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

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 Commission proposal (on sections not yet discussed) and new changes compared to previous versions of the compromise (made either on the Commission proposal or on the Presidency text) are in **bold and underlined** and in ~~striketrough~~ and highlighted in light grey shading.

Text marked in **bold and underlined** and in ~~striketrough~~ 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 and the related definitions:

CHAPTER II with related recitals and definition: Recitals 20-24, Article 3(35), Articles 5-17

CHAPTERS III, IV & V AND RELATED DEFINITIONS ORGANISED BY SECTIONS:

- Section II – Authorisation of SoHO Establishments: Recital 32, Art. 3(21), 3(40), 3 (56), 25, 48, 27, 49, 49a, 49b, 49c.
 - Section III – Registration of SoHO Importers: Recital 40, Art. 3(20), 3(20a), 3(67), 26, 28, 42, 43.
 - Section IV – Inspections: Recitals 25, 26, Articles 3(32), 3(36), 3(37), 3(44), 3(46), Articles 29, 30, 31, 32.
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CHAPTER II with related recitals and definition

Recital

Whereas:

- (20) **SoHO** competent authorities should be designated by the Member States for all the areas that fall within the scope of this Regulation. While Member States are best placed to identify the **SoHO** competent authority or authorities for each area, for example by geography, topic or substance, they should also be required to designate a single **SoHO** National Authority that ensures appropriately coordinated communication with other Member States' **SoHO** National competent Authorities and with the Commission, **as well as other tasks assigned in this Regulation**. The SoHO National Authority should be considered the same as the designated competent authority in Member States where only one **SoHO** competent authority is designated.
- (21) For the performance of **SoHO** supervisory activities aimed at verifying the correct application of SoHO legislation, Member States should designate **SoHO** competent authorities that act independently and impartially. It is therefore important that their function of oversight is separate and independent from the performance of SoHO activities. In particular, **SoHO** competent authorities should be free from undue political influence and from industry interference that might affect their operational impartiality.
- (22) For the performance of **SoHO** supervisory activities aimed at verifying the correct application of SoHO legislation, Member States should designate **SoHO** competent authorities that act in the public interest, are appropriately resourced and equipped, and offer guarantees of impartiality, professionalism and transparency. When infringements relate to direct health risks, and the publication of information regarding those infringements can contribute to risk mitigation and the protection of **SoHO** donors, recipients, or offspring from medically assisted reproduction **or public health**, **SoHO** competent authorities should, where necessary, be able to prioritise transparency of their enforcement activities over the protection of confidentiality of the **party one** that has infringed the Regulation.

- (23) The correct application and enforcement of the rules falling within the scope of this Regulation require an appropriate knowledge of those rules. It is therefore important that the staff performing **SoHO** supervisory activities have an appropriate professional background and are regularly trained, in accordance with their area of competence, on the obligations resulting from this Regulation.
- (24) When there is doubt about the regulatory status of a particular substance, product or activity under this Regulation, **SoHO** competent authorities should consult with the relevant authorities responsible for other relevant regulatory frameworks, namely medicinal products, medical devices, organs or food, with the aim of ensuring coherent procedures for the application of this Regulation. **SoHO c**Competent authorities should inform the SoHO Coordination Board of the outcome of their consultations. When SoHOs ~~or SoHO preparations~~ are used to manufacture products regulated under other Union legislation, ~~or as the starting and raw material thereof~~, **SoHO** competent authorities should cooperate with the relevant authorities on their territory. This cooperation should aim to reach an agreed approach for any subsequent communications between the authorities responsible for SoHO and for the other relevant sectors, as needed, regarding authorisation and monitoring of the SoHOs or ~~the product manufactured from~~ SoHOs **derived products**. It should in principle be the responsibility of the Member States to decide on a case-by-case basis on the regulatory status of a substance, product or activity. However, in order to ensure consistent decisions across all Member States with regard to borderline cases, the Commission should be empowered to, on its own initiative or at the duly substantiated request of a Member State, decide on the regulatory status of a particular substance, product or activity under this Regulation.

CHAPTER I

GENERAL PROVISIONS

Article 3

Definitions

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

CHAPTER II

COMPETENT MEMBER STATES’ SoHO COMPETENT AUTHORITIES

Article 5

Designation of SoHO ~~competent~~ competent-authorities

1. Member States shall designate the **SoHO** competent authority or authorities ~~to on to~~ which they confer responsibility for the SoHO supervisory activities ~~provided for in Chapter III~~. The ~~organisation~~ authority or ~~organisations~~ authorities designated shall be independent from any SoHO entity.
2. ~~For the same territory, a~~ A Member State may confer responsibilities for SoHO supervisory activities ~~to on to~~ more than one **SoHO** competent authority, at national, regional or local level.

3. Member States shall ensure that **SoHO** competent authorities:
- (a) have the autonomy to act and make decisions independently and impartially while respecting **the constitutional, organisational and administrative structure of the internal administrative organisational requirements determined by the Constitutions of the Member States;**
 - (b) have the necessary **legal** powers:
 - (i) to properly perform their **SoHO** supervisory activities **they have been made responsible for**, including **having** access to the premises of, and documents and samples kept by, SoHO entities and any third parties contracted by a SoHO entity;
 - (ii) to order the immediate suspension or cessation of a SoHO activity that poses immediate risk to SoHO donors, SoHO recipients, **offspring from medically assisted reproduction** or the general public;
 - (iii) ~~to take decisions on the access and re-use of personal data;~~
 - (c) have, **or have access to**, sufficient resources, operational capacity, and expertise to achieve the aims of, and fulfil their obligations under, this Regulation;
 - (d) ~~are governed by appropriate~~ **respect the are subject to appropriate** confidentiality obligations in **order to comply** ~~accordance with Article 75.~~
4. ~~Each~~ **When a** Member State **designates only one SoHO competent authority in accordance with paragraph 1, the SoHO competent authority** shall ~~designate a~~ **also be appointed as the** single SoHO National Authority. **When a Member State designates more than one SoHO competent authorities in accordance with paragraph 1, it shall appoint one SoHO National Authority among them as the SoHO National Authority, without prejudice of national law, in accordance with national law,** ~~conformity with Member States' constitutional requirements,~~ **The SoHO National Authority shall be** responsible for coordinating exchanges with the Commission and with other Member States' SoHO National Authorities **the activities as set out referred to in Article 9(1a).**

The appointment of one SoHO National Authority should not preclude from delegating certain activities to other SoHO competent authorities, in particular, when there is a need for a rapid communication of information related to serious adverse events or serious adverse reactions that have implications for more than one Member State.

