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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 annex
Subject:	ANNEX to the 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 annex.

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ANNEX

ANNEX

to the

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

ANNEX

Information to be included in the written agreement between the importing SoHO establishments and the third-country supplier(s) referred to in Article 1

The written agreement between the importing SoHO establishments and the third-country supplier(s) shall contain the following information:

(1) identification and contact details of the third-country supplier(s) and the sub-contractor(s) of the third-country supplier(s);

(2) the start date of the written agreement;

(3) the end date of the written agreement including the procedure for the renewal of the written agreement;

(4) the specifications set by the importing SoHO establishments – based on the technical guidelines published by the European Centre for Disease Prevention and Control and by the European Directorate for the Quality of Medicines & Health Care or on other guidelines referred to in Article 27(6) of Regulation (EU) 2024/1938, including, if applicable, tests to be performed – to be met by the third-country supplier(s) in order to ensure equivalent quality and safety of the SoHO, and, in case of SoHO preparations, also equivalent effectiveness, to the standards laid down in Regulation (EU) 2024/1938;

(5) the agreed roles and responsibilities of both parties in ensuring that the imported SoHO complies with equivalent quality and safety requirements, and in case of SoHO preparations, equivalent effectiveness requirements, including the agreed roles and responsibilities in providing the required information for an application for the authorisation of SoHO preparations;

(6) a clause ensuring that the third-country supplier(s) provide(s) the information enabling the importing SoHO establishment to comply with the requirements laid down in Annex I and point B of Annex II to Commission Implementing Regulation (EU) 2026/XXX.[1] [*OP please insert reference to C(2026)7800*];

(7) a clause ensuring that the third-country supplier(s) provide(s) the information that enables the verification of equivalence between the imported SoHO in terms of quality and safety and, in case of SoHO preparations, also in terms of effectiveness, and the SoHO authorised in accordance with Regulation (EU) 2024/1938;

(8) a clause ensuring that the third-country supplier(s) and the importing SoHO establishments, report to each other, pursuant to the technical guidelines referred to in point 4, any serious adverse events or reactions which may influence the quality and safety and, in case of SoHO preparations, also the effectiveness of the SoHO imported or to be imported by the importing SoHO establishments;

(9) a clause ensuring that the third-country supplier(s) inform(s) the importing SoHO establishments of any changes or updates specified in Articles 4 and 5;

(10) a clause ensuring that the competent authority or authorities in the Union has/have the right to inspect remotely or on-site the activities, including the facilities, of the third-country supplier(s) or entity/entities sub-contracted by those supplier(s),

[1] Commission Implementing Regulation (EU) 2026/XXX of XXX laying down rules for the application of Regulation (EU) 2024/1938 of the European Parliament and of the Council as regards the information to be provided in an application for authorisation as an establishment importing substances of human origin (OJ L, 2026/XXX, XXX, ELI: XXX).

during the duration of the written agreement and for a period of 2 years following its termination, and providing for the right of the importing SoHO establishments to regularly audit their third-country supplier(s);

(11) the agreed conditions to be met for the transport of the SoHO between the third-country supplier(s) and the importing SoHO establishments;

(12) a clause ensuring that donor records relating to the imported SoHO are kept by the third-country supplier(s) or its sub-contractor(s), pursuant to Regulation (EU) 2024/1938;

(13) provisions for regular review and, where necessary, revision of the written agreement, including in order to reflect any changes in the requirements of quality, safety and effectiveness laid down in Regulation (EU) 2024/1938,

(14) provisions for the termination of the written agreement in case of non-compliance;

(15) a clause ensuring that the third-country supplier(s) keep(s) an updated list of all procedures relating to the quality, safety and effectiveness of the SoHO imported or to be imported and a commitment to provide the list and the related documents on request and to notify, without delay, the importing SoHO establishments of the relevant changes in the procedures having a potential impact on the quality, safety and effectiveness, including changes in the tests to be performed;

(16) a clause ensuring that, where the SoHO is imported from a third country where one or more tests required by the technical guidelines referred to in point 4 are not performed, the third country supplier(s) provide(s) a sample allowing those tests to be performed by a SoHO entity.