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From:	Presidency
To:	Delegations
No. prev. doc.:	14066/22 REV 1, 11061/23, 10846/23, 11432/23, 11823/23
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 - <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 4 September 2023.

Text marked in **bold and underlined** and in ~~strikethrough~~ reflects changes made in this text compared to the Commission proposal with the following specificities: Changes proposed to definitions presented in 10846/23 are highlighted in **yellow shading**. Changes proposed to other definitions as presented in 14066/22 REV1 are highlighted in **grey shading**. References in the text to provisions presented in earlier Presidency compromises (10846/23, 11061/23, 11432/23, 11823/23) reflect the numbering presented therein.

Besides that, the Presidency is presenting the text of the following Chapters and the related definitions (31, 33, 38, 41, 42, 66) in the beginning of the document:

Chapter VIII – Supply Continuity: Articles 3(41), 3(42), 3(66), -62, 62, 63, 64, 65, 66;

Chapter IX – SoHO Coordination Board: Articles 3(33), 67, 68;

Chapter X – Union Activities: Articles 3(38), 69, 69a, 70, 71, 72;

Chapter XI – EU SoHO Platform: Articles 3(31), 73, 74;

Chapter XII – Procedural Provisions: Articles 75, 76, 77, 78, 79, 80;

Chapter XIII – Transitional Provisions: Articles 81, 82, 82a, 83, 84;

Chapter XIV – Final Provisions: Articles 85, 86, 87.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on standards of quality and safety for substances of human origin intended for human
application and repealing Directives 2002/98/EC and 2004/23/EC

CHAPTER I

GENERAL PROVISIONS

Article 3

Definitions

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

- (31) 'EU SoHO Platform' means the digital platform established by the Commission, **referred to in Chapter XI** to exchange information concerning SoHO activities;
- (33) 'the **SoHO** compendium' means a list kept up-to-date by the SoHO Coordination Board of decisions, taken at Member State level, and opinions, issued by **SoHO** competent authorities and by the SCB, on the regulatory status of specific substances, products or activities and published on the EU SoHO platform;¹
- ~~[(38) 'Union training' means activities for the personnel of competent authorities and, where appropriate, for personnel of delegated bodies performing SoHO supervisory activities;]~~
- (41) 'critical ~~essential~~ SoHO': means a SoHO for which an insufficient supply will result in serious harm or risk of harm to patients **recipients' health**;

¹ Definition 33 'the SoHO compendium' maintains the same wording as proposed by the SE presidency in document 10846/23 and appears here to facilitate the comprehension.

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

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

CHAPTER VIII

SUPPLY CONTINUITY

Article -62

Critical SoHO supply sufficiency

- 1. Member States, in collaboration with SoHO National Authorities and SoHO entities within their respective tasks, shall make all reasonable efforts within their territories to ensure a sufficient, adequate and resilient supply of critical SoHOs and to ensure that recipients needs are appropriately met.**
- 2. Member States shall make all reasonable efforts to facilitate public participation in SoHO donation activities for critical SoHOs, with a view to ensuring a broad SoHO donor base and a sufficient and resilient supply and responsive increases in donation rates when risks of shortage are detected, in accordance with Article 54. In so doing, they shall encourage the collection of SoHO with a strong public and non-profit sector involvement.²**
- 3. Member States shall establish appropriate mechanisms for the continuous monitoring of the supply continuity of critical SoHOs within their territory.**

² For clarification, the Presidency is presenting the changes made to the original text of Article 62(2) which were moved here:

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

Establishment of National SoHO emergency plans

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

In developing national SoHO emergency plans, Member States shall ensure cooperation and consultation, as appropriate, with their health surveillance bodies, military medical services, civil protection services and other services routinely involved in emergency responses. Member States shall implement national SoHO emergency plans in coordination with other response actions at national or Union level, if adopted, and, where relevant, in a manner consistent with the national prevention, preparedness and response plans developed in accordance with Article 6 of Regulation (EU) 2022/2371 and Directive (EU) 2022/2557.

