Council of the European Union

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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	24 April 2015
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2015) 2619 final
Subject:	COMMISSION DELEGATED REGULATION (EU) No …/.. of 24.4.2015 supplementing Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Union and third countries in drug precursors, and repealing Commission Regulation (EC) No 1277/2005

Delegations will find attached document C(2015) 2619 final.

Encl.: C(2015) 2619 final

EUROPEAN
COMMISSION

Brussels, 24.4.2015
C(2015) 2619 final

COMMISSION DELEGATED REGULATION (EU) No …/..

of 24.4.2015

supplementing Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Union and third countries in drug precursors, and repealing Commission Regulation (EC) No 1277/2005

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Drug precursors are chemicals which have wide legitimate uses but which can also be used to produce illegal drugs. Regulation (EC) No 273/2004 lays down measures for monitoring trade in drug precursors within the EU, while Regulation (EC) No 111/2005 governs trade in drug precursors between the EU and third countries.

In December 2013 these two Regulations were amended in order to strengthen the control of acetic anhydride (main heroin precursor) by making the registration of end-users compulsory in intra-EU trade. The control of the external trade of medicinal products containing ephedrine and pseudoephedrine (methamphetamine precursors) was strengthened through the introduction of a new Category 4 for those products.

Commission Regulation (EC) No 1277/2005 contains the implementing rules for the overall trade in drug precursors. The present Commission Delegated Regulation is intended to (1) align the rules contained in Commission Regulation (EC) No 1277/2005 with the Lisbon Treaty and (2) adapt those rules to the latest amendments to the drug precursors legislation. The Delegated Regulation and a parallel new Implementing Act will replace Commission Regulation (EC) No 1277/2005, once both new Acts will be in force.

The main features of Commission Regulation (EC) No 1277/2005 are maintained in this draft Delegated Regulation (and in the accompanying Implementing Regulation). The changes relate in particular to the conditions for granting registrations and the possibility to use simplified procedures for pre-export notifications and for export authorisations for medicinal products.

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, appropriate and transparent consultations, including at expert level, have been carried out in the preparation of this delegated act. The relevant documents have been transmitted in a timely and appropriate manner to the European Parliament and to the Council. The Group of Experts on drug precursors was consulted in the meeting held on 10 November 2014.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

On the basis of Council Regulation (EC) No 111/2005, as amended by Regulation (EU) No 1259/2013 of the European Parliament and of the Council, the Commission is empowered to adopt Delegated acts to lay down conditions for granting licences and to determine cases where a licence is not required, by the third subparagraph of Article 6(1); to lay down conditions for granting registrations and to determine cases where a registration is not required, by the third subparagraph of Article 7(1); to establish the criteria to demonstrate the licit purpose of a transaction by Article 8(2); to determine the information required to monitor trade, by the second subparagraph of Article 9(2); to fix the conditions for determining the lists of the countries of destination for exports of scheduled substances of Categories 2 and 3, by Article 11(1); to establish the criteria for determining simplified procedures for pre-export

notifications, by Article 11(3), and for export authorisations, by Article 19; to specify the requirements concerning the information to be provided on the implementation of the monitoring measures as regards trade in drug precursors, by Article 32(2) of Regulation (EC) No 111/2005.

On the basis of Regulation (EC) No 273/2004 of the European Parliament and of the Council, as amended by Regulation (EU) No 1258/2013, the Commission is empowered to adopt Delegated acts concerning the requirements and conditions for granting licences and registrations by Article 3(8); for operators to provide information by Article 8(3); and concerning the information to be provided on the implementation of the monitoring measures as regards trade in drug precursors by Article 13(2).

COMMISSION DELEGATED REGULATION (EU) No …/..

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supplementing Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Union and third countries in drug precursors, and repealing Commission Regulation (EC) No 1277/2005

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors[1], and in particular Articles 3(8), 8(3) and 13(2) thereof,

Having regard to 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[2], and in particular in the third subparagraph of Article 6(1), the third subparagraph of Article 7(1), Article 8(2), the second subparagraph of Article 9(2), Article 11(1) and (3), Article 19 and Article 32(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 1277/2005[3] lays down provisions for the implementation of Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 in the field of drug precursors. Both Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 have been amended after the adoption of Regulation (EC) No 1277/2005 so as to include empowerments to adopt delegated and implementing acts pursuant to Articles 290 and 291 of the Treaty. Therefore, new rules should be adopted in accordance with the new empowerments.

