Council of the European Union

Brussels, 26 November 2026
(OR. en)

16447/26

SAN 837
DELACT 182

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	25 November 2026
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2026) 8185 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... supplementing Regulation (EU) 2024/1938 of the European Parliament and of the Council as regards obligations and procedures for establishments importing substances of human origin

Delegations will find attached document C(2026) 8185 final.

Encl.: C(2026) 8185 final

EUROPEAN
COMMISSION

Brussels, 25.11.2026
C(2026) 8185 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 25.11.2026

supplementing Regulation (EU) 2024/1938 of the European Parliament and of the Council as regards obligations and procedures for establishments importing substances of human origin

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT AND LEGAL ELEMENTS OF THE DELEGATED ACT

Article 47(4) of Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 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[1], empowers the European Commission to adopt delegated acts in accordance with Article 77 of that Regulation, to supplement that Regulation by laying down obligations and procedures for importing substances of human origin (SoHO) establishments regarding the import of SoHO in order to verify equivalent standards of quality, safety and effectiveness of such imports.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In line with paragraph 4 of the Common Understanding on Delegated Acts between the European Parliament, the Council and the European Commission, annexed to the Interinstitutional Agreement on better law-making of 19 April 2016[2], appropriate and transparent consultations, including at expert level, have been carried out in the preparation of this delegated act.

Member States' experts were consulted in the context of the Expert Group 'Competent Authorities on Substances of Human Origin'[3] that met on 4 March 2026.

1 OJ L, 2024/1938, 17.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj.
2 OJ L 123, 12.5.2016, p. 1.
3 Reference E01718 in the Register of Commission Expert Groups and other similar entities.

COMMISSION DELEGATED REGULATION (EU) …/...

of 25.11.2026

supplementing Regulation (EU) 2024/1938 of the European Parliament and of the Council as regards obligations and procedures for establishments importing substances of human origin

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 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[1], and in particular Article 47(4) thereof,

Whereas:

(1) Pursuant to Regulation (EU) 2024/1938, imported substances of human origin (SoHO) are to be equivalent, in terms of quality, safety and effectiveness, to SoHO originating in the Union.

(2) In particular, considering that effectiveness of SoHO means the extent to which the human application of SoHO achieves the intended biological or clinical outcome in the SoHO recipient, verification of equivalence of effectiveness is relevant when SoHO preparations are imported, but not when SoHO other than SoHO preparations are imported.

(3) Pursuant to Article 48(2) of Regulation (EU) 2024/1938, importing SoHO establishments are to put in place written agreements with their third-country suppliers. Those agreements are to specify, among other things, the requirements to be met to ensure the equivalence between SoHO to be imported and SoHO originating in the Union as regards the quality, safety and effectiveness. This Regulation supplements Regulation (EU) 2024/1938 in relation to the procedural step of putting in place written agreements by specifying the requirements to be included in those agreements to ensure that the equivalent standards of quality, safety and effectiveness are fully met.

(4) In order to ensure that imported SoHO preparations have a high level of quality, safety and effectiveness, the assessment of the application for authorisation of imported SoHO preparations is an essential part of the authorisation of an importing SoHO establishment. Therefore, the application for authorisation of such SoHO preparations should be submitted simultaneously with the application for the importing SoHO establishment authorisation.

(5) Regulation (EU) 2024/1938 does not prevent Member States from maintaining or introducing within their territories more stringent national measures on the condition

[1] OJ L, 2024/1938, 17.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj.

that those measures are compatible with Union law and are proportionate to the risk to human health including in the light of relevant scientific knowledge. To avoid imports of SoHO that are not compliant with the more stringent national measures applicable in the countries to which they will be distributed, it should be the responsibility of the importing SoHO establishment to verify compliance of imported SoHO with such measures.

(6) Pursuant to Article 46(2) and (3) of Regulation (EU) 2024/1938, SoHO establishments, including importing SoHO establishments, are to seek prior written authorisation for significant changes to the terms of the authorisation. Considering the particular characteristics of importing SoHO establishments, including activities performed in third countries, and in order to ensure the equivalence of the quality, safety and effectiveness of the imported SoHO, this Regulation should supplement Article 46(2) and (3) of Regulation (EU) 2024/1938 by specifying the significant changes that require prior written authorisation.

(7) In order to enable effective oversight, the competent authorities should be notified of certain changes other than significant changes or cases of critical non-compliance that may impact the quality, safety or effectiveness of imported SoHO, so that they can request or implement follow-up action.