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

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

(b) the names and contact details of their SoHO National Authority referred to in paragraph 4;

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

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

Article 6

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

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

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

Article 7

Independence and impartiality

1. **When performing their tasks and exercising their powers, €SoHO** competent authorities shall act independently **and impartially**, in the public interest and free from any external influence.
2. **SoHO c**Competent authorities shall ensure that ~~their personnel~~ **performing SoHO supervisory activities** have no ~~direct or indirect economic, financial or personal~~ **other** interest that might be considered prejudicial to their independence and, in particular, that they are not in a situation that may, directly or indirectly, affect the impartiality of their professional conduct.
3. ~~Paragraphs 1 and 2 shall also apply to delegated bodies.~~

Article 8

Transparency

1. ~~Without prejudice to Article 75,~~ **SoHO** competent authorities shall:
 - (a) carry out their **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**
In particular, and they shall
 - (b) make **any enforcement decision taken, in particular according to Articles 19(1d), 21(6)–(8), 27(3)–(5), 28(5)–(7) or 29(9) point (g), and the reasons for it,** accessible and clear to the public ~~decisions taken in cases where:~~
 - (i) a SoHO entity **does not comply with the provisions** ~~has failed to comply with any of its obligations under of this Regulation, and/or~~

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

~~(c) By derogation of point (a) decisions concerning SoHO entities carrying out SoHO activities for the purpose of public security, defence or military matters shall not be subject to publication requirements provided for in this Regulation.~~

2. Paragraph 1 shall not affect **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 ~~in their internal rules.~~
4. ~~Paragraphs 1, 2 and 3 shall also apply to delegated bodies.~~

Article 9

General responsibilities and obligations

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

1a. The SoHO National Authority appointed in accordance with Article 5(4) shall be responsible for coordinating the information exchanges with the Commission and, with other Member States' SoHO National Authorities, as well as other tasks, and, between authorities in the Member State, provided for in Articles 4(2), 13(1), (2) and (4), 14(1), (2) and (3), 18(1) and, (2) and (4), 28(3), 35(10a) and (11), 33(1), 36(2), 63(2) and (3), 64(2) and (3), as well as for carrying out the tasks set out in articles 18(1), (2) and (4), 35(10) and (11), and 67(2). The SoHO National Authority may also be responsible for the tasks provided for in Article 13(1).

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

- (a) **have, or have access to,** a sufficient number of suitably qualified **and experienced** personnel to carry out the **SoHO** supervisory ~~functions~~ **activities they have been made responsible for** ~~provided for in this Regulation,~~ **efficiently and effectively**;
- (aa) have procedures in place to ensure compliance with the confidentiality obligations and maintain professional secrecy set out in Article 75;**
- (b) ~~procedures to~~ ensure the independence, impartiality, effectiveness, quality, suitability for purpose and consistency of their SoHO supervisory activities;
- (c) **have** appropriate and properly maintained ~~facilities~~ **premises** and equipment to ensure that **the** personnel can perform their SoHO supervisory activities efficiently and effectively;
- (d) **have** a quality management system **or standardised documented procedures in place** for their SoHO supervisory activities **they have been made responsible for** that includes a plan for continuity of their activities in case of ~~exceptional circumstances~~ **crisis situations that impede the normal performance of their tasks**;
- (da) develop and implement, or provide access to, training programmes to ensure that personnel performing SoHO supervisory activities receive, for their area of competence, appropriate training;**
- (db) provide opportunities for their personnel to participate in the Union training referred to in Article 69 where such training is available and relevant.**

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

Article 10

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

**-1a. A Member States may empower~~able~~ a SoHO competent authority made responsible
for any of the SoHO supervisory activities~~y~~ as setreferred to-out in Articles 22, 23, 29,
30, 31, 33(1), 34(1), 35(1a),-(2), (3) point (a), (4), (5), (6), (6a), (7),-(8), (9) and, (10) point
(a) and (12)-to delegate that SoHO supervisory activity to one or more otherdelegated
bodies, provided.**

**Member States shall ensure that the delegated bodies have~~has~~ the legal powers needed
to effectively perform the activities delegated to itthem and to fulfil the requirements in
Article 11.**

1. ~~Member States and~~ **SoHO C**ompetent authorities that delegate ~~certain~~ SoHO supervisory activities **in accordance with paragraph -1a** to a delegated body referred to in Article 6 shall ~~conclude~~ **have in place** a written **agreement-arrangement** ~~agreement on the delegation~~ **with that delegated body.**

~~2.1~~ **The delegating SOHO c**ompetent authorities shall ensure that ~~the~~ **such a written** **agreement-arrangement** ~~agreement referred to in paragraph 1~~ includes **at least** the following:

- (a) a precise description of the SoHO supervisory activities that the delegated body is expected to perform, and the conditions under which those activities are expected to be performed;
- (b) the conditions ~~to be met by~~ **that** the delegated body, ~~including that the delegated body:~~
 - (i) ~~has the expertise, equipment and infrastructure required to perform those SoHO supervisory activities delegated to it;~~

¹ **Proposal to merge 1 and 2 into one paragraph.**

- ~~(ii) — has a sufficient number of suitably qualified and experienced staff;~~
- ~~(iii) — participates in certification or other schemes at Union level, when available, to ensure the uniform application of principles of good practices required for their relevant sector;~~
- ~~(iv) — has sufficient powers to perform the SoHO supervisory activities delegated to it;~~
- (c) a precise description of **the** arrangements ensuring an efficient and effective coordination between the delegating **SoHO** competent authorities and the delegated body;
- (d) provisions for **on** the fulfilment of the obligations of the delegated body as set out in Articles 11 and 12;-

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

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

Article 11

Obligations of the delegated bodies

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

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

(-ab) carry out the SoHO supervisory activities delegated to them in a transparent manner;

- (a) ~~communicate to~~**inform** the delegating **SoHO** competent authorities, on a regular basis and whenever those **delegating SoHO** competent authorities so request, **of** the outcome of the SoHO supervisory activities performed by them;
- (b) immediately inform the delegating **SoHO** competent authorities whenever the outcome of the delegated SoHO supervisory activities indicates non-compliance or points to the likelihood of non-compliance, unless specific **written** arrangements established between those **delegating SoHO** competent authorities and the delegated bodies provide otherwise; and
- (c) **fully** cooperate with the delegating **SoHO** competent authorities, including by providing access to their premises and facilities **and information, including IT systems documentation.**

2. Delegated bodies are subject to the provisions of Articles 7, 15 and 75 ~~shall apply to delegated bodies and in full and, where relevant, to the provisions of Articles 24 and 32 shall apply insofar as they are relevant for the delegated activities.~~

Article 12

Obligations of the delegating **SoHO competent authorities**

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

- (a) ~~organise~~**conduct regularly** audits or inspections of such **the delegated** bodies, as necessary taking into account participation of such **the delegated** bodies in certification or other schemes referred to in Article ~~10(12)~~, point (b)(iii). **The interval between such audits shall be determined by the delegating SoHO competent authority, taking into account the participation of such the delegated bodies in certification or other schemes referred to in Article 10(12), point (b)(iii), as well as the scope and the impact of the delegated SoHO supervisory activities on the quality and safety of SoHOs;**

- (b) fully or partly withdraw the delegation without delay when necessary, and in particular in cases where:
- (i) there is evidence that ~~such~~the delegated bodies are failing to properly perform the SoHO supervisory activities delegated to them;
 - (ii) the delegated bodies have failed to take appropriate and timely action to remedy ~~the~~ such shortcomings performance failures identified; or
 - (iii) there is evidence that the independence or impartiality of the delegated bodies has ~~been shown to be~~en compromised.

Article 13

**Communication and coordination between ~~SoHO~~SoHO competent authorities ~~in the SoHO~~
sector**

1. Where more than one authority is competent to perform SoHO supervisory activities in a Member State pursuant to Article 5(2), the ~~Member State~~ Member State or the SoHO National Authority shall ensure efficient and effective coordination between all ~~SoHO~~the SoHO competent authorities ~~involved~~concerned in order to ensure guarantee consistency and effectiveness of the SoHO supervisory activities ~~as set by this Regulation~~ performed on its territory.
2. Within a Member State, ~~€~~SoHO competent authorities shall cooperate with each other ~~and with the Commission~~. They shall communicate information to each other and, in particular, to the SoHO National Authority as necessary for the effective implementation of the SoHO supervisory ~~functions~~ activities ~~provided for in this Regulation,~~ including the activities of the the SoHO National Authority as referred to in Article 9(1a).