(2) Although Regulation (EC) No 273/2004 deals with domestic trade and Regulation (EC) No 111/2005 deals with international trade, many of the provisions are common to both Regulations. In order to ensure coherence, it is justified to adopt a single delegated act covering both Regulations.

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1 OJ L 47, 18.2.2004, p. 1.

2 OJ L 22, 26.1.2005, p. 1.

3 Commission Regulation (EC) No 1277/2005 of 27 July 2005 laying down implementing rules for Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and for Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors - (OJ L 202, 3.8.2005, p.7.

(3) In order to ensure legal certainty and a coherent enforcement of the provisions of this Regulation, it is necessary to give a definition of 'business premises'.

(4) Licenses and registrations which are required for operators willing to carry out activities involving certain substances (drug precursors), which can be used for the illicit manufacture of narcotic drugs or psychotropic substances, should be granted only to reliable operators applying for it. These operators should have taken adequate measures aiming at the secure handling and storage of those drug precursors and should have appointed an identifiable responsible officer able to ensure that activities involving these substances take place in compliance with the pertinent legal provisions.

(5) Certain operators dealing with drug precursors for medical use, such as pharmacies and dispensaries of veterinary medicine, could be exempted from the requirement of having been granted a license or a registration in order to carry out activities involving such substances. The same could be applicable to certain public authorities.

(6) Operators carrying out activities related to drug precursors which are not intended for the Union market, but have been brought into the customs territory of the Union, should provide information showing that the exportation of those substances was made in compliance with relevant International conventions to demonstrate the licit purposes of the corresponding transaction.

(7) Operators established in the Union should provide certain basic details on the activities they have carried out in order to facilitate the monitoring, by the competent authorities, of trade in drug precursors.

(8) For the purposes of minimising the risk of diversion of certain drug precursors, their exportation should be preceded by a pre-export notification and by an export authorisation.

(9) There are frequent changes in relation to the lists of third countries of destination for exports of scheduled substances of Categories 2 and 3 of the Annex to Regulation (EC) No 111/2005. In order to allow for a swift update of those lists, in accordance with the criteria for those lists determined in this Regulation, these lists should be published on the website of the Commission.

(10) In order to ease the administrative burden for trade in certain categories of drug precursors, a simplified procedure for pre-export notification and for export authorisation should be provided.

(11) To improve the coordination of the implementation of the monitoring measures, it is appropriate that the Member States provide the Commission regularly with information concerning drug precursors seized or detained.

(12) In order to ensure consistency, legislative coherence and legal certainty, this Delegated Regulation should apply from the same date as the Implementing Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down conditions for granting licences and registrations, determines cases where a licence and a registration are not required, establishes the criteria to demonstrate the licit purpose of a transaction, determines the information required to monitor trade, fixes the conditions for determining the lists of the countries of destination for exports of scheduled substances of Categories 2 and 3, establishes the criteria for determining simplified procedures for pre-export notifications and for export authorisations and specifies the requirements concerning the information to be provided on the implementation of the monitoring measures as regards trade in drug precursors.

Article 2

Definitions

For the purposes of this Regulation, 'business premises' shall mean building(s) together with the land occupied by an operator at each single location.

Article 3

Conditions for granting licences

1. In order to obtain a licence pursuant to Article 6(1) of Regulation (EC) No 111/2005, the operator shall appoint an officer responsible for the trade in scheduled substances listed in Category 1 of the Annex to that Regulation, notify the competent authority of the name and contact details of that officer and notify them immediately of any subsequent modification of this information.

The responsible officer shall ensure that import, export or intermediary activities take place in compliance with the pertinent legal provisions and shall be empowered to represent the operator and to take the decisions necessary for performing that task.

