

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

CHAPTER I

SUBJECT MATTER AND DEFINITIONS

Article 1

This Regulation lays down rules for the monitoring of trade between the Community and third countries in certain substances frequently used for the illicit manufacture of narcotic drugs and psychotropic substances (hereinafter referred to as drug precursors) for the purpose of preventing the diversion of such substances. It applies to imports, exports and intermediary activities.

This Regulation shall be without prejudice to special rules in other fields pertaining to trade in goods between the Community and third countries.

Article 2

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

- (a) 'scheduled substance' means any substance listed in the Annex, including mixtures and natural products containing such substances, but excluding medicinal products as defined by Directive 2001/83/EC of the European Parliament and of the Council⁽¹⁾, pharmaceutical preparations, mixtures, natural products and other preparations containing scheduled substances that are compounded in such a way that such substances cannot be easily used or extracted by readily applicable or economically viable means;
- (b) 'non-scheduled substance' means any substance which, although not listed in the Annex, is identified as having been used for the illicit manufacture of narcotic drugs or psychotropic substances;
- (c) 'import' means any entry of scheduled substances having the status as non-Community goods into the customs territory of the Community, including temporary storage, the placing in a free zone or free warehouse, the placing under a suspensive procedure and the release for free circulation within the meaning of Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code⁽²⁾;
- (d) 'export' means any departure of scheduled substances from the customs territory of the Community, including the departure of scheduled substances that requires a customs declaration and the departure of scheduled substances after their storage in a free zone of control type I or free warehouse within the meaning of Regulation (EEC) No 2913/92;
- (e) 'intermediary activities' means any activity to arrange purchase and sale or supply of scheduled substances carried out by any natural or legal person who aims to obtain agreement between two parties or to do so through acting on behalf of at least one of these parties without taking these substances into its possession or taking control of the carrying out of such transaction; this definition shall also include any activity carried out by any natural or legal person established in the Community involving purchase and sale or supply of scheduled substances without these substances being introduced into the Community customs territory;

- (f) ‘operator’ means any natural or legal person engaged in import, export of scheduled substances or intermediary activities relating thereto, including persons pursuing the activity of making customs declarations for clients on a self-employed basis, either as their principal occupation or as a secondary activity related to another occupation;
- (g) ‘exporter’ means the natural or legal person chiefly responsible for export activities by virtue of the economic and legal relationship to the scheduled substances and to the consignee and, where appropriate, who lodges the customs declaration or on whose behalf the customs declaration is lodged;
- (h) ‘importer’ means the natural or legal person chiefly responsible for the import activities by virtue of the economic and legal relationship to the scheduled substances and to the consignor and who lodges the customs declaration or on whose behalf the customs declaration is lodged;
- (i) ‘ultimate consignee’ means any natural or legal person to which the scheduled substances are delivered; this person may be different from the end-user;
- (j) ‘committee procedure’ means the procedure provided for in Article 30(2);
- (k) ‘International Narcotics Control Board’ means the Board established by the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol.

CHAPTER II

MONITORING OF TRADE

SECTION 1

Documentation and labelling

Article 3

All imports, exports or intermediary activities involving scheduled substances shall be documented by the operators 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.

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.

Article 5

Operators shall ensure that labels are affixed on any packaging containing scheduled substances 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, as stated in the Annex, contained in the mixture or in the natural product. Operators may, in addition, affix their customary labels.

SECTION 2

Licensing and registration of operators

Article 6

1 Operators established in the Community, 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 licence shall be issued by the competent authority of the Member State in which the operator is established.

In considering whether to grant a licence, the competent authority shall take into account the competence and integrity of the applicant.

The committee procedure shall be used to lay down provisions determining cases where a licence is not required, setting out further conditions for the granting of licences and establishing a model for licences. These provisions shall guarantee a systematic and consistent control and monitoring of operators.

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.

Article 7

1 Operators established in the Community, 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 register immediately and update as necessary the addresses of the premises at which they conduct those activities. This obligation shall be carried out with the competent authority in the Member State in which the operator is established.

2 The committee procedure shall be used to establish the conditions for exemption from the controls of certain categories of operators and of operators engaged in the export of small

quantities of scheduled substances listed in Category 3. These conditions shall ensure that the risk of diversion of scheduled substances is minimised.

Article 8

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

2 The committee procedure shall be used 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 Community customs territory can be monitored by the competent authorities and the risk of diversion be minimised.

SECTION 3

Provision of information

Article 9

1 Operators established in the Community 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.

2 Operators shall provide the competent authorities with information in summary form about their export, import or intermediary activities. The committee procedure shall be used to determine the information that is required by the competent authorities in order to allow them to monitor these activities.

Article 10

1 In order to facilitate cooperation between the competent authorities of the Member States, operators established in the Community 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.

SECTION 4

Pre-export notification

Article 11

1 All exports of scheduled substances listed in Category 1 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 Community to the competent authorities of the country of destination, in accordance with Article 12(10) of the United Nations Convention. The committee procedure shall be used to determine the list of the countries of destination in order to minimise the risk of diversion by ensuring systematic and consistent monitoring of exports of scheduled substances to these countries.

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.

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 committee procedure shall be used to determine such procedures and to establish the common criteria to be applied by the competent authorities.