3. In cases where a SoHO competent authority~~ies provide~~ issues an opinion² to a SoHO entity~~;~~
~~upon its request pursuant to Article 40(2),~~ on the applicability of this Regulation to a
particular substance, product or activity ~~within~~ on their its territory, ~~that~~ these SoHO
competent authority~~ies~~ shall notify the SoHO National Authority of that opinion² issued,
which, in turn, shall notify the ~~SoHO Coordination Board ('SCB')³ of the opinion given to the~~
SoHO entity.
4. Following a ~~reasoned~~ duly substantiated request from a ~~competent~~ the SoHO National
Authority of another Member State, the ~~competent~~ SoHO National Authority shall without
undue delay, and ensuring consideration of aspects of confidentiality as set out in Article
75, inform the requesting ~~competent~~ SoHO National Authority of the outcome of the SoHO
supervisory activities concerning a SoHO entity on its territory, and, as necessary and
proportionate, provide the requesting SoHO National Authority with the relevant
documentation related to activities ~~records~~ referred to in Articles 29 and 30.

~~4a. By derogation of paragraph 4, the SoHO National Authority shall not communicate to
other SoHO National Authorities the outcome of SoHO supervisory activities concerning
SoHO entities carrying out SoHO activities for the purpose of public security, defence
or military matters.~~

Article 14

~~Obligations to~~ eConsultation and cooperation with authorities of other regulatory sectors

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

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

³ In case the SoHO Coordination Board would be introduced for the first time, the full name should be kept.

1. In all cases where questions arise as to the regulatory status of a substance, product or activity, the SoHO competent authorities in the SoHO sector shall, in addition to what is set out in Article 13(2) of this Regulation, consult, via the SoHO National Authority, with the competent authorities established in other relevant Union legislation referred to in Article 2(3) paragraph -1a, as appropriate relevant, with a view to reaching a consensus decision on the regulatory status. In such cases, SoHO competent authorities in the SoHO sector involved in the consultation shall also consult the SoHO compendium referred to Article 3 point (33), and consider and take into account any relevant regulatory status decision and take into account any relevant opinion included therein the SoHO compendium.
2. In the course of the consultation referred to in paragraph 1, the SoHO competent authorities in the SoHO sector involved in such consultation may also, via the SoHO National Authority, submit a request to the SCB for ~~its~~ an opinion on the regulatory status of the substance, product or activity under this Regulation. The SoHO competent authorities and shall do so in all cases where ~~the competent authorities, after~~ following the consultations referred to in paragraph 1, have not lead to they are not in a position to where take a decision in that respect on the regulatory status of such substance, product or activity can be taken in the Member State concerned. The SoHO competent authorities in the SoHO sector involved in the consultation shall take into account the opinion issued by the SCB following such a request.

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

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

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

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

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

5. ~~For~~**In the case of** SoHOs ~~that are intended to be subsequently used to manufacture products under other Union legislation, or as the starting and raw material thereof, as referred to in Article 2(3); or~~ **for** SoHOs ~~that are intended to be combined with medical devices, as referred to in Article 2(4), the~~ **SoHO** competent authority **in the SoHO sector** shall cooperate with the authorities responsible for the supervisory activities under ~~other~~**the** relevant Union legislation **as referred to in Article 2(3)**, with a view to ensuring coherent oversight. During ~~that~~**the** process, the **SoHO** competent authorities may seek the assistance **and advice** of the SCB **concerning, inter alia, good cooperation practices that ensure coherent oversight when SoHOs change regulatory status.**
6. The consultation and cooperation referred to in paragraphs 1, 2 and 5 may also be initiated on the basis of a request **from a SoHO entity** for advice **an opinion**²~~from a SoHO entity, as referred to in Article 40.~~

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

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

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

Article 15

Right of appeal

1. Where decisions are taken by **SoHO** competent authorities concerning natural or legal persons, those decisions shall be subject to such persons' right of appeal in accordance with national legislation.
2. The right of appeal shall not affect the obligation of **SoHO** competent authorities to take prompt action to eliminate or contain the risks to human health in accordance with this Regulation.
3. ~~Paragraphs 1 and 2 shall also apply to delegated bodies.~~

Article 16

General obligations concerning the personnel of competent authorities

1. ~~Competent authorities shall:~~

- ~~(a) have, or have access to, a sufficient number of personnel so that SoHO supervisory activities can be performed efficiently and effectively;~~
- ~~(b) ensure that the personnel performing SoHO supervisory activities are suitably qualified and experienced;~~
- ~~(c) have procedures or arrangements in place to ensure that personnel performing SoHO supervisory activities are free from any conflict of interest;~~
- ~~(d) have procedures in place to ensure confidentiality and maintain professional secrecy.~~

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

- ~~(a) declare in writing any direct or indirect interests referred to in Article 7(2) and update that declaration yearly and whenever the declared information changes or any new interest arises;~~
- ~~(b) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and in a consistent manner;~~
- ~~(c) keep up to date in their area of competence and receive regular additional training as necessary;~~
- ~~(d) participate in training in the subject matter and on the obligations of competent authorities resulting from this Regulation, as referred to in paragraph 3.~~

3. ~~Competent authorities, in cooperation with delegated bodies as necessary, shall develop and implement training programmes for the purpose of ensuring that personnel performing SoHO supervisory activities receive the training referred to in paragraph 2, points (b), (c) and (d). Competent authorities shall maintain records of the training undertaken by their personnel. Competent authorities shall provide opportunities for their personnel to participate in the Union training referred to in Article 69 where such Union training is available and appropriate.~~
4. ~~Paragraphs 1, 2 and 3 shall also apply to delegated bodies.~~

Article 17

Obligations as regards Commission controls verifications

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

- (a) take appropriate follow-up measures to remedy the shortcomings identified through such controls verifications;
- (b) ~~give~~ **provide** the necessary technical assistance and ~~provide~~ the available documentation, upon justified request, ~~and~~ **as well as** other ~~technical~~ support that Commission experts request to enable them to perform verification ~~controls~~ efficiently and effectively, **including facilitating** ~~;~~ and
- (c) ~~give the necessary assistance to ensure that the Commission experts have~~ **give** access to all premises or part of premises, and to information, including IT systems, **of the SoHO competent authority or delegated body** relevant for the execution of their duties.

Section II – Authorisation of SoHO Establishments:

Recital 32, Art. 3(21), 3(40), 3 (56), 25, 48, 27, 49, 49a, 49b, 49c.

Recital

(32) **SoHO c**Competent authorities should review the SoHO entities registered in their territory and ensure that those entities that carry out ~~both~~ processing and storage, **release, import or export** of SoHOs 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. Competent authorities should consider the impact on safety, quality and efficacy of the SoHO activities carried out at SoHO entities that do not meet the definition of a SoHO establishment and decide whether particular entities should be subject to establishment authorisations due to the risk or scale associated with their activities. Similarly, SoHO entities that have a poor record in terms of compliance with reporting or other obligations might be suitable candidates for authorisation as SoHO establishments.