2. The operator concerned shall fulfil all the following requirements and conditions:

(a) the operator shall take adequate measures against the unauthorised removal of scheduled substances of Category 1 of Annex I to Regulation (EC) No 273/2004 and of the Annex to Regulation (EC) No 111/2005 from the places of storage, production, manufacture and processing of scheduled substances and to secure business premises;

(b) the operator shall make an application containing the following:

i. the full name, address, telephone and/or fax numbers and e-mail address of the applicant;

ii. the full name of the responsible officer and his/her contact details;

iii. a description of the position and tasks of the responsible officer;

iv. the full addresses of the business premises;

v. the description of all the places where operations described under point x take place;

vi. information showing that the adequate measures referred to in paragraph 2(a) have been taken;

vii. the name and the CN code of the scheduled substances as stated in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005;

viii. in the case of a mixture or natural product an indication of the following:

a. the name of the mixture or natural product;

b. the name and CN code of the scheduled substances as stated in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005 contained in the mixture or natural product;

c. the maximum percentage of such scheduled substances in the mixture or natural product;

ix. a description of the envisaged type of operations referred to in Article 3 of Regulation (EC) No 273/2004 and in Article 6(1) of Regulation (EC) No 111/2005;

x. an authenticated copy of the Register of companies or activities, where relevant;

xi. a certificate of good conduct of the operator concerned and of the responsible officer or a document showing that they offer the necessary guarantee for the proper conduct of the operations or the information allowing the competent authority to obtain such document.

3. If the operator has already been granted the status of an Authorised Economic Operator in accordance with Article 5a of Council Regulation (EEC) No 2913/92[4]; he may indicate the AEO certificate number when making the application for a licence for the purpose of the competent authority being able to take his AEO status into consideration.

4. Upon written request from the relevant competent authority, the applicant shall submit any relevant additional information.

5. Where the applicant is a natural person, points (ii) and (iii) of paragraphs 2(b) shall not apply, and point (iv) of paragraph 2(b) shall only apply where relevant.

[4] Council Regulation (EEC) No 2913/92 establishing the Community Customs Code of 12 October 1992 (OJ L 302, 19.10.1992, p. 01).

6. Without prejudice to measures adopted in accordance with Article 10(1) of Regulation (EC) No 273/2004 and with Article 26(3) of Regulation (EC) No 111/2005, the competent authority shall refuse the granting of the licence if the conditions set out in Article 3(2) (b) of this Regulation are not fulfilled or if there are reasonable grounds for suspecting that the scheduled substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.

7. In the case of trade between the Union and third countries referred to in Regulation (EC) No 111/2005, the competent authority may either limit the validity of the licence to a period not exceeding three years or may require operators to demonstrate at intervals not exceeding three years that the conditions under which the licence was granted are still fulfilled.

The validity of licences issued before the entry into force of this Regulation shall not be affected.

8. A licence shall not be transferable.

9. The licence holder shall apply for a new licence where any of the following are envisaged:

(a) the addition of a scheduled substance;

(b) the start of a new operation;

(c) the change of the location of the business premises where the operations take place.

In such cases, the existing licence shall cease to be valid on the earlier of the following dates:

(i) the date of expiry of validity where a term of validity has been fixed in accordance with Article 3(6) of this Regulation or in accordance with Article 3(5) of Regulation (EC) No 273/2004;

(ii) the date of commencement of validity of the new licence.

10. Paragraph 9 shall also apply to licences issued before the date of application of this Regulation.

11. Paragraphs 2 to 6 and 8, 9 and 10 shall also apply for the purpose of obtaining licences pursuant to Article 3(2) of Regulation (EC) No 273/2004, with the exception of special licences.

12. The public authorities referred to in Article 3(2) and (6) of Regulation (EC) No 273/2004 shall comprise customs, police and official laboratories of competent authorities.

Article 4

Cases where a licence is not required

Pharmacies, dispensaries of veterinary medicine, customs, police, armed forces and official laboratories of competent authorities may be exempted from the requirement of licensing pursuant to Article 6(1) of Regulation (EC) No 111/2005 insofar as these operators use drug precursors within the scope of their official duties.

The operators set out in the first paragraph are also exempted from the following:

(a) the provision of documentation referred to in Article 3 of Regulation (EC) No 111/2005;

(b) the obligation to appoint a responsible officer set out in Article 3(1) of this Regulation.

Article 5

Conditions for granting registrations

1. In order to obtain a registration pursuant to Article 7(1) of Regulation (EC) No 111/2005, the operator shall appoint an officer responsible for the trade in scheduled substances listed in Category 2 of the Annex to that Regulation, notify the competent authority of the name and contact details of that officer and notify them immediately of any subsequent modification of this information.

