Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Union and third countries in drug precursors

CHAPTER II

MONITORING OF TRADE

SECTION 1

Documentation and labelling

Article 3

[[F1]All imports, exports or intermediary activities involving scheduled substances, with the exception of substances listed in Category 4 of the Annex, shall be documented by the operator by way of customs and commercial documents, such as summary declarations, customs declarations, invoices, cargo manifests, transport and other shipping documents.**]**

Those documents shall contain the following information:

(a) the name of the scheduled substance as stated in the Annex, or, in the case of a mixture or a natural product, its name and the name of any scheduled substance, as stated in the Annex, contained in the mixture or in the natural product, followed by the term 'DRUG PRECURSORS';

(b) the quantity and weight of the scheduled substance and, in the case of a mixture or a natural product, the quantity, weight, and, if available, the percentage of any scheduled substance contained therein; and

(c) the names and addresses of the exporter, the importer, the ultimate consignee and, where applicable, the person involved in the intermediary activities.

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

Article 4

The documentation referred to in Article 3 shall be kept by the operators for a period of three years from the end of the calendar year in which the operation took place. The documentation shall be organised in such a way, electronically or in paper form, that it is readily available for inspection by the competent authorities upon request. The documentation may be provided via image medium or other data medium, provided that the data, when made readable, match the documentation in appearance and content, are available at all times, can be made readable without delay and can be analysed by automated means.

[F1 Article 5

Operators shall ensure that labels are affixed on any packaging containing scheduled substances, except substances listed in Category 4 of the Annex, indicating their name as stated in the Annex, or, in the case of a mixture or a natural product, its name and the name of any scheduled substance, except substances listed in Category 4 of the Annex, as stated in the Annex, contained in the mixture or in the natural product. Operators may, in addition, affix their customary labels.**]**

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

SECTION 2

Licensing and registration of operators

Article 6

[F1 1 Unless otherwise provided, operators established in the Union, other than customs agents and transporters when acting solely in that capacity, engaged in import, export or intermediary activities involving scheduled substances listed in Category 1 of the Annex, shall hold a licence. The competent authority of the Member State in which the operator is established shall issue the licence.

In considering whether to grant a licence, the competent authority shall take into account the competence and integrity of the applicant, in particular the absence of any serious infringement or repeated infringements of legislation in the field of drug precursors and the absence of a record of any serious criminal offence.

The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to set out the conditions for granting licences and for determining cases where a licence is not required.**]**

2 The licence may be suspended or revoked by the competent authorities whenever the conditions under which the licence was issued are no longer fulfilled or where there are reasonable grounds for suspecting that there is a risk of diversion of scheduled substances.

[F2 3 The Commission shall establish a model for licences by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).**]**

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

F2 Inserted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

[F1 Article 7

1 Unless otherwise provided, operators established in the Union, other than customs agents and transporters when acting solely in that capacity, engaged in import, export or intermediary activities involving scheduled substances listed in Category 2 of the Annex, or in the export of scheduled substances listed in Category 3 of the Annex, shall hold a registration. The competent authority in the Member State in which the operator is established shall issue the registration.

In considering whether to grant a registration, the competent authority shall take into account the competence and integrity of the applicant, in particular the absence of any serious infringement or repeated infringements of legislation in the field of drug precursors and the absence of a record of any serious criminal offence.

The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to set out the conditions for granting registrations and for determining cases where a registration is not required.

2 The competent authority may suspend or revoke the registration where the conditions under which the registration was issued are no longer fulfilled or where there are reasonable grounds for suspecting that there is a risk of diversion of scheduled substances.**]**

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

[F1 Article 8

1 When the scheduled substances are entered into the customs territory of the Union for unloading or transhipment, for temporary storage, for their storage in a free zone of control type I or a free warehouse, or for their placing under the external Union transit procedure, the licit purposes must be demonstrated by the operator, upon request by the competent authorities.