Article 3

Definitions

(21) ‘export’ means ~~distribution of~~ **activities carried out to send** SoHOs **from the Union** ~~or SoHO preparations to a~~ third country~~ies~~.

(40) ‘SoHO establishment’ means a SoHO entity that

~~(new a) — carries out both~~ **any of the following activities, separately or not:** processing **and** storage, **release, or import or export** of SoHOs **and**

~~(new b) — releases SoHOs or either one of these activities combined with release;~~

~~/(56) ‘releasing responsible officer person’ means a the nominated individual in a SoHO establishment entity that has responsibility for SoHO release; /~~

CHAPTER III

SoHO SUPERVISORY ACTIVITIES

Article 25

SoHO establishment authorisation system

1. **SoHO c**Competent authorities shall establish and maintain a system for receiving and processing requests for the authorisation of SoHO establishments **in their territory. The system shall allow for the suspension and/or withdrawal of authorisations.**
2. **SoHO c**Competent authorities shall authorise as SoHO establishments the SoHO entities that both process and store, **release, import or export or process and release or store and release** SoHOs, in accordance with Article 27.
 - 2a. **SoHO competent authorities shall include all SoHO activities carried out by a SoHO establishment in the authorisation granted, including those SoHO activities carried out outside of the premises of the SoHO establishments.**
3. ~~Competent authorities may decide that certain SoHO entities that do not process and store SoHO also need to be authorised as SoHO establishments, in particular SoHO entities that:~~
 - ~~(a) have significant influence on the safety and quality of SoHOs due to the scale, criticality or complexity of the SoHO activities they perform; or~~
 - ~~(b) carry out SoHO activities in connection with multiple SoHO establishments.~~
3. **Competent authorities may decide that certain SoHO entities, that do not meet the SoHO establishment definition also need to be authorised as such, in particular SoHO entities that:**
 - (a) have significant influence on the safety and quality of SoHOs due to the scale, criticality or complexity of the SoHO activities they perform; or**

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

4. ~~Paragraph 3 shall not apply to SoHO entities that import SoHO.~~
5. SoHO establishment authorisations shall be valid throughout the Union for the period defined in the terms of the authorisation, when such a time period has been defined, or until a **SoHO** competent authority has suspended or withdrawn the authorisation or the establishment has ceased to conduct SoHO activities. Where a Member State has adopted a more stringent measure, in accordance with Article 4, which relates to a specific SoHO establishment authorisation, that Member State may decline to recognise the validity of the SoHO establishment authorisation of another Member State ~~pending verification that the more stringent measure has been met~~ **until it has verified compliance with the more stringent measure.**
6. The Commission may adopt implementing acts to specify uniform procedures and working methods for establishing and maintaining a SoHO establishment authorisation system.

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

CHAPTER V

GENERAL OBLIGATIONS ON SoHO ESTABLISHMENTS

Article 48

SoHO establishment authorisation

1. SoHO establishments shall not carry out any of the SoHO activities that qualify them as an establishment according to art 3 (40) listed in article 2(1a), without prior SoHO establishment authorisation. This shall apply whether all activities are carried out by the establishment itself or one or more are contracted to another SoHO entity.
2. In cases where SoHO establishments contract other SoHO entities to perform part or all of certain SoHO activities, the SoHO establishments shall ensure that those contracted SoHO entities carry out those contracted activities in compliance with the provisions of this Regulation. Such contracted SoHO entities may ~~shall agree to~~ be audited by the contracting SoHO establishments or inspected by the SoHO competent authority, in particular in cases where the contracted entity has not been accredited, certified or authorised, as part of a national programme, for the specific activities carried out under the contract. ~~to verify that the contracted activities are carried out in compliance with this Regulation. In addition, the contracted entities shall agree to be inspected by competent authorities if the authorities require such inspection. The SoHO establishments shall document these agreements.~~
3. The requirement to obtain a SoHO establishment authorisation shall be without prejudice to more stringent measures put in place by a Member State pursuant to Article 4 and directly affecting the activities carried out in the SoHO establishment or contracted SoHO entities concerned pursuant to paragraph 2 of this Article.

CHAPTER III

SoHO SUPERVISORY ACTIVITIES

Article 27

Authorisation of SoHO establishments

1. **SoHO** competent authorities shall provide guidelines and templates to allow that applications ~~from SoHO entities~~ for their authorisation ~~as~~ **of** SoHO establishments are submitted in accordance with Article 49. When developing these guidelines and templates, **SoHO** competent authorities shall ~~consult~~ **take into account** the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c). **SoHO competent authorities may use the secure communication channel on the EU SoHO Platform for the exchange, with the SoHO establishment entity, of documents relating to the application for an authorisation.**
2. Upon receipt of an application for the authorisation of a SoHO establishment, **SoHO** competent authorities shall:
 - (a) acknowledge receipt of the application **without undue delay** ~~within 14 working days~~;
 - (b) assess the application;
 - (c) examine agreements between the applicant SoHO establishment and any **SoHO entities** ~~third parties~~ contracted by that SoHO establishment to perform SoHO activities;
 - (d) request that the applicant SoHO establishment provides supplementary information, if needed;
 - (e) carry out an on-site ~~system~~ inspection of the applicant SoHO establishment **pursuant to Article 29**, and, where applicable, **on-site or document review based inspections** ~~of third parties~~ **SoHO entities or third parties** contracted by the SoHO establishment ~~to perform SoHO activities~~, pursuant to Article **30(1)** ~~29~~;

- (f) inform the applicant, without undue delay, of the outcome of the assessment and inspections referred to in points (b), (c), (d) when relevant, and (e) ~~and of the decision on the authorisation~~;
 - (g) grant or refuse the authorisation of the applicant SoHO establishment as a SoHO establishment, as appropriate, and indicate which **SoHO and which** SoHO activities are covered **for each SoHO** by the authorisation and which conditions apply, if any;
 - (h) ~~assess and, as appropriate, approve~~ **authorise** ~~subsequent changes made by the SoHO establishment to the information provided in the application and communicated to them according to Article 49(2);~~
 - (i) submit information regarding the **granted** authorisation **to the SoHO establishment**, by amending ~~accordingly~~ the status of the SoHO entity **into SoHO establishment** ~~concerned, and including the name and contact details of the SoHO establishment authorisation holder, in the EU SoHO Platform as referred to in Chapter XI~~ without undue delay.
 - (j) assess and, as appropriate, ~~approve~~ **authorise any significant** ~~subsequent changes made by the SoHO establishment to the information provided in the application and communicated to them according to Article 49(2),~~ **and update the information in the EU SoHO Platform.**⁴
3. **SoHO c**ompetent authorities may, **in accordance with national legislation**, suspend the authorisation of a SoHO establishment, or of certain SoHO activities the establishment is authorised to perform, if SoHO supervisory activities demonstrate or give reasonable grounds for suspecting, that the SoHO establishment in question:
- (a) does not comply with the conditions of its authorisation; ~~or the provisions of this Regulation; and~~
 - (b) **does not comply with the provisions of this Regulation and** that non-compliance, or suspected non-compliance, implies a risk to the safety of SoHO donors or recipients or offspring from medically assisted reproduction, ~~or unnecessary wastage of SoHOs.~~

⁴ Para j shows revision to the original para h that is proposed to be moved.