- ~~2. Member States shall make all reasonable efforts to promote public participation in SoHO donation activities, in particular for critical SoHOs, with a view to ensuring a resilient supply and responsive increases in donation rates when risks of shortage are detected. In so doing, they shall encourage the collection of SoHO with a strong public and non-profit sector involvement.~~
3. Member States shall **draw up the plans referred to in paragraph 1 laying down the following elements**~~specify the following in the plans referred to in paragraph 1:~~
 - (a) potential risks to the supply of critical SoHOs;
 - (b) the **designation of** critical SoHO entities **and any other relevant third party to be involved in the supply of critical SoHOs** ~~to be involved;~~
 - (c) the powers and responsibilities of SoHO competent authorities **in cases of emergency as referred to in paragraph 1;**

- (d) ~~channels and procedures for sharing~~ the information exchanged between SoHO National competent authorities ~~including competent authorities of other Member States and other parties concerned, as appropriate,~~ via the EU SoHO Platform;
- (e) ~~a procedure for the development of preparedness~~ and response measures ~~plans~~ for specific identified risks, in particular those concerning communicable disease outbreaks, war or terrorist attacks and environmental disasters;
- (f) a procedure for the assessment and authorisation in the context of an emergency situation and in accordance with paragraph 4, ~~when justified,~~ of requests from SoHO entities for derogations to the standards defined in Chapters VI and VII.

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

4. Member States shall ensure that any derogation granted in accordance with paragraph 3, point (f), is time-limited and is justified insofar as it implies risks that are lower than the risk of shortage of the critical specific SoHO.
5. Member States shall take into account the guidance of the ECDC, for emergencies related to epidemiological outbreaks, and of the guidelines published by the EDQM, for emergency planning in general.
6. Member States shall inform the critical SoHO entities of their national SoHO emergency plans and shall review every 4 years such ~~regularly their national SoHO emergency plans~~ in order to take into account changes in the designation of critical SoHOs entities, the organisation of SoHO competent authorities and the experience gained from implementing the plans and simulation exercises.

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

7. The Commission may adopt implementing acts describing:
- (a) rules for the establishment of the national SoHO emergency plans provided for in paragraph 1 to the extent necessary to ensure the consistent and effective management of supply interruptions;
 - (b) the role of stakeholders and the supportive role of the ECDC in the establishment and operation of national SoHO emergency plans.

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

Article 63

Supply alerts for critical SoHOs

1. Critical SoHO entities shall, without undue delay, ~~send~~~~launch~~ a SoHO supply alert to their **SoHO** competent authorities in case of a significant interruption **of supply of critical SoHOs**, indicating the underlying reasons, the expected impact on **recipients** patients and any mitigating actions taken, including possible alternative supply channels if appropriate. Interruptions shall be considered significant when:
 - (a) the application of critical SoHO or the distribution of critical SoHO for the manufacture of products defined in other Union legislation, as referred to in Article 2(3), is cancelled or postponed, or significantly risks to be cancelled or postponed, due to unavailability; and
 - (b) The situation referred to in point (a) ~~this~~ poses a serious risk to health.
2. **SoHO** ~~€~~competent authorities that receive an alert referred to in paragraph 1 shall:
 - (a) communicate the SoHO supply alert to their SoHO National Authority;
 - (b) implement **appropriate** measures to mitigate the risks, ~~if and~~ to the extent possible; and

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

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

Article 64

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

1. By way of derogation from Article 21, SoHO competent authorities may permit, on a request from a SoHO entity duly justified by a health emergency, the distribution or preparation for immediate application of SoHO preparations within their territory in cases where the procedures referred to in that Article have not been carried out, provided that:
- (a) the use of those SoHO preparations is in the interest of public health;
 - (b) the SoHO preparations have a level of quality and safety equivalent to that required by this Regulation; and,
 - (c) the SoHO preparation is for immediate application to a specific recipient, who has no therapeutic alternative, the treatment cannot be postponed and where the recipient's prognosis is life-threatening, and the benefit outweighs the risks.

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

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

- (a) indicate the period of time for which ~~the permission~~ the permit referred to in paragraph 1 is granted ~~or shall define conditions enabling to clearly establish that period of time;~~

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

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

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

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

Article 65

~~Additional emergency measures by Member States~~

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

Article 66

SoHO entity emergency plans

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

CHAPTER IX

SOHO COORDINATION BOARD

Article 67

SoHO Coordination Board

1. The SoHO Coordination Board is hereby established in order to promote coordination between Member States concerning the implementation of this Regulation and the delegated and implementing acts adopted pursuant to it, and to support them in that coordination, as well as to facilitate cooperation with stakeholders in that regard.
2. Each Member State shall nominate two permanent members and two alternates representing the SoHO National Authority and, where the Member State chooses, the Ministry of Health **or other relevant bodies**. The SoHO National Authority may nominate members from other competent authorities, but those members shall ensure that the views and suggestions they make are endorsed by the SoHO National Authority. The Board may ~~also~~ invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate.