(8) In addition to regular imports of SoHO, this Regulation should address situations where recipients who have had SoHO stored in a third country for autologous or within-relationship use request importing SoHO establishments to import those SoHO from a third-country supplier or third-country suppliers, where the importing SoHO establishments have no written agreement in place with that supplier or those suppliers and where those imports are not covered by the terms of their existing authorisation. Considering the one-off nature and limited scope of those requests, and to avoid unnecessary administrative burden, procedures should be established to exempt importing SoHO establishments from the requirements laid down in this Regulation in respect of written agreements and significant changes to the terms of their existing authorisation for one-off imports of SoHO intended for autologous or within-relationship use.

(9) As Regulation (EU) 2024/1938 applies from 7 August 2027, this Regulation should apply from the same date,

HAS ADOPTED THIS REGULATION:

Article 1

Written agreement

The written agreement referred to in Article 48(2) of Regulation (EU) 2024/1938 shall include the information listed in the Annex to this Regulation.

Article 2

Application for the authorisation of SoHO preparations and verification of the equivalence of quality, safety and effectiveness standards

1. Substances of human origin (SoHO) entities that intend to import SoHO preparations intended for human application shall submit, in accordance with Article 39 of Regulation (EU) 2024/1938, an application for authorisation of those SoHO preparations to the SoHO competent authority of the Member State where they are

based at the same time as the application for the authorisation of the importing SoHO establishment is submitted in accordance with Article 48 of that Regulation.

2. For each newly imported SoHO preparation, authorised importing SoHO establishments shall submit a self-standing application for a SoHO preparation authorisation.

3. The importing SoHO establishment shall supplement the verification of equivalence through audits of third country suppliers and, if applicable, sampling.

Article 3

Compliance with national measures

Before any import of SoHO takes place, the importing SoHO establishment shall verify whether the Member State where that establishment is based and where applicable, the Member States where the SoHO are intended to be distributed, have established more stringent measures referred to in Article 4 of Regulation (EU) 2024/1938, and shall take all necessary action to ensure compliance with such measures.

Article 4

Significant changes to the terms of the authorisation

Without prejudice to the requirements set out in Article 46(2) and (3) of Regulation (EU) 2024/1938, the importing SoHO establishment shall request prior written authorisation for significant changes related to:

(a) any modification of the imported SoHO preparations;

(b) the third-country supplier(s) and sub-contractor(s) of the third-country supplier(s);

(c) the donor testing applied in the third country, including any relevant national or international accreditation of the laboratories performing the donor testing in the third country;

(d) the relocation to new premises or the modification of the premises of the importing SoHO establishment;

(e) the relocation to new premises or the modification of the premises of the third-country supplier(s) having an impact on the conditions under which SoHO activities are carried out.

Article 5

Notification

The importing SoHO establishment shall notify, without delay, the SoHO competent authority of:

(a) any revocation or suspension, in part or full, of the authorisation of the third-country supplier(s) to export SoHO;

(b) any other decision taken by the authorities of the country in which the third-country supplier(s) is or are established, and which may be relevant to the quality, safety or effectiveness of imported SoHO;

(c) any critical non-compliance identified during an inspection of the third-country supplier(s) by the third-country authorities or any competent authority of the Union;

(d) any critical non-compliance identified during an audit of the third-country supplier(s) carried out by, or on behalf of, the importing SoHO establishment;

(e) its intention to distribute the imported SoHO in additional Member States other than the ones previously reported.

Article 6
Procedures for one-off imports

1. For the purposes of this Regulation, 'one-off import' means the one-time import of SoHO intended for autologous or within-relationship use in the intended recipient of those SoHO.

2. Importing SoHO establishments are not required to put in place a written agreement referred to in Article 1 for one-off imports, provided that the imported SoHO are not used in anyone other than the intended recipient of those SoHO.

3. Where an importing SoHO establishment undertakes a one-off import of SoHO originating from a third-country supplier or third-country suppliers not covered by the terms of its existing authorisation, that import shall not be considered as a significant change referred to in Article 4, if the importing SoHO establishment is authorised to import the same type of SoHO from another third-country supplier or other third-country suppliers.

Article 7
Entry into force and application

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

It shall apply from 7 August 2027.

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

Done at Brussels, 25.11.2026

For the Commission
The President
Ursula VON DER LEYEN