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

4. In cases where **SoHO** competent authorities have confirmed non-compliances referred to in paragraph 3 and SoHO establishments are not able to rectify them in the specified time period, **SoHO** competent authorities shall, in accordance with national legislation, withdraw the authorisation of a SoHO establishment.
5. **SoHO c**Competent authorities may, in accordance with national legislation, withdraw the authorisation of a SoHO establishment if the **SoHO** competent authorities have confirmed that the SoHO establishment ~~no longer complies with updated criteria for authorisation or the SoHO establishment has repeatedly~~ **does not** failed to comply with the conditions of its authorisation, **or and that a risk to SoHO donors or recipients or offspring from medically assisted reproduction is identified which and that risk cannot be resolved during a suspension.**
6. In cases of authorisation suspension or withdrawal, as referred to in paragraphs 3, 4 and 5, **SoHO** competent authorities shall amend accordingly the authorisation status of the SoHO establishment concerned in the EU SoHO Platform as referred to in Chapter XI without undue delay.

CHAPTER V

GENERAL OBLIGATIONS ON SoHO ESTABLISHMENTS

Article 49

Application for SoHO establishment authorisations

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

SoHO establishments shall also, without undue delay, inform their SoHO competent authorities of any changes of an administrative nature, related to the SoHO establishment authorisation, including a change of responsible person.
3. The legal entity that holds the authorisation for the SoHO establishment ~~authorisation holders~~ shall be based in the Member State where the SoHO establishment is authorised ~~the Union~~.

Releasing officers~~responsible person for release of SoHOs~~

1. In cases where a SoHO ~~establishment~~entity releases SoHOs or SoHO preparations **for human application**, ~~for distribution for human application~~, or for the manufacture of products regulated by other Union legislation, ~~or as the starting and raw material thereof~~, as referred to in Article 60, **the responsible person, as referred to in Article 37a**, ~~that establishment~~entity shall designate **one or more releasing officers**~~a person responsible for release~~.
- 1a. The nominated releasing officers shall be communicated to the SoHO competent authority.**
2. **TheA releasing officer** ~~The responsible person for release of SoHOs~~ shall be in possession of a diploma, certificate or other evidence of formal qualifications in the field of medical, **pharmaceutical** or biological **life** sciences awarded on completion of a university course of study or a course **qualification** recognised as equivalent by the Member State concerned and shall have at least 2 years of experience in ~~the a~~the relevant field.
3. **TheA releasing officer** ~~The responsible person for release of SoHOs~~ may delegate the tasks **to carry out the activity** specified in paragraph 1 to other persons who shall be qualified by training and experience to perform such tasks. In such cases, that person shall perform those tasks under the responsibility of the **releasing officer who will always be responsible for the release**. ~~responsible person for release of SoHOs~~. **The responsibility of releasing SoHOs may be delegated to an alternate in case of short term absence of a releasing officer, on condition that the alternate meets the requirements specified in paragraph 2.**

⁵ This Article is adapted based on Article 38 which will be moved here. Moreover, the provisions of Article 49a as presented in 11823/23 are now reflected in Article 37a as presented in 12955/23

Responsible Physician

1. ~~Each~~ SoHO establishment shall designate a ~~responsible~~ physician who ~~resides and~~ carries out its tasks in the same Member State and who shall at least fulfil the following conditions and have the following qualifications:
 - (a) possession of formal qualification as a physician **and**
 - (b) at least two years' practical experience in **the a**-relevant fields.
2. The ~~responsible~~ physician referred to in paragraph 1 shall be responsible for at least the following tasks:
 - (a) development, review and approval of policies and procedures for establishing and applying SoHO donor eligibility criteria, **procedures for SoHO collection** and criteria for the allocation of SoHOs ~~and SoHOs preparations~~;
 - (aa) supervision of the implementation of policies and procedures referred to in point (a) when they are carried out by SoHO entities contracted by the SoHO establishment;**
 - (b) **the clinical aspects of** investigation of suspected adverse **reactions** ~~occurrences~~ in SoHO donors, **SoHO** ~~and recipients~~ **and offspring from medically assisted reproduction from the perspective of the SoHO establishment.**
 - (c) design and supervision, **in collaboration with treating physicians,** of clinical data collection activities to support evidence gathering to support applications for SoHO preparation authorisations pursuant to Article 41;
 - (d) other tasks of relevance to the health of **SoHO** donors, ~~and~~ **SoHO** recipients **and offspring from medically assisted reproduction** of SoHOs collected or supplied by the SoHO establishment.

⁶ This Article is adapted based on Article 51 which will be moved here.

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

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

Article ~~49c~~^{39⁷}

Export

new 1. SoHO establishments~~entities~~ shall ensure that SoHOs ~~or SoHO preparations~~ **released for export** ~~exported or re-exported from the Union~~ comply with the relevant requirements of this Regulation.

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

new 2. By derogation from paragraph -1, SoHOs not complying with all the relevant standards and guidelines referred to in Articles 58 and 59 may be released for export in the circumstances of exceptional release pursuant to Article 61(new 3).⁸

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

⁷ This Article is adapted based on Article 39 which will be moved here.

^{2.} ~~Reference to Article 61(3) will be reviewed when Chapter VII will be drafted.~~

Section III – Registration of SoHO Importers: Recital 40, Art. 3(20), 3(20a), 3(67), 26, 28, 42, 43.

Recital

(40) — The concept of a plasma master file (PMF) was established in Commission Directive 2003/63/EC⁹. Since that Directive provided for a specific regulatory role for the European Medicines Agency (EMA) in relation to authorisation of plasma for fractionation, the SCB should also collaborate with the relevant EMA expert working groups to exchange experience and good practices so that criteria for the eligibility of donors of plasma for fractionation and of donors of blood for transfusion are implemented by Member States in a consistent and coherent way.

CHAPTER I

Article 3

Definitions

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

(20) ‘import’ means activities carried out to bring SoHOs or SoHO preparations into the Union from a third country, including the organisation of such activities and physical verification of coherence with associated documentation, the appropriateness of transport conditions, the integrity of packaging and the adequacy of labelling **before their release** before release;

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

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

⁹ — Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 159, 27.6.2003, p. 46).

CHAPTER III

SoHO SUPERVISORY ACTIVITIES

Article 26

Importing SoHO entity authorisation system

1. ~~Competent authorities shall establish and maintain a system for receiving and processing requests for the authorisation of importing SoHO entities.~~
2. ~~Competent authorities shall authorise as importing SoHO entities the SoHO entities that import SoHOs pursuant to Article 28.~~
3. ~~Importing SoHO entity authorisations shall be valid throughout the Union for the period defined in the terms of the authorisation, when such a time period has been defined, or until a competent authority has suspended or withdrawn the authorisation or the entity has ceased to conduct SoHO activities. Where a Member State has adopted a more stringent measure, in accordance with Article 4, which relates to a specific importing SoHO entity authorisation, that Member State may decline to recognise the validity of the importing SoHO entity authorisation of another Member State pending verification that the more stringent measure has been met.~~
4. ~~The Commission shall adopt implementing acts to specify uniform procedures and working methods for establishing and maintaining an importing SoHO entity authorisation system.~~