The board may also invite, where relevant, other Union institutions, bodies, offices and agencies. In such cases, they shall have an observer ~~role~~ **status**.

3. Member States shall submit the names and affiliation of their nominated members, **together with one declaration of interest for any member stating the absence of any financial or other interest,** to the Commission, ~~who~~. **The Commission** shall publish **in the EU SoHO Platform** the membership list, **the name, the institution of origin and the declaration of interest of each nominated member** ~~in the EU SoHO Platform~~.
4. The Commission shall **co-chair** the meetings of the SCB **together with the SoHO National Authority of a Member State, rotating in turn**. ~~The chair shall not take part in votes of the SCB.~~

5. The Commission shall provide the secretariat for the SCB in accordance with Article 72.
- 5a. The **SCB shall deliberate by consensus as far as possible. If consensus cannot be achieved, the SCB shall deliberate and adopt an opinion or other positions by, at least, a majority of two thirds of the votes of all the Member States, rounded up to the following integer number when the result is not an integer number. The representative of the Commission co-chairing the SCB shall not take part in votes of the SCB. Each Member State shall have one vote.**
6. **When establishing the SCB, the** rules of procedure of the SCB **shall be** put forward by the Commission, **and shall be approved by the SCB within the first semester of functioning. They** shall, in particular, lay down procedures for the following:
- (a) meeting scheduling;
 - (b) ~~reaching consensus~~ **deliberating** and voting;
 - (c) the adoption of opinions or other positions, including in cases of urgency;
 - (d) **submission of** requesting **for** advice to the SCB, ~~including eligibility criteria for requests for advice to the SCB,~~ and for other communications ~~with~~ **to** the SCB;
 - (e) consultation **procedures** with advisory bodies established under other relevant Union legislation;
 - (f) the delegation of ~~routine~~ tasks to working groups, including on vigilance, inspection, traceability, and on the applicability of the provisions of this Regulation;
 - (g) the delegation of ad-hoc tasks to SCB members or technical experts to explore and report to the SCB on specific technical topics, as required;
 - (h) invitation of experts to take part in the work of the SCB working groups and or to contribute to ad-hoc tasks, on the basis of their personal experience and expertise or on behalf of recognised Union level or global professional associations;
 - (i) invitation of individuals, organisations, or public entities in the capacity of observers;

- (j) the rules for declarations regarding conflict of interests of invited experts;
 - (k) the composition and rules of procedure for the working groups and the delegation of ad-hoc tasks.
7. The Commission shall, by means of implementing acts, adopt the necessary measures for the establishment, **and** management ~~and functioning~~ of the SCB.

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

Article 68

Tasks of the SoHO Coordination Board

1. The SCB shall assist ~~the Member States'~~ **SoHO** competent authorities regarding ~~any issue related to the coordination of~~ **ed** implementation of this Regulation and the implementing and delegated acts adopted pursuant to it, by:
- (a) preparing opinions, at the request of **SoHO** competent authorities, **via their SoHO National authorities,** in accordance with Article 14(2) first sub-paragraph, on the regulatory status under this Regulation of a substance, product or activity and ~~transmitting its~~ **including such** opinions ~~to~~ **in the SoHO compendium. By [... years after the data of publication of this Regulation] the SCB shall draw up a list of the existing products, substances, or activities for which an opinion on the regulatory status under this Regulation has not been prepared,;**
 - (b) when preparing the opinions referred to in point (a) of this paragraph, initiating, at Union level, a consultation with equivalent advisory bodies established in other relevant Union legislation in accordance with Article 14(2) second sub-paragraph, and including in the compendium the opinions concerning the Union legislation to be applied in cases where there is agreement with the equivalent advisory bodies;

- (c) ~~exchanging and documenting best practices on the implementation of the SoHO supervisory activities, and publishing agreed and documented best practices on the~~ **implementation of SoHO supervisory activities on the** EU SoHO Platform;
- (d) recording information notified in accordance with Article 14(3), and including such information in the **SoHO** compendium;
- (da) define criteria of ‘critical SoHO’ and the criteria to be qualified as critical SoHO entity, and review and update those criteria on the EU SoHO Platform;**
- (db) documenting practices among Member States for establishing the conditions for compensation as referred to in article 54(2);**
- (dc) providing assistance and advice for the cooperation between SoHO competent authorities and other competent authorities, with a view to ensuring coherent oversight when SoHOs change regulatory status, as provided for in article 14(5);**
- (dd) providing advice on the minimum necessary evidence for the authorisation of a particular SoHO preparation, as referred to in article 22(4);**
- (e) liaising for the exchange of experience and good practices, as relevant, with the EDQM and the ECDC regarding technical standards, and with the EMA on authorisations and supervisory activities concerning the implementation of the PMF certification pursuant to Directive 2003/63/EC, to support the harmonised implementation of standards and technical guidelines;
- (f) collaborating for the effective organisation of joint inspections and joint SoHO preparation ~~authorisations~~ **assessment** involving more than one Member State;
- (fa) providing advice to the Commission on the functional specifications of the EU SoHO platform;**
- (g) providing assistance in other matters related to the coordination as referred to above.