2 The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to establish the criteria to determine how the licit purposes of the transaction may be demonstrated, in order to ensure that all movements of scheduled substances within the customs territory of the Union can be monitored by the competent authorities and the risk of diversion be minimised.**]**

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

SECTION 3

Provision of information

[F1 Article 9

1 Operators established in the Union shall notify the competent authorities immediately of any circumstances, such as unusual orders and transactions involving scheduled substances, which suggest that such substances intended for import, export or intermediary activities might be diverted for the illicit manufacture of narcotic drugs or psychotropic substances.

To that end, operators shall provide any available information, such as:

a the name of the scheduled substance;

b the quantity and weight of the scheduled substance;

c the names and addresses of the exporter, the importer, the ultimate consignee and, where applicable, the person involved in the intermediary activities.

That information shall only be collected for the purposes of preventing the diversion of scheduled substances.

2 Operators shall provide the competent authorities with information in summary form about their export, import or intermediary activities.

The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to determine the information that is required by the competent authorities in order to allow them to monitor those activities.

The Commission shall specify by means of implementing acts the procedural rules on the provision of such information, including, where appropriate, in electronic form to the European database on drug precursors established under Regulation (EC) No 273/2004 of the European Parliament and of the Council[(1)] ('the European database'). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).**]**

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

Article 10

1 In order to facilitate cooperation between the competent authorities of the Member States, operators established in the **[**F1Union**]** and the chemical industry, in particular as regards non-scheduled substances, the Commission shall, in consultation with the Member States, draw up and update guidelines.

2 These guidelines shall provide, in particular:

a information on how to identify and notify suspect transactions;

b a regularly updated list of non-scheduled substances to enable the industry to monitor on a voluntary basis the trade in such substances.

3 The competent authorities shall ensure that the guidelines are regularly disseminated in accordance with the objectives of these guidelines.

[F2 4 In order to respond rapidly to new diversion trends, the competent authorities of the Member States and the Commission may propose to add a non-scheduled substance to the list referred to in paragraph 2(b) in order to temporarily monitor its trade. Detailed arrangements and criteria for the inclusion or deletion from that list shall be specified in the guidelines referred to in paragraph 1.

5 If voluntary monitoring by the industry is considered insufficient to prevent the use of a non-scheduled substance for the illicit manufacture of narcotic drugs or psychotropic substances, the Commission may add the non-scheduled substance to the Annex by means of delegated acts in accordance with Article 30b.**]**

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

F2 Inserted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

SECTION 4

Pre-export notification

Article 11

[F1 1 All exports of scheduled substances listed in Categories 1 and 4 of the Annex and exports of scheduled substances listed in Categories 2 and 3 of the Annex to certain countries of destination shall be preceded by a pre-export notification sent from the competent authorities in the Union to the competent authorities of the country of destination, in accordance with Article 12(10) of the United Nations Convention. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b of this Regulation to determine the lists of the countries of destination for export of scheduled substances listed in Categories 2 and 3 of the Annex in order to minimise the risk of diversion of scheduled substances.**]**

The country of destination shall be allowed a period of 15 working days to reply, at the end of which the export operation may be authorised by the competent authorities of the Member State of export, if no advice from the competent authorities of the country of destination is received indicating that this export operation might be intended for the illicit manufacture of narcotic drugs or psychotropic substances.

2 In the case of the scheduled substances to be notified in accordance with paragraph 1, the competent authorities of the Member State concerned shall, prior to the export of such substances, supply the information specified in Article 13(1) to the competent authorities of the country of destination.

The authority supplying such information shall require the authority in the third country receiving the information to keep confidential any trade, business, commercial or professional secret or any trade process referred to therein.

[F1 3 Simplified pre-export notification procedures may be applied by the competent authorities where they are satisfied that this will not result in any risk of diversion of scheduled substances. The Commission shall be empowered to adopt delegated acts in accordance with

Article 30b to determine such procedures and to establish the common criteria to be applied by the competent authorities.**]**

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

SECTION 5

Export authorisation

Article 12

1 Exports of scheduled substances that require a customs declaration, including exports of scheduled substances leaving the **[**F1customs territory of the Union**]** following their storage in a free zone of control type I or free warehouse for a period of at least 10 days, shall be subject to an export authorisation.