The responsible officer shall ensure that import, export or intermediary activities take place in compliance with the pertinent legal provisions and shall be empowered to represent the operator and to take the decisions necessary for performing that task.

2. The operator of scheduled substances of Category 2 of the Annex to Regulation (EC) No 111/2005 shall make an application containing the information and documents as referred to in Article 3(2)(b) with the exception of points (vi), (x) and (xi) .of Article 3(2)(b), unless so requested by the competent authority.

The same applies to the operator engaged in the export of scheduled substances of Category 3 of the Annex to Regulation (EC) No 111/2005.

3. Article 3(3) and (4) shall also apply.

4. The first sub-paragraph of paragraph 2 and paragraph 3 shall apply mutatis mutandis to operators and users referred to in Article 3(6) of Regulation (EC) No 273/2004 in respect of scheduled substances of Category 2 of Annex I to that Regulation.

5. Users of scheduled substances of category 2A of Annex I to Regulation (EC) No 273/2004 shall also provide information on the use of the scheduled substances.

Article 6

Cases where a registration is not required

The following categories may be exempt from the registration requirement pursuant to Article 7(1) of Regulation (EC) No 111/2005:

(a) Pharmacies, dispensaries of veterinary medicine, customs, police, official laboratories of competent authorities and armed forces, insofar as these operators use drug precursors within the scope of their official duties;

(b) Operators engaged in the export of scheduled substances listed in Category 3 of the Annex to Regulation (EC) No 111/2005, if the sum of quantities concerned by their exports during

the course of the preceding calendar year (1 January-31 December) does not exceed the amounts specified in Annex I to this Regulation. When those amounts are exceeded within the current calendar year, the operator shall comply with the registration requirement immediately.

(c) Operators engaged in export of mixtures containing scheduled substances listed in Category 3 of the Annex to Regulation (EC) No 111/2005, if the amount of the scheduled substance contained in the mixtures does not exceed, during the course of the preceding calendar year, the amounts specified in Annex I to this Regulation. When those amounts are exceeded within the current calendar year, the operator shall comply with the registration requirement immediately.

Article 7

Conditions for exemptions from certain requirements

For the purposes of Article 6 of Regulation (EC) No 273/2004, customers shall inform their suppliers whether that Article is applicable to them.

Article 8

Criteria for determining the licit purposes of a transaction

1. The operator shall provide information that the consignment has left the country of export in accordance with the national provisions in force adopted pursuant to Article 12 of the Convention of the United Nations against illicit traffic in Narcotic Drugs and Psychotropic substances[5] to demonstrate the licit purpose of his transaction pursuant to Article 8(1) of Regulation (EC) No 111/2005.

2. For that purpose, the operator shall either use the model set out in Annex II to this Regulation or present the import authorisation referred to in Article 20 of Regulation (EC) No 111/2005 or the customer declaration referred to in Article 4 of Regulation (EC) No 273/2004.

Article 9

Information required to monitor trade

1. For the purposes of Article 8(2) of Regulation (EC) No 273/2004 operators shall inform the competent authorities in a summary form of the quantities of scheduled substances used or supplied and, in the case of supply, of the quantity supplied to each third party.

For scheduled substances of Category 3 of Annex I to Regulation (EC) No 273/2004, the first paragraph shall apply only upon request by the competent authorities.

[5] Council Decision of 22 October 1990 (OJ L 326, 24.11.1990, p.56).

2. For the purposes of Article 9(2) of Regulation (EC) No 111/2005, operators shall inform the competent authorities about the following:

(a) exports of scheduled substances subject to an export authorisation;

(b) all imports of scheduled substances of Category 1 of the Annex to Regulation (EC) No 111/2005 requiring an import authorisation or all cases where scheduled substances of Category 2 of the Annex to Regulation (EC) No 111/2005 are entered into a free zone of control type II, placed into a suspensive procedure other than transit, or released for free circulation;

(c) all intermediary activities involving scheduled substances of Categories 1 and 2 of the Annex to Regulation (EC) No 111/2005.

3. The information referred to in paragraph 2(a) shall be organised by making reference to the countries of destination, quantities exported and the reference numbers of the export authorisations as the case may be.

4. The information referred to in paragraph 2(b) shall be organised by making reference to the third country of export and the reference number of the import authorisations as the case may be.