2. The Commission may adopt implementing acts describing criteria and procedures for the consultation of advisory ~~bodies~~^{groups} established under other relevant Union legislation **in the performance of the SCB tasks.**

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

CHAPTER X

UNION ACTIVITIES

Article 69

Union training and exchange of SoHO competent authorities' personnel

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

~~In the Union training organised, the Commission shall cover at least, the following topics, as appropriate:~~
 - ~~(a) the implementation of this Regulation;~~
 - ~~(b) procedures relevant for the SoHO supervisory activities of the competent authorities;~~
 - ~~(c) the functionality and use of the EU SoHO Platform;~~
 - ~~(d) other knowledge and skills relevant to facilitate SoHO supervisory activities.~~
2. The Commission may provide Union training to personnel of **SoHO** competent authorities of EEA Member States, ~~and~~ of countries that are applicants or candidates for Union membership and to personnel of bodies to whom specific responsibilities for SoHO **supervisory** activities have been delegated. It may organise aspects of the training in collaboration with international organisations and regulators working in the field of SoHOs.
3. **SoHO** ~~C~~competent authorities shall ensure that the knowledge **and materials** acquired through the Union training activities referred to in paragraph 1 of this Article ~~is~~ **are** disseminated as necessary and appropriately used in the personnel training activities referred to in Article 169.

4. The Commission may support, in cooperation with the **SoHO National Authorities** ~~Member States~~, the organisation of programmes for the exchange of **SoHO** competent authorities' personnel between two or more Member States and for the temporary secondment of personnel from one Member State to the other as part of personnel training.
5. The Commission shall maintain a list of the **SoHO** competent authority personnel that have successfully completed the Union training referred to in paragraph 1, with a view to facilitating joint activities, in particular those referred to in Articles 23, 31, and ~~70~~⁴. The Commission shall make this list available to the **SoHO National Authorities** ~~Member States~~.
6. ~~The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this Regulation by laying down rules on the organisation of the training activities referred to in paragraph 1 and of the programmes referred to in paragraph 4.~~

Article 69a

Information exchange

The Commission shall hold regular meetings with the SoHO National Authorities designated by the Member States, delegations of experts designated by the Member States and other relevant parties to exchange information on the experience acquired.

Article 70

Commission verification~~controls~~ in Member States

1. The Commission shall perform **verifications to confirm whether** ~~controls, including audits, in the Member States~~ **effectively apply** ~~to verify the effective application of the requirements relating to:~~
 - (a) **SoHO** competent authorities and delegated bodies provided for in Chapter II;
 - (b) the SoHO supervisory activities ~~provided for in Chapter III~~ as carried out by **SoHO** competent authorities and delegated bodies;

- (c) the notification and reporting requirements of this Regulation.
2. The Commission shall organise the ~~controls~~ **verifications** referred to in paragraph 1 in cooperation with the **SoHO National Authorities** Member States, and shall carry them out in a manner that avoids unnecessary administrative burden.
3. When performing the ~~controls~~ **verifications** referred to in paragraph 1, the Commission experts shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c), on ~~inspection, vigilance and any other~~ SoHO supervisory activities ~~as needed~~.
4. ~~Experts from the Member States may assist~~ **The Commission experts**, in carrying out the ~~controls~~ **verifications** referred to in paragraph 1, **may be supported by experts from the SoHO competent authorities**. ~~The Commission shall select~~ **ed** ~~the experts from the Member States, whenever possible, from the list referred to in Article 69(5), and~~. **Experts from the SoHO competent authorities** shall **be given** them same rights of access as the Commission experts.
5. Following each **verification** ~~control~~, the Commission shall:
- (a) prepare a draft report on the findings and, where appropriate, include recommendations **addressing** ~~on how best to address~~ the shortcomings **identified**;
 - (b) send a copy of the draft report referred to in point (a) to the concerned **SoHO National Authority** ~~Member State~~ for its comments;
 - (c) take the comments ~~of the Member State~~ referred to in point (b) into account in preparing the final report; and
 - (d) make publicly available **a summary of** the final report **on the EU SoHO platform** ~~referred to in point (e) and the comments of the Member State referred to in point (b)~~.