Where scheduled substances are re-exported within 10 days from the date of their placing into a suspensive procedure or under a free zone of control type II, an export authorisation shall not be required.

[F1However, exports of scheduled substances listed in Category 3 of the Annex shall only be subject to an export authorisation where pre-export notifications are required.**]**

2 Export authorisations shall be issued by the competent authorities of the Member State where the exporter is established.

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

Article 13

1 The application for export authorisations referred to in Article 12 shall contain at least the following:

a the names and addresses of the exporter, the importer in the third country, any other operator involved in the export operation or shipment, and the ultimate consignee;

b the name of the scheduled substance as stated in the Annex or, in the case of a mixture or a natural product, its name and eight-digit CN code and the name of any scheduled substance, as stated in the Annex, contained in the mixture or in the natural product;

c the quantity and weight of the scheduled substance and, in the case of a mixture or a natural product, the quantity, weight, and, if available, the percentage of any scheduled substance contained therein;

d details of the transport arrangements, such as the expected date of dispatch, method of transport, name of the customs office where the customs declaration is to be made and, where available at this stage, identification of the means of transport, itinerary,

expected point of exit from **[**[F1]customs territory of the Union**]** and the point of entry into the importing country;

e in the cases referred to in Article 17, a copy of the import authorisation issued by the country of destination; and

f the number of the licence or registration referred to in Articles 6 and 7.

[[F2]An application for an export authorisation for exports of scheduled substances listed in Category 4 of the Annex shall contain the information set out in points (a) to (e) of the first subparagraph.**]**

2 A decision on the application for an export authorisation shall be taken within a period of 15 working days from the date on which the competent authority considers the file to be complete.

That period shall be extended if, in the cases referred to in Article 17, the competent authorities are obliged to make further enquiries under the second subparagraph of that Article.

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

F2 Inserted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

Article 14

1 If the details of the itinerary and means of transport are not provided in the application, the export authorisation shall state that the operator must supply those details to the customs office of exit or other competent authorities at the point of exit from the **[**[F1]customs territory of the Union**]** before the physical departure of the consignment. In such cases the export authorisation shall be annotated accordingly at the time of issue.

Where the export authorisation is presented to a customs office in a Member State other than that of the issuing authority, the exporter shall make available any certified translation of parts or all of the information contained on the authorisation, upon request.

2 The export authorisation shall be presented to the customs office when the customs declaration is made, or in the absence of a customs declaration, at the customs office of exit or other competent authorities at the point of exit from the **[**[F1]customs territory of the Union**]**. The authorisation shall accompany the consignment to the third country of destination.

The customs office of exit or other competent authorities at the point of exit from the **[**[F1]customs territory of the Union**]** shall insert the necessary details referred to in Article 13(1)(d) in the authorisation and affix its stamp thereon.

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

Article 15

Without prejudice to measures adopted in accordance with Article 26(3), the granting of the export authorisation shall be refused if:

(a) details supplied in accordance with Article 13(1) are incomplete;

(b) there are reasonable grounds for suspecting that the details supplied in accordance with Article 13(1) are false or incorrect;

(c) in the cases referred to in Article 17, it is established that the import of the scheduled substances has not been authorised by the competent authorities of the country of destination, or

(d) there are reasonable grounds for suspecting that the substances in question are intended for the illicit manufacture of narcotic drugs or psychotropic substances.

Article 16

The competent authorities may suspend or revoke an export authorisation whenever there are reasonable grounds for suspecting that the substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.

Article 17

Whenever, under an agreement between the **[**F1Union**]** and a third country, exports are not to be authorised unless an import authorisation has been issued by the competent authorities of that third country for the substances in question, the Commission shall communicate to the competent authorities of the Member States the name and address of the competent authority of the third country, together with any operational information obtained from it.