SECTION 5

Export authorisation

Article 12

1 Exports of scheduled substances that require a customs declaration, including exports of scheduled substances leaving the customs territory from the Community 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.

However, 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, or where these substances are exported to certain countries of destination to be determined in accordance with the committee procedure in order to ensure an appropriate level of control.

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

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 Community customs territory 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.

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.

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 Community customs territory 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 Community customs territory. 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 Community customs territory shall insert the necessary details referred to in Article 13(1)(d) in the authorisation and affix its stamp thereon.

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 Community 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.

Article 18

The period of validity of the export authorisation within which the goods must have left the Community Customs territory 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.

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 committee procedure shall be used to determine such procedures and to establish the common criteria to be applied by the competent authorities.

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 Community. The import authorisation shall be issued by the competent authorities of the Member State where the importer is established.

However, where the substances referred to in subparagraph 1 are unloaded or transhipped, under temporary storage, stored in a free zone of control type I or free warehouse, or placed into the Community transit procedure, such import authorisation shall not be required.

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 Community customs territory 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.

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 Community 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.

CHAPTER III

POWERS OF COMPETENT AUTHORITIES

Article 26

1 Without prejudice to the provisions of Articles 11 to 25 and of paragraphs 2 and 3 of this Article, the competent authorities of each Member State shall prohibit the introduction of scheduled substances into the Community customs territory or their departure from it, if there are reasonable grounds for suspecting that the substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.

2 The competent authorities shall detain or suspend release of the scheduled substances for the time necessary to verify the identification of the scheduled substances or compliance with the rules of this Regulation.

3 Each Member State shall adopt the measures necessary to enable the competent authorities, in particular:

- a to obtain information on any orders for or operations involving scheduled substances;
- b to enter operators' business premises in order to obtain evidence of irregularities;
- c to establish that a diversion or attempted diversion of scheduled substances has taken place.

4 For the purpose of preventing specific risks of diversion in free zones as well as in other sensitive areas such as customs warehouses, Member States shall ensure that effective controls are applied to operations carried out in these areas at every stage of these operations, and that the controls are no less stringent than those applied in the other parts of the customs territory.

5 The competent authorities may require the operators to pay a fee for the issuing of licences, registrations and authorisations. Such fees shall be levied in a non-discriminatory way and shall not exceed the approximate cost of processing the application.

CHAPTER IV

ADMINISTRATIVE COOPERATION

Article 27

For the purposes of applying this Regulation and without prejudice to Article 30, the provisions of Regulation (EC) No 515/97 shall apply *mutatis mutandis*. Each Member State shall communicate to the other Member States and to the Commission the name of the competent authorities appointed to act as correspondents in accordance with Article 2(2) of that Regulation.

CHAPTER V

IMPLEMENTING MEASURES AND AMENDMENTS

Article 28

In addition to the implementing measures referred to in this Regulation, the Committee shall lay down, where necessary, detailed rules to ensure the effective monitoring of trade between the Community and third countries in drug precursors for the purpose of preventing the diversion of such substances, in particular with regard to the design and use of export and import authorisation forms.

Article 29

The committee procedure shall be used to adapt the Annex to this Regulation, to take account of any amendments to the Annex to the United Nations Convention.

Article 30

1 The Commission shall be assisted by the Drug Precursors Committee (hereinafter referred to as the Committee).

2 Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3 The Committee shall adopt its rules of procedure.

CHAPTER VI

FINAL PROVISIONS

Article 31

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.

Article 32

The competent authorities in each Member State shall, at least once each year, communicate to the Commission all relevant information on the implementation of the monitoring measures laid down in this Regulation, and on scheduled substances used for the illicit manufacture of narcotic drugs or psychotropic substances and methods of diversion and illicit manufacture, and their licit trade, uses and needs.

On the basis of that information, the Commission shall, in consultation with the Member States, evaluate the effectiveness of this Regulation and, in accordance with Article 12 (12) of the United Nations Convention, draw up an annual report to be submitted to the International Narcotics Control Board.

The Commission shall report to the Council on the functioning of this Regulation by the end of August 2008.

Article 33

The Commission is hereby authorised to adopt a position, on behalf of the Community, in favour of amendments to tables I and II of the Annex to the United Nations Convention which conform to the Annex to this Regulation.

Article 34

Regulation (EEC) No 3677/90 is repealed with effect from 18 August 2005.

References to the repealed Regulation shall be construed as references to this Regulation.

Article 35

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 18 August 2005. However, Articles 6(1), 7(2), 8(2), 9(2), 11(1) and (3), 12(1), 19, 28 and 30 shall apply as from the day of entry into force of this Regulation in order to permit the adoption of the measures provided for in those Articles. Such measures shall enter into force at the earliest on 18 August 2005.

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

Done at Brussels, 22 December 2004.

For the Council

The President

C. VEERMAN

Status: This is the original version (as it was originally adopted).

- (1) [OJ L 311, 28.11.2001, p. 67](#). Directive as last amended by Directive 2004/27/EC of the European Parliament and of the Council ([OJ L 136, 30.4.2004, p. 34](#)).
- (2) [OJ L 302, 19.10.1992, p. 1](#). Regulation as last amended by the 2003 Act of Accession.