Article 71

Cooperation with the EDQM

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

Article 72

Assistance by the Union

1. To facilitate the fulfilment of the requirements provided for in this Regulation, the Commission shall support implementation by:
 - (a) providing secretariat and technical, scientific and logistic support to the SCB and its working groups;
 - (b) funding Commission verification~~controls~~ in Member States, including the costs of Member State experts assisting the Commission ~~in such controls~~;
 - (c) providing funding from the relevant Union programmes in support of public health to:
 - (i) support collaborative work between SoHO competent authorities and organisations representing groups of SoHO entities and SoHO professionals with the aim to facilitate effective and efficient implementation of this Regulation, including for training activities referred to in article 69(1) and programmes for the exchange of SoHO competent authorities' personnel referred to in article 69(4);
 - (ii) co-finance a cooperation agreement with the EDQM to support the development and updating of technical guidelines ~~supporting~~ in order to support the ~~coherent~~ consistent implementation of this Regulation.

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

2. With regard to the support referred to in paragraph 1, point (a), the Commission shall, in particular, organise the meetings of the SCB and its working groups, **the meetings with SoHO National Authorities**, the travel of members of the SCB, reimbursement and special allowances for scientific experts that participate in those meetings, ~~and ensure the appropriate follow-up.~~
3. Upon request from Member States, technical support may be provided, through the Technical Support Instrument established by Regulation (EU) 2021/240 of the European Parliament and of the Council³, for the reform of national or regional SoHO supply supervision, provided those reforms aim to achieve compliance with this Regulation.
4. In order to perform the activities referred to in paragraph 1 to the mutual benefit of the Commission and of the beneficiaries, relating to preparation, management, monitoring **and verifications**, ~~audit, and control~~, as well as to support expenditure, the Commission shall have recourse to the technical and administrative assistance it might need.

³ Regulation (EU) 2021/240 of the European Parliament and of the Council of 10 February 2021 establishing a Technical Support Instrument (OJ L 57, 18.2.2021, p. 1).

CHAPTER XI

EU SoHO PLATFORM

Article 73

Establishment, management and maintenance of the EU SoHO Platform

1. The Commission shall establish, manage and maintain ~~the~~ **a digital platform** ~~EU SoHO Platform~~ to facilitate effective and efficient exchange of information concerning SoHO activities in the Union, as provided for in this Regulation **(‘EU SoHO Platform’)**.
2. ~~The Commission shall make a summary of data of public interest and make it accessible to the public on the EU SoHO Platform in aggregated and anonymised formats. The EU SoHO Platform shall provide a channel for restricted exchange of information and data between competent authorities, and between SoHO entities and their respective competent authorities.~~
3. The processing of personal data, **including health data,** by the **SoHO entities, the SoHO competent authorities, the** Member States and the Commission through the EU SoHO Platform ~~and any one of its components~~ shall only be carried out **in cases where it is necessary for the performance of the tasks, the achievement of the objectives and the fulfilment of obligations as laid down in this Regulation. The processing of personal data shall be carried out in accordance with the applicable Union data protection legislation** ~~for the purpose of performing SoHOs related activities in accordance with this Regulation and in compliance with the applicable data protection legislation.~~
4. The Commission, **after having consulted the SCB,** shall adopt delegated acts in accordance with Article 77 supplementing this Regulation by laying down technical specifications regarding the ~~establishment,~~ management and maintenance of the EU SoHO Platform.

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

Article 74

General functionalities of the EU SoHO Platform

1. The EU SoHO Platform shall enable SoHO entities, **SoHO** competent authorities, Member States and the Commission to process information, data and documents concerning SoHOs **and SoHO activities**, including the submission, retrieval, storage, management, handling, exchange, analysis, publication and deletion of such data and documents as provided for in this Regulation.
2. The EU SoHO platform shall ~~also provide~~ **a channel for restricted** ~~a secure environment for the exchange of information~~ **and data:**
 - (a) **between Member States' SoHO National Authorities;**
 - (b) **between two SoHO competent authorities within the Member States or between a SoHO competent authority and its SoHO National Authority;**
 - (c) **between SoHO National A** ~~competent authorities~~ and the Commission, in particular in relation to **activity data concerning SoHO entities, the summaries of notifications and investigation reports of confirmed SAR or SAE, SAO SoHO and rapid alerts and SoHO supply alerts;**
 - (d) **between SoHO National Authorities and the SCB; and**
 - (e) **between SoHO National Authorities and the ECDC for SoHO rapid alerts related to communicable diseases, according to article 36(3).**

The EU SoHO platform shall also provide a secure communication channel for the exchange of information between SoHO entities and their respective SoHO competent authorities, when the SoHO competent authorities choose to use the EU SoHO Platform for such exchanges.