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

Authorisation of importing SoHO entities establishments

1. **SoHO** competent authorities shall **authorise** ~~provide guidelines and templates to allow that applications from SoHO entities for their authorisation as importing SoHO establishments the SoHO entities that import SoHO are submitted in accordance with Article 43. In developing these guidelines and templates, competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).~~
- 1a. Articles 25(1), 25(5), 25(6) and 27 shall apply, mutatis mutandis, to the authorisation of importing SoHO establishments.**
- 1b. In cases of import of human plasma for the manufacture of medicinal products, the authorisation may be based on information provided as part of a plasma master file (PMF) as referred to in Directive 2003/63/EC.**
2. Upon receipt of an application for ~~an~~ **the authorisation of an importing SoHO entity establishment authorisation**, **SoHO** competent authorities shall **act in accordance with perform the actions set out in Article 27(2). In particular, SoHO competent authorities shall also assess the procedures in place at the applicant importing SoHO establishment to ensure that the imported SoHOs are equivalent, in terms of safety, quality and effectiveness, to SoHOs and SoHO preparations authorised according to the provisions of this Regulation, before release.**
 - (a) ~~acknowledge receipt of the application within 14 working days;~~
 - (b) ~~assess the application;~~
 - (c) ~~examine agreements between the applicant SoHO entity and any third parties contracted by that SoHO entity to perform SoHO activities;~~
 - (d) ~~request that the applicant provides supplementary information, if needed;~~
 - (e) ~~inform the applicant, without undue delay, of the outcome of the assessment and examinations referred to in points (b), (c) and (d) where relevant, and of the decision on the authorisation;~~

- (f) ~~grant or refuse the authorisation of the applicant as an importing SoHO entity, as appropriate, and indicate which SoHOs are covered by the authorisation and which conditions apply, if any;~~
- (g) ~~assess and, as appropriate, approve subsequent changes made by the SoHO importing entity and communicated to them as referred to in Article 43(3);~~
- (h) ~~submit information regarding the authorisation, by amending accordingly the status of the SoHO entity concerned, and including the name and contact details of the importing SoHO entity authorisation holder, in the EU SoHO Platform as referred to in Chapter XI, without undue delay.~~

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

- 3. ~~In cases where the applicant intends to distribute the imported SoHOs to other Member States, competent authorities may perform the actions set out in paragraph 2, points (b), (c) and (d), in consultation with the SoHO National Authorities of the Member States concerned.~~
- 4. **The SoHO** ~~Competent authorities may require to inspect any party in a third country supplying SoHOs to the applicant prior to granting or refusing the importing SoHO entity establishment authorisation, in particular in cases where the application concerns regular and repeated import of SoHOs from the same party.~~

- ~~5. Competent authorities may suspend the authorisation of an importing SoHO entity if SoHO supervisory activities demonstrate or give reasonable grounds to suspect:~~
- ~~(a) that the SoHO entity in question does not comply with the conditions of the authorisation or the provisions of this Regulation; and~~
 - ~~(b) that this non-compliance, or suspected non-compliance, implies a risk to the safety of recipients or offspring from medically assisted reproduction.~~
- ~~6. Competent authorities shall specify a period of time for the investigation of a suspected non-compliance and for the importing SoHO entity to rectify a confirmed non-compliance, during which the suspension shall remain in place. In cases where competent authorities have confirmed non-compliances referred to in paragraph 5 and the importing SoHO entity is not able to rectify them in the specified time period, competent authorities shall withdraw the authorisation of the importing SoHO entity.~~
- ~~7. Competent authorities may, in accordance with national legislation, withdraw the authorisation of an importing SoHO entity if the competent authorities have confirmed that the importing SoHO entity no longer complies with updated criteria for authorisation or the importing SoHO entity has repeatedly failed to comply with the conditions of its authorisation.~~
- ~~8. In cases of authorisation suspension or withdrawal, as referred to in paragraphs 5, 6 and 7, competent authorities shall amend accordingly the authorisation status of the SoHO entity concerned in the EU SoHO Platform as referred to in Chapter XI without undue delay.~~
9. By derogation from paragraph 1, **SoHO** in case of emergency competent authorities may authorise imports of **a** SoHOs for immediate **human** application to a specific **SoHO** recipient, when **requested by the SoHO entity responsible for that application and when** justified by the clinical circumstances on a case-by-case basis.

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

10. The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this Regulation by laying down specific criteria for the assessments, examinations and inspections in the course of the authorisation.
11. Where, in the case of risk to quality and safety of imported SoHOs, imperative grounds of urgency so require, the procedure provided for in Article 78 shall apply to delegated acts adopted pursuant to this Article.

Article 42¹⁰

Importing SoHO ~~entity~~ establishment authorisation

1. SoHO ~~entities~~ establishments shall not import SoHOs without a prior importing SoHO ~~entity~~ establishment authorisation.
2. ~~In the case of importing SoHO entities that only import human plasma that is intended to be used for the manufacture of medicinal products regulated by other Union legislation and is included in a plasma master file (PMF) as referred to in Directive 2003/63/EC, paragraph 1 of this Article shall not apply.~~

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

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

¹⁰ Articles 42 and 43 will be moved to the articles related to establishments in Chapter V as they are not entities anymore but establishments

Application for importing SoHO entity establishment authorisations

1. **Article 49 shall apply *mutatis mutandis* to the applications for importing SoHO establishments authorisation** ~~SoHO entities shall send applications for authorisation as importing SoHO entities to their competent authorities.~~
 - 1a. **Prior to applying for importing SoHO establishment authorisation, SoHO establishments shall put in place written agreements with one or more third country suppliers. Such agreements shall include the elements described in paragraph 2 of this Article.**
2. The applicant SOHO **establishment** ~~entity~~ shall **also** provide:

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

 - (a) **details of third parties contracted included in the a written agreements between the applicant SoHO establishment and any third country parties supplier contracted to perform supply SoHO activities. This Such written agreement shall include, at least:**
 - (i) details of the third country supplier contracted;**
 - (ii)(i) the quality and safety requirements to be met to ensure the equivalency of the quality and safety standards of the SoHO to be imported;**
 - (iii)(ii) the right of the SoHO competent authorities to inspect the activities, including the facilities, of any third country supplier entities or organisation sub-contracted by that supplier third parties from a third country, contracted by the importing SoHO establishment.**
 - (b) **documentation proving that the procedures they the third country suppliers have in place will ensure that the imported SoHOs will be equivalent, in terms of safety, quality and effectiveness, to SoHOs authorised according to the provisions of this Regulation.**

3. ~~The importing SoHO entity shall not make any substantial changes to the importing SoHO activities subject to the authorisation without the prior written approval of its competent authority. The same shall apply in case of changes in the importing SoHO entity authorisation holder's details.~~
4. The importing SoHO **establishment** ~~entity authorisation holder~~ shall ~~be based in the Union, and~~ be responsible for the physical reception and visual examination and verification of imported SoHOs prior to their release. The importing SoHO **establishment** ~~entity~~ shall verify coherence between the SoHO received and the associated documentation and conduct an examination of the integrity of packaging, ~~and the compliance of~~ labelling and transport conditions ~~with~~ **taking into account** the relevant standards and technical guidelines as referred to in Articles 57, 58 and 59.
5. An authorised importing **SoHO establishment** ~~entity~~ may delegate the physical reception, visual examination and verification referred to in paragraph 4 to the **SoHO** entity that will apply the SoHO to the **SoHO** recipient in cases where imports are organised for individual named **SoHO** recipients.

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

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

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

SECTION IV – INSPECTIONS

Recitals 25, 26, Articles 3(32), 3(36), 3(37), 3(44), 3(46), Articles 29, 30, 31, 32.