5. The information referred to in paragraph 2(c) shall be organised by making reference to the third countries involved in these intermediary activities and the export or import authorisation as the case may be. Operators shall provide further information, upon request of the competent authorities.

6. The competent authorities shall treat the information referred to in this Article as confidential business information.

Article 10

Conditions for determining the lists of the countries of destination for exports of scheduled substances of Categories 2 and 3

The lists referred to in Article 11(1) of Regulation (EC) No 111/2005 shall include all of the following:

(a) third countries with whom the Union has concluded a specific agreement on drug precursors;

(b) third countries which have requested to receive pre-export notifications in accordance with Article 12(10) of the 1988 United Nations Convention against illicit traffic in narcotic drugs and psychotropic substances.

(c) third countries which have requested to receive pre-export notifications in accordance with Article 24 of the 1988 United Nations Convention against illicit traffic in narcotic drugs and psychotropic substances.

The lists of the specific countries of destination for export of scheduled substances listed in Categories 2 and 3 of the Annex referred to in points (a), (b) and (c) shall be published on the website of the Commission.

Article 11

Criteria for determining simplified procedures for pre-export notifications

1. Pursuant to Article 11(3) of Regulation (EC) No 111/2005, the competent authority may send a simplified pre-export notification covering several export operations carried out within a specific time period of either 6 or 12 months, in case of exports intended for the simplified export authorisation procedure.

2. The competent authority of the country of export shall supply the information specified in Article 13(1) of Regulation No 111/2005 to the competent authority of the third country of destination.

3. The competent authority shall inform the country of destination accordingly and use to that purpose the PEN-online system or the 'Multilateral Chemical Reporting Notification' set out in Annex III of this Regulation.

Article 12

Criteria for determining simplified procedures for export authorisations

1. Following an application by the operator concerned the competent authority may grant an export authorisation by simplified procedure pursuant to Article 19 of Regulation (EC) No 111/2005 in cases of frequent exports of one specific scheduled substance listed in Categories 3 and 4 of the Annex to that Regulation involving the same exporter established in the Union and the same importer in the same third country of destination covering a specific time period of either 6 or 12 months.

Such simplified export authorisation may only be granted in the following cases:

(a) where during previous exports the operator has shown the capacity to fulfil all obligations in relation to those exports, and has not committed any offences against relevant legislation;

(b) where the competent authority can satisfy itself as to the licit purposes of those export operations.

2. The application for a simplified export authorisation shall contain at least the following:

(a) the names and addresses of the exporter, the importer in the third country, and the ultimate consignee;

(b) the name of the scheduled substance, as stated in the Annex to Regulation (EC)

No 111/2005, or, in the case of a mixture or natural product, its name and CN code and the name of any scheduled substance, as stated in the Annex to Regulation (EC) No 111/2005, contained in the mixture or natural product;

(c) the maximum quantity of the scheduled substance intended for export;

(d) the intended specific time period for the export operations.

3. The competent authority shall take the decision on the application for simplified export authorisation within a period of 15 working days from the date on which it received the required information.

4. In case of emergency medical care, where the conditions under paragraph 1 (a) and (b) of this Article are fulfilled, the competent authority shall take the decision on the application for simplified export authorisation for exports of scheduled substances of Category 4 listed in the Annex to Regulation (EC) No 111/2005 immediately or at the latest within 3 working days after receipt of the application.

Article 13

Conditions and requirements concerning the information to be provided on the implementation of the monitoring measures

1. Member States shall submit the communications referred to in Article 32(1) of Regulation (EC) No 111/2005 and Article 13(1) of Regulation (EC) No 273/2004 to the Commission, in the month following each calendar quarter. The communications shall contain the information on all cases where the release of scheduled and non-scheduled substances was suspended or the scheduled and non-scheduled substances were detained.

2. That information shall include the following:

(a) the name of the substances;

(b) if known, the origin, provenance and destination of the substances;

(c) the quantity of the substances, their customs status and the means of transport used.

3. At the end of every calendar year, the Commission shall communicate to all Member States the information received pursuant to paragraph 1.

Article 14

Repeal

Regulation (EC) No 1277/2005 is repealed.

Article 15

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

It shall apply from 1 July 2015.

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

Done at Brussels, 24.4.2015

For the Commission
The President
Jean-Claude JUNCKER