2a. The EU SoHO Platform shall ~~It shall also~~ provide public access to information regarding:

- (a) the registration and authorisation status of SoHO entities and ~~the SoHO~~ establishment identification code;**
- (b) SoHO preparations authorised;**
- (c) annual SoHO Activity Report and annual SoHO vigilance report, in aggregated and anonymised formats, after their approval by SoHO National Authorities;**
- (d) relevant best practices agreed and documented by the SCB;**
- (e) technical guidelines for quality management published by the EDQM;**
- (f) the name, the institution of origin and the declaration of interest of each SCB member;**
- (g) the SoHO compendium;**
- (h) the conditions established in national legislation for reimbursement or allowances, including the setting of an upper limit to SoHO donors for losses related to their participation in SoHO donations.**

The EU SoHO Platform shall **also** indicate the applicable guidelines to be followed to meet the technical standards laid down in Articles 56 and 59.

3. The Commission shall adopt implementing acts laying down technical specifications for the EU SoHO Platform, including its functions, the roles and responsibilities of each of the parties listed in paragraph 1, the retention periods for personal data and the technical and organisational measures to ensure the safety and security of personal data processed, **including health data**.

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

CHAPTER XII

PROCEDURAL PROVISIONS

Article 75

Confidentiality

1. Unless otherwise provided for in this Regulation or in national legislation on confidentiality, and without prejudice to Regulation (EC) No 1049/2001 of the European Parliament and of the Council⁴, each party involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:
 - (a) ~~personal data, including health data, in accordance with Article 76;~~
 - (b) ~~the effective implementation of this Regulation, in particular for the purpose of authorisations, inspections, investigations or Commission controls~~ **verifications**.
2. Information may be exchanged on a confidential basis between **SoHO** competent authorities and between **SoHO** competent authorities and the Commission, ~~but~~ **and** shall not be disclosed without the prior agreement of the authorities from whom that information originates.
3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and **SoHO** competent authorities with regard to the exchange of information and the dissemination of alerts, nor the obligations of persons to provide information under national criminal law.

⁴ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries **with which they have concluded bilateral or multilateral confidentiality arrangements**, as necessary and proportionate for the protection of human health.
5. **Without prejudice to national legislation on the publication of the outcome of SoHO supervisory activities, SoHO** Competent authorities may publish or make otherwise available to the public the outcome of SoHO supervisory activities regarding individual SoHO entities provided that the following conditions are met:
- (a) the SoHO entity concerned is given the opportunity to comment on the information that the **SoHO** competent authority intends to publish or make otherwise available to the public, prior to its publication or release, taking into account the urgency of the situation;
 - (b) the information which is published or made otherwise available to the public takes into account the comments expressed by the SoHO entity concerned or is published or released together with such comments;
 - (c) the information concerned is made available in the interest of public health protection and is proportionate to the severity, extent and nature of the associated risk;
- (ca) the information or data made available to the public does not unnecessarily undermine the protection of commercial interests of a SoHO entity or any other natural or legal person;**
- (cb) the information or data made available to the public does not undermine the protection of court proceedings and legal advice.**

6. Regarding information or data that is, by its nature, covered by professional secrecy and that is obtained by competent authorities in carrying out SoHO supervisory activities, **SoHO** competent authorities may only publish or make that information or data available to the public, **without prejudice to national legislation**, provided that the **conditions described in paragraph 5 points (c) apply**. ~~following conditions are met:~~
- (a) ~~the information or data made available to the public is in the interest of public health protection and is necessary and proportionate to the severity, extent and nature of the associated risk;~~
- (b) ~~the information or data made available to the public does not unnecessarily undermine the protection of commercial interests of a SoHO entity or any other natural or legal person;~~
- (c) ~~the information or data made available to the public does not undermine the protection of court proceedings and legal advice.~~
7. ~~The provisions of this Article shall also apply to delegated bodies.~~

Article 76

Data protection

- 1. Member States shall apply Regulation (EU) 2016/679 to the processing of personal data, including health data, carried out in the Member States pursuant to this Regulation.**
- 1a. Regulation (EU) 2018/1725 shall apply to the processing of personal data, including health data, carried out by the Commission pursuant to this Regulation.**