RECITALS ON INSPECTIONS

- (25) **SoHO** ~~Competent~~ authorities should perform **SoHO** supervisory activities regularly, on the basis of a risk assessment and with appropriate frequency, on entities and activities governed by this Regulation. The frequency of **SoHO** supervisory activities and the mode **inspections are carried out** ~~whether on-site or by remote document review,~~ should be established by the **SoHO** competent authorities, having regard to the need to adjust the **degree of** control ~~effort~~ to the risk and to the level of compliance expected in the different situations, including the possible violations of this Regulation perpetrated through fraudulent or other illegal practices and previous compliance history. Accordingly, the likelihood of non-compliance with all the areas of this Regulation should be taken into account when scheduling **SoHO** supervisory activities.
- (26) Commission experts should be able to perform ~~controls, including audits~~ **verifications**, in Member States to ~~verify~~ **address** the effective application of the relevant requirements ~~of competent authorities and of the supervisory activity systems~~ **included in this Regulation**. Commission ~~controls~~ **verifications** should also serve to investigate and collect information on enforcement practices or problems, emergencies and new developments in Member States. Official ~~controls~~ **verifications** should be performed by personnel who are independent, free from any conflict of interest and in particular who are not in a situation which, directly or indirectly, could affect their ability to carry out their professional duties in an impartial manner.

Article 3

Definitions

- (32) — ‘SoHO supervisory activity’ means any activity as provided for in Chapter III ~~the this~~ **Regulation and** performed by a **SoHO** competent authority or by a delegated body in order to verify and enforce compliance with this Regulation, **including registration, authorisation and oversight activities such as inspection, vigilance and activity monitoring, and including coordination of the performance of such activities within a Member State;**
- (36) — ‘audit’ means a systematic and independent examination to determine whether activities and the related results of such activities comply with legislation and planned arrangements and whether these arrangements are applied effectively and are suitable to achieve the objectives;
- (37) — ‘inspection’ means a formal, **systematic, independent** and objective control by a **SoHO** competent authority or delegated body to assess compliance with **the requirements of** this Regulation and other relevant Union or national legislation ~~and to identify, if applicable, the need for corrective or preventive action to achieve compliance;~~
- (44) — ‘on-site inspection’ means an inspection carried out at the premises of the SoHO establishment, or other SoHO entity, concerned;
- (46) — ‘joint inspection’ means an inspection carried out **with the participation of** by inspectors ~~sent for that purpose by other~~ from more than one Member States;

CHAPTER III

SoHO SUPERVISORY ACTIVITIES

Article 29

Inspections of SoHO establishments

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

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

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

- (a) announced routine system inspections;
- (b) announced or unannounced inspections, **in particular** in particular in the case of **for the** investigations of fraudulent or other illegal activities, or on the basis of **information that might indicate** information that might indicate non-compliance with the rules of this Regulation;
- (c) **announced or unannounced** inspections **targeted at a specific activity or topic** as provided for in Articles 22(6), Article 27(2), point (ed), Article 28(4), **30(1)**, Article 31 and Article 35(5).

2. **SoHO c**ompetent authorities that during inspections identify non-compliances with the rules of this Regulation may include follow-up inspections, where necessary and proportionate, to verify **that SoHO establishments have undertaken appropriate** that SoHO establishments have undertaken effective **compliance with the** corrective and preventive **actions.**
actionsmeasures laid down in the report.
3. ~~Competent authorities of the Member State in which the SoHO establishment is located shall carry out the inspections.~~
4. ~~Competent authorities shall carry out on-site inspections of SoHO establishments and, where applicable, of any third parties contracted by the SoHO establishment to perform SoHO activities.~~
5. By derogation from paragraph 4, **SoHO** competent authorities **shall carry out on-site inspections referred to in this Article. Exceptionally, SoHO competent authorities** may conduct inspections, in full or in part, by **virtual or hybrid** means, **or by remote document review** of a remote document review, provided that:
- (a) such inspection mode does not **pose** pose **overlook** a risk to the safety and quality of SoHOs;
 - (b) such **the type of inspection carried out such inspection mode** does not prejudice the effectiveness of inspections; ~~and~~
 - ba) **confidentiality, professional secrecy and protection of SoHO donors, SoHO recipients or offspring of medically assisted reproduction are is respected; and**
 - (c) the maximum interval between two on-site inspections pursuant to paragraph ~~11~~ **10** is not exceeded.
6. **SoHO c**ompetent authorities shall ensure that inspections are carried out by inspectors meeting the requirements set out in Article 32.

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

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

- (a) The technical guidelines published by the ECDC and by the EDQM referred to in Articles 56(4), point (a), and 59(4), point (a), as applicable, the inspectors shall consider the standards or elements thereof, to be met, insofar as they are addressed by the guidelines;
- (b) other guidelines as referred to in Articles 56(4), point (b), and 59(4), point (b), **adopted by the Member State, according to paragraph 8,** the inspectors **shall consider the standards or elements thereof, to be met, insofar as they are addressed by the guidelines** ~~shall assess on a case-by-case basis such guidelines in terms of level of safety, quality and efficacy achieved, as applicable, and accept or decline whether that level is equivalent to the level set by the technical guidelines referred to in Articles 56(4), point (a), and 59(4), point (a);~~
- (c) other technical methods **applied in specific circumstances,** as referred to in Articles 56(4), point (c), and 59(4), point (c), the inspectors shall evaluate **and verify that these methods guarantee** ~~the risk assessment and record provided, assess the adequacy~~ **with the guidelines and the achievement of equivalent levels of quality and safety.** ~~of the technical methods applied. For this assessment, the SoHO establishments shall provide the inspectors with all the necessary information, pursuant to Articles 56(7) and 59(7).~~

8. In cases **referred to in** ~~of~~ paragraph 7 **a**, second subparagraph, point (b), ~~the~~ **where SoHO Member State** competent authorities, prior to the inspection, **shall** have ~~accepted~~ **adopted** the level **of** safety **and**, quality ~~and efficacy~~ achieved by those other guidelines, as equivalent to the level set by the technical guidelines referred to in paragraph 7, second subparagraph, point (a), **and shall have made them available at the EU SoHO Platform** ~~the inspectors shall consider the standards or elements thereof, to be met, insofar as they are addressed by the guidelines.~~
9. Inspectors ~~may~~ **shall** carry out **at least** one **or more** ~~or more of~~ the following activities: **in the SoHO establishment or their contracted SoHO entities or third parties**:
- (a) inspect **premises** ~~SoHO establishment facilities and, where applicable, the facilities of any third parties contracted by the SoHO establishment concerning SoHO activities;~~
 - (b) evaluate and verify the procedures and the SoHO activities performed ~~in SoHO establishments and, where applicable, in facilities of third parties that are relevant to the requirements of this Regulation;~~
 - (c) examine any documents or other records ~~kept by SoHO establishments and, where applicable, third parties relating to the requirements of this Regulation and in particular Chapter V thereof;~~
 - (d) **if applicable,** evaluate the design and implementation of the quality management system in place pursuant to Article 50;
 - (e) take samples for analysis, ~~and~~ copies of documents, **and photographic or video recording,** if required;
 - (f) evaluate the emergency plan in place in accordance with Article 66, where applicable;
 - (g) order the suspension or cessation of any procedure or activity where necessary and proportionate to the risk detected. **In such case, the inspector shall take all the necessary steps without undue delay inform the SoHO competent authority immediately.**

