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From:	Presidency
To:	Delegations
Subject:	Proposal for a Regulation of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC <i>- Presidency compromise proposal</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 2 June 2023.

Text marked in **bold and underlined** and in ~~striketrough~~ reflects changes made in this text compared to the Commission proposal.

The Presidency's explanations of amendments made in the articles in the first compromise proposal for Chapter II will be provided during the discussions at the Working Party. The text contains three footnotes which are meant to clarify specific presentational aspects of the text to Delegations.

CHAPTER II

COMPETENT-MEMBER STATES' SoHO AUTHORITIES*Article 5***Designation of SoHO ~~competent~~ authorities**

1. Member States shall designate the competent authority or authorities ~~to-on~~ 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~~ more than one competent authority, at national, regional or local level.
3. Member States shall ensure that 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** confidentiality obligations in accordance with Article 75.
4. Each Member State shall designate a single SoHO National Authority, in **accordance with national law**, ~~conformity with Member States' constitutional requirements~~, responsible for ~~coordinating exchanges with the Commission and with other Member States' SoHO National Authorities~~ **the activities set out in Article 9(1a)**.
5. Member States shall submit to the EU SoHO Platform ~~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 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,** ~~Competent~~ authorities shall act independently **and impartially**, in the public interest and free from any external influence.
2. Competent authorities shall ensure that their personnel have no direct or indirect economic, financial or personal 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, competent authorities shall carry out their SoHO supervisory activities they have been made responsible for in a transparent manner. In particular, and they shall make any enforcement decision taken, and the reasons for it, accessible and clear to the public ~~decisions taken~~ in cases where a SoHO entity has failed to comply with any of its obligations under this Regulation and where such failure ~~causes or may cause~~ poses a serious risk to human health.
2. Paragraph 1 shall ~~not affect~~ be without prejudice to national legislation on access to information.
3. 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. 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~~ on their territory with the requirements set out in this Regulation.
 - 1a. The SoHO National Authority shall be responsible for coordinating the information exchanges with the Commission, with other Member States' SoHO National Authorities and between authorities in the Member State, provided for in Articles 4(2), 13(1), (2) and (4), 14(1), (2) and (3), 28(3), 63(2) and (3), 64(2), as well as for carrying out the tasks set out in articles 18(1), (2) and (4), 35(10) and (11), and 67(2).

2. 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 confidentiality and maintain professional secrecy;

(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 **in place** for their SoHO supervisory activities 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 bodies

-1a. A Member State may enable a competent authority made responsible for any SoHO supervisory activity as set out in Articles 22, 23, 29, 30, 31, 33(1), 34, 35-(2), (4) and (5) to delegate that SoHO supervisory activity to one or more delegated bodies, provided that the delegated body has the legal powers needed to effectively perform the activities delegated to it.

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

~~2.1~~—Competent authorities shall ensure that ~~the~~ **such a written** agreement ~~referred to in paragraph 4~~ includes 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;~~
 - ~~(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;~~

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

- (c) a precise description of **the** arrangements ensuring an efficient and effective coordination between the delegating 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. 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 ~~6~~ **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 competent authorities, on a regular basis and whenever those **delegating** competent authorities so request, **of** the outcome of the SoHO supervisory activities performed by them;
- (b) immediately inform the delegating competent authorities whenever the outcome of the delegated SoHO supervisory activities indicates non-compliance or points to the likelihood of non-compliance, unless specific arrangements established between those **delegating** competent authorities and the delegated bodies provide otherwise; and

- (c) **fully** cooperate with the delegating competent authorities, including by providing access to their premises ~~and facilities~~ **and documentation**.

2. Articles 7, 15 and 75 shall apply to delegated bodies and Articles 24 and 32 shall apply insofar as they are relevant for the delegated activities.

Article 12

Obligations of the delegating competent authorities

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 ~~and 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 competent authority, taking into account 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~~ **been** compromised.

Communication and coordination between ~~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~~SoHO National Authority shall ensure efficient and effective coordination between all ~~SoHO~~the competent authorities ~~involved~~concerned, in order to ~~ensure~~guarantee consistency and effectiveness of ~~the~~ SoHO supervisory activities ~~as set by this Regulation across~~performed on its territory.
2. **Within a Member State**, ~~C~~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~~.
3. In cases where a 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 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 request from ~~a competent~~the SoHO National Authority of another Member State, the ~~competent~~SoHO National Authority shall without undue delay 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.

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 here, the full name would be shown.

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, on the one hand, and the competent authorities for organs designated under Directive 2010/53/EU and the competent authorities designated under other Union legislation referred to in Article 2(3), on the other hand.

1. In all cases where questions arise as to the regulatory status of a substance, product or activity, **the 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, competent authorities **in the SoHO sector involved in the consultation** shall also consult the **SoHO compendium referred to Article 3 point (33) and take into account any relevant regulatory status decision or opinion included in the SoHO compendium.**
2. In the course of the consultation referred to in paragraph 1, the 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 competent authorities** ~~and~~ shall do so in all cases where ~~the competent authorities, after~~ **following** the consultations referred to in paragraph 1, **they** are not in a position to take a decision ~~in that respect~~ **on the regulatory status.** **The 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 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 consult, before issuing its opinion and** in accordance with Article 68(1), point (b), with the **relevant** equivalent advisory bodies established in other relevant Union legislation referred to in Article 2(3).

3. **When a consultation leads to a consensus decision,** ~~The competent~~ **SoHO National** ~~authorities~~ shall inform the SCB of the subsequent **regulatory status** decision taken in ~~their~~ **its** Member State, ~~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** on its own initiative, by means of implementing acts, determine the regulatory status of a substance, product or activity under this Regulation, in case questions arise in that respect, 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 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 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 competent authorities may seek the assistance **and advice** of the SCB **concerning 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 opinion²~~ from a SoHO entity, as referred to in Article 40.

6a. In case a competent authority in the SoHO sector takes any enforcement decision concerning a SoHO entity that also performs activities regulated under other Union legislation and overseen by competent authorities as referred to in paragraph -1a, the 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 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 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.~~

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

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

- (a) take appropriate follow-up measures to remedy the shortcomings identified through suchthe controls ~~provided for in Article 70~~;
- (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 controls efficiently and effectively, including facilitating ÷ and
- (c) ~~give the necessary assistance to ensure that the Commission experts have access to all premises or part of premises, and to information, including IT systems, relevant for the execution of their duties.~~