1. Personal data required for the application of Articles 5(5) and ~~610(2a)~~, ~~Article 18(3), point (a)~~, Articles 19(2) and 21(3), Article 27(2), ~~Article 28(2)~~, Articles 35 and 36, Article 53(1), points (f) and (g), Article 53(3), Article 58(11), and Articles 63 and ~~75~~ shall be collected for the purpose of identifying the relevant contact persons within the relevant SoHO entities, **SoHO** competent authorities or delegated bodies, and shall only be processed further for the purpose of ensuring the administration and transparency of the supervisory activities and SoHO activities concerned.
2. Personal data, including data concerning health, required for the application of Articles ~~74~~ **73** and ~~75-74~~ shall, **where absolutely necessary**, be processed in the interest of public health and, ~~in particular~~, for the following **purposes**:
 - (a) to help to identify and evaluate risks associated with a particular SoHO donation or SoHO donor;
 - (b) to process relevant information on clinical outcome monitoring.

2a. Personal data at an individual level shall not be exchanged with regulatory authorities nor entities of third countries.

3. Personal data, including data concerning health, required for the application of Articles 35, 36, 41, **45** and 47, Article 53(1), points (f) and (g), Article 53(3), and Article 58(11), (13) and (14), shall only be processed for the purpose of ensuring safety and quality of SoHOs and protecting the concerned SoHO donors, SoHO recipients and offspring from medically assisted reproduction. Those data shall be directly related to the performance of the supervisory activities and SoHO activities concerned and be limited to the extent necessary and proportionate for that purpose.

4. All information shall be processed by the Commission, Member States, **SoHO** competent authorities, including SoHO National Authorities, delegated bodies and SoHO entities, including any third party contracted by a SoHO entity, as applicable, in such a way that the personal data of the subjects remain protected in accordance with the applicable legislation on personal data protection. ~~**They** The Commission, Member States, competent authorities, including SoHO National Authorities, delegated bodies and SoHO entities, including any third party contracted by a SoHO entity,~~ shall, in particular, minimise the risk that subjects can be identified and shall limit the information processed to elements necessary and appropriate for carrying out their tasks and fulfilling their obligations under this Regulation.
5. The Commission, Member States, **SoHO** competent authorities, including SoHO National Authorities, delegated bodies and SoHO entities, including any third party contracted by a SoHO entity, shall implement appropriate technical and organisational measures to protect information and personal data processed, **including health data**, against unauthorised or unlawful access, disclosure, dissemination, alteration, destruction or accidental loss, in particular where the processing involves transmission over a network.
6. In relation to their responsibilities to process personal data to comply with the obligations of this Regulation, the SoHO entities and **the SoHO** competent authorities of the Member States shall be regarded as controllers as defined in Article 4, point (7), of Regulation (EU) 2016/679 and they are bound by the rules of that Regulation.
7. In relation to its responsibility to establish and manage the EU SoHO Platform, as referred to in Article 73 and the processing of personal data, **including health data**, that might result from that activity, the Commission shall be regarded as controller as defined in Article 3, point (8), of Regulation (EU) 2018/1725 and it is bound by the rules of that Regulation.

8. For the purposes of this Article, the Commission is empowered to adopt delegated acts in accordance with Article 77 supplementing this Regulation by laying down the retention periods for personal data, **including health data**, as appropriate to their purpose and specific criteria that would allow identification of data relevant for public health protection as referred to in paragraph 2.

Article 77

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Articles 28(10), 42(3), 53(6), 58(15), 69(6), 73(4), and 76(8) shall be conferred on the Commission for an indeterminate period of time from ... [OP please insert the date = date of entry into force of this Regulation].
3. The delegation of power referred to in Articles 28(10), 42(3), 53(6), 58(15), 69(6), 73(4), and 76(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

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

Article 78

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 77(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