10. **Subsequent to the inspection referred to in Article 27(2) point (e), SoHO** Competent authorities shall carry out **periodic** inspections pursuant to paragraph 1a, point (a), **regularly, so that the interval between two on-site inspections shall not exceed, in any event, 4 years,** on a risk basis and with **an appropriate frequency, according to the risk.** **The frequency of inspections shall** taking account of:
- (a) identified risks associated with: (i) the **type of SoHOs that are subject to the authorisation** processed and stored; **and** (ii) the **SoHO** activities of the SoHO establishments, in particular the processes carried out;
 - (b) the **SoHO** establishments' past record as regards the outcome of previous inspections ~~carried out on them~~ and their compliance with the rules of this Regulation;
 - (c) ~~results from~~ certification or accreditation by international bodies, ~~where those bodies verify provisions that are equivalent to those in this Regulation; and~~ **where relevant;**
 - (d) the reliability and effectiveness of the quality management systems referred to in Article 50.
11. ~~The interval between two on-site inspections shall not exceed 4 years.~~
12. ~~Competent authorities shall consider on-site inspections carried out in the course of the authorisation of an establishment in accordance with Article 27(2), point (d), as the first on-site inspection in the sense of this Article.~~
13. ~~**SoHO** Competent authorities shall provide immediate preliminary feedback on their findings at the request of the SoHO establishment concerned.~~
14. Following each inspection, the **SoHO** competent authorities shall draw up a report on the findings of the inspection ~~that concern compliance with the legal and technical requirements applicable under this Regulation~~ and provide it to the SoHO establishment concerned. In the report, **when the result of the inspection so requires, if applicable,** the **SoHO** competent authorities ~~may~~ **shall, as appropriate,** set out any corrective or preventive action needed or ~~may~~ **shall** request the SoHO establishment to respond with a proposal for such actions, with associated dates for completion.

- ~~15. Where more than one authority is competent to perform SoHO supervisory activities in a Member State pursuant to Article 5(2), on a reasoned request from another competent authority in their Member State, the competent authority shall forthwith communicate the report referred to in paragraph 14 of this Article to the requesting competent authority.~~
16. For the purpose of ~~standardised~~ inspections referred to in paragraph 1 of this Article, **SoHO** competent authorities shall ~~consult~~ **take into account** the relevant best practices **on inspections** agreed and documented by the SCB as referred to in Article 68(1), point (c).
17. The Commission may adopt implementing acts concerning the procedures to be followed for inspections of SoHO establishments.

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

Article 30

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

1. **SoHO c**ompetent authorities may carry out inspections pursuant to Article 29(1) ~~on of~~ SoHO entities other than SoHO establishments, **and of the third parties contracted,** as necessary and proportionate to the risks associated with the SoHOs and the SoHO activities registered for that SoHO entity, and the SoHO entity's past **compliance** records, ~~in particular as regards the outcome of previous inspections carried out on it and its compliance with the rules of this Regulation.~~
2. In the cases referred to in paragraph 1, Article 29 shall apply, *mutatis mutandis*, to the inspection of SoHO entities other than SoHO establishments **and of the third parties contracted.**
3. ~~For the purpose of a standardised approach to the inspection of SoHO entities other than SoHO establishments, SoHO competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).~~

Joint inspections

1. At a request of one or more SoHO competent authorities via their SoHO National Authorities~~competent authorities~~ to another SoHO National Authority, inspections pursuant to Articles 29(1) and 30(1) may be carried out with the participation of ~~by~~ inspectors sent for that purpose by other ~~from more than one~~ Member State as a joint inspection.
2. With the previous consent of the SoHO National Authority, ~~the~~ SoHO competent authority receiving a request for a joint inspection, shall make all reasonable efforts to accept such request, taking into account their available resources, ~~and coordinate and support that inspection,~~ in particular in cases where:
 - (a) the SoHO entity to be inspected performs SoHO activities in more than one Member State, and concerns that have impact in the requesting Member State ~~it is demonstrated, or there is reasonable ground for suspecting, that the activities carried out on the territory of another Member State pose a risk to the safety and quality of SoHOs distributed in the requesting Member State;~~
 - (b) SoHO competent authorities of the requesting Member State require specialist technical expertise of another Member State for that inspection;
 - (c) the SoHO competent authorities ~~iesy~~ involved of the Member States receiving the request agrees that there are other reasonable ~~other reasonable~~ grounds for conducting a joint inspection.
3. The SoHO competent authorities participating in a joint inspection shall conclude an written agreement prior to carrying out the inspection. Such written agreement shall specify ~~that defines~~ at least the following:
 - (a) the scope and objective of the joint inspection;

- (b) the roles of the participating inspectors during and following the inspection, **including the designation of the SoHO competent authority leading the inspection** including the designation of an authority leading the inspection;
- (c) the powers and responsibilities of each of the **SoHO competent** authorities **involved**.

The **SoHO competent** authorities participating **in the joint inspection** shall commit themselves in that agreement to jointly accept the results of the inspection.

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

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

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

The competent authority for the SoHO entity or SoHO establishment concerned shall, prior to the inspection, inform that SoHO entity or SoHO establishment about the joint inspection, unless **there are reasons against such prior communication** the competent authorities concerned have reasonable grounds to suspect illegal or fraudulent activity.

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

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

- 6a. **For the purposes of coordinating and performing joint inspections SoHO competent authorities shall take into account the relevant best practices agreed and documented by the SCBoHO coordination board, as referred to in article 68(1), point (c).**

Specific obligations concerning inspectors

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

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

2. **SoHO** ~~Competent~~ authorities shall provide inspectors with a specific induction training before inspectors take up their duties. For the specific induction training, **SoHO** competent authorities shall **take into account** ~~consult~~ the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).
3. **SoHO** ~~Competent~~ authorities shall ensure that the specific induction training includes at least the following:
 - (a) the inspection techniques and procedures ~~to be followed, including practical exercises;~~
 - (b) an overview of relevant Union and national inspection guidance, **where applicable**, and the best practices agreed and documented by the SCB as referred to in Article 68(1), point (c);
 - (c) ~~an~~ **an** overview of the authorisation systems in the Member State concerned;
 - (d) the applicable legal framework for the performance of SoHO supervisory activities;
 - (e) **an overview of the** technical aspects concerning SoHO activities;
 - (f) SoHO technical guidelines as referred to in Articles 56 and 59;

- (g) an overview of the organisation and functioning of national regulatory authorities in the field of SoHOs and related fields;
- (h) an overview of the national health system and SoHO organisational structures in the Member State concerned.

4. SoHO ~~Competent~~ authorities shall ensure that the specific induction training is complemented by specialised adequate ~~specialised~~ training for inspection of specific types of establishments and by continuous training, as appropriate, ~~throughout the career of the inspectors.~~ SoHO ~~Competent~~ authorities shall ~~make all reasonable efforts~~ endeavour to ensure that inspectors that participate in joint inspections have completed the relevant Union training referred to in Article 69(1) and are included in the list referred to in Article 69(5).
5. Inspectors may be assisted by technical experts provided that the SoHO competent authorities ensure that those experts comply with the requirements of this Regulation, ~~in particular with the obligations set out in Articles 7, 75 and 76.~~
6. ~~Paragraphs 1 to 5 shall also apply to delegated bodies.~~