The competent authorities in the Member States shall satisfy themselves as to the authenticity of such import authorisation, if necessary by requesting confirmation from the competent authority of the third country.

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

Article 18

The period of validity of the export authorisation within which the goods must have left the **[**F1customs territory of the Union**]** shall not exceed six months from the date of issue of the export authorisation. Under exceptional circumstances, the period of validity may be extended, upon request.

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

[F1 Article 19

Simplified procedures to grant an export authorisation may be applied by the competent authorities where they are satisfied that this will not result in any risk of diversion of scheduled substances. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to determine such procedures and to establish the common criteria to be applied by the competent authorities.**]**

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

SECTION 6

Import authorisation

Article 20

Imports of scheduled substances listed in Category 1 of the Annex shall be subject to an import authorisation. An import authorisation may only be granted to an operator established in the **[**F1Union**]**. The import authorisation shall be issued by the competent authorities of the Member State where the importer is established.

[F1However, where the substances referred to in the first paragraph are unloaded or transhipped, under temporary storage, stored in a free zone of control type I or a free warehouse, or placed under the external Union transit procedure, such import authorisation shall not be required.**]**

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

Article 21

1 The application for the import authorisations referred to in Article 20 shall contain at least the following:

a the names and addresses of the importer, the exporter of the third country, any other operator involved and the ultimate consignee;

b the name of the scheduled substance as stated in the Annex or, in the case of a mixture or a natural product, its name and the eight-digit CN code and the name of any scheduled substance, as stated in the Annex, contained in the mixture or in the natural product;

c the quantity and weight of the scheduled substance and, in the case of a mixture or a natural product, the quantity, weight, and, if available, the percentage of any scheduled substance contained therein;

d if available, details of the transport arrangements, such as methods and means of transport, and date and place of envisaged import activities, and

e the number of the licence or registration referred to in Articles 6 and 7.

2 A decision on the application for an import authorisation shall be taken within a period of 15 working days from the date on which the competent authority considers the file to be complete.

Article 22

The import authorisation shall accompany the consignment from the point of entry into the **[**F1customs territory of the Union**]** to the premises of the importer or ultimate consignee.

The import authorisation shall be presented to the customs office when the scheduled substances are declared for a customs procedure.

Where the import authorisation is presented to a customs office in a Member State other than that of the issuing authority, the importer shall make available any certified translation of parts or all information contained on the authorisation, upon request.

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

Article 23

Without prejudice to measures adopted in accordance with Article 26(3), the granting of the import authorisation shall be refused if:

(a) details supplied in accordance with Article 21(1) are incomplete;

(b) there are reasonable grounds for suspecting that the details supplied in accordance with Article 21(1) in the application are false or incorrect, or

(c) there are reasonable grounds for suspecting that the scheduled substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.

Article 24

The competent authorities may suspend or revoke the import authorisation whenever there are reasonable grounds for suspecting that the substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.

Article 25

The period of validity of the import authorisation within which the scheduled substances must have been entered into the customs territory of the **[**F1Union**]** shall not exceed six months from the date of issue of the import authorisation. Under exceptional circumstances, the period of validity may be extended, upon request.

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

(1) **[**[F1]Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1).**]**

Textual Amendments

F1 Substituted by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

Changes to legislation:
There are outstanding changes not yet made to Council Regulation (EC) No 111/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by S.I. 2019/742 reg. 14(29)
- Art. 2(a) words substituted by S.I. 2019/742 reg. 14(3)(a)
- Art. 2(c) substituted by S.I. 2019/742 reg. 14(3)(b)
- Art. 2(d) substituted by S.I. 2019/742 reg. 14(3)(c)
- Art. 2(e) words substituted by S.I. 2019/742 reg. 14(3)(d)(i)
- Art. 2(e) words substituted by S.I. 2019/742 reg. 14(3)(d)(ii)
- Art. 2(l) inserted by S.I. 2019/742 reg. 14(3)(e)
- Art. 13(1)(d) words substituted by S.I. 2019/742 reg. 14(11)