Article 79

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 80

Penalties

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

CHAPTER XIII

TRANSITIONAL PROVISIONS

Article 81

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

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

3. For blood establishments referred to in paragraph 1, **SoHO** competent authorities shall:
- (a) verify whether those establishments meet the definition of SoHO establishment in Article 3, point (40);
 - (b) submit the information referred to in Article ~~18(3)~~**37(1a)**, points (a) and ~~(d)~~, and information regarding the registration and authorisation status according to the verification referred to in point (a) of this paragraph to the EU SoHO Platform as referred to in Chapter XI.
4. For tissue establishments referred to in paragraph 1, the Commission shall:
- (a) verify whether those establishments meet the definition of SoHO establishment in Article 3, point (40);
 - (b) transfer the relevant information from the EU Tissue Establishment Compendium of the EU Coding Platform laid down in Directive 2006/86/EC, including the information regarding the registration and authorisation status according to the verification referred to in point (a) of this paragraph, to the EU SoHO Platform as referred to in Chapter XI of this Regulation;
 - (c) inform the **SoHO** competent authorities of the establishments that do not meet the definition of SoHO establishment according to the verification referred to in point (a).
5. **SoHO c**ompetent authorities shall inform those establishments not meeting the definition of SoHO establishment, according to the verification referred to in paragraph 3, point (a), and paragraph 4, point (a) and based on the information referred to in paragraph 4, point (c), that they are deemed to be registered as SoHO entities only and that they, as such, are subject to the obligations relevant for SoHO entities provided for under this Regulation.

5a. By derogation from paragraphs 3 and 4, SoHO entities carrying out SoHO activities for the purposes of public security, defence or military matters shall not be subject to publication requirements provided for in this Regulation.

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

Article 82

Transitional provisions concerning SoHO preparations

1. The preparations resulting from tissue and cell preparation processes designated, authorised, accredited or licensed on the basis of Article 6(2) of Directive 2004/23/EC before the date of application of this Regulation shall be deemed to be authorised as the corresponding SoHO preparations in accordance with this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.
2. Blood components that were verified by **SoHO** competent authorities as complying with applicable quality and safety requirements for blood components on the basis of Article 5(3) and Article 23 of Directive 2002/98/EC or with the blood component monographs included in the edition of the Guide to the preparation, use and quality assurance of blood components of the EDQM indicated on the EU SoHO Platform on ... [OP please insert the date = two years after the date of entry into force of this Regulation], or that were otherwise designated, authorised, accredited or licensed under national legislation before the date of application of this Regulation, shall be deemed to be authorised as the corresponding SoHO preparations in accordance with this Regulation and shall, as such, be subject to the relevant obligations provided for under this Regulation.
3. **SoHO c**Competent authorities shall submit the information referred to in paragraphs 1 and 2 to the EU SoHO Platform, and link those entries to the respective SoHO entities.

4. The Commission may adopt implementing acts in order to establish uniform procedures for ensuring that SoHO preparations deemed to be authorised pursuant to paragraphs 1 and 2 are fully documented in line with the requirements for SoHO preparation authorisation in this Regulation.

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

Article 82a

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

Entities carrying out one or more of the SoHO activities as listed in Article 2(1)(d), (e), (f), (g), (h), (i) and (l) with SoHOs not addressed expressly in Directives 2002/98/EC nor 2004/23/EC, before ...[OP please insert the date = date of application of this Regulation] shall be allowed to continue their activities regarding those SoHOs until [OP please insert the date = one year after the date of application of this Regulation], without applying this Regulation, except for the following requirements:

- (a) registration as SoHO entities pursuant to Article 37;**
- (b) application for SoHO preparation authorisation, where required pursuant to Article 40;**
- (c) application for a SoHO establishment authorisation, where required pursuant to Article 48;**
- (d) compliance with the standards referred to in Chapters VI and VII for the SoHO activities carried out during the transition phase.**

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

Article 83

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

1. SoHOs already released for distribution before ... [OP please insert the date = date of application of this Regulation] shall not be subject to the relevant obligations provided for under this Regulation, ~~provided those SoHOs are distributed at the latest by ... [OP please insert the date = one year after the date of application of this Regulation]~~ and under the condition that those SoHOs were fully compliant with the applicable Union legislation and national law in force at the time when those SoHOs were released for distribution.
2. SoHOs which have been distributed before ... [OP please insert the date = date of application of this Regulation] and kept under appropriate control conditions until that date shall not be subject to the relevant obligations provided for under this Regulation.
3. SoHOs already in storage before ... [OP please insert the date = date of application of this Regulation], and for which no alternative SoHOs are available, in particular because the SoHOs are autologous, intended for within couple use or highly matched for a specific recipient, shall only be subject to Article 61. Those SoHOs shall be subject to that Article from... [OP please insert date = date of application of this Regulation].

Article 84

Transitional measures for the adoption of certain delegated and implementing acts

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

CHAPTER XIV

FINAL PROVISIONS

Article 85

Repeals

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

Article 86

Evaluation

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

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

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

Article 87

Entry into force and application

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

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

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

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President
