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

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

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

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

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

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

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

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

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