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to:	Working Party on Customs Union
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Subject:	Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) no 111/2005 laying down rules for the monitoring of trade between the community and third countries in drug precursors - Revised Presidency compromise text

Delegations will find attached a revised compromise text on the above proposal, prepared by the Presidency.

Changes compared to doc. 6244/1/12 are indicated in bold/underline.

2012/0250 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

After consulting the European Data Protection Supervisor[1],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Pursuant to Article 32 of 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[2], the Commission presented on 7 January 2010 a report to the Council and the European Parliament on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors[3].

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1 OJ C , , p.

2 OJ L 22, 26.1.2005, p. 1.

3 Report from the Commission to the Council and the European Parliament pursuant to Article 16 of Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 and to Article 32 of Council Regulation (EC) No 111/2005 on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors, COM(2009)709 final.

(2) The Commission report pointed out that, in the existing Union control system for drug precursors, medicinal products containing ephedrine and pseudoephedrine, whose trade was not controlled, were diverted into the illicit drug manufacture outside the Union, as a substitute to internationally controlled ephedrine and pseudoephedrine. The Commission therefore recommended strengthening the control of international trade in medicinal products containing ephedrine or pseudoephedrine exported from or transiting through the Union customs territory which are diverted for the illicit manufacture of drugs.

(3) In its Conclusions on the functioning and implementation of the Union drug precursors legislation of 25 May 2010, the Council of the European Union invited the Commission to make a proposal to amend Council Regulation (EC) No 111/2005 accordingly.

(4) It is important that the definition of scheduled substances be clarified: the term 'pharmaceutical preparation' stemming from the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988 (hereinafter referred to as the "United Nations Convention") should be replaced by the relevant terminology of the Union legislation, 'medicinal products', and the term 'other preparations' should be deleted as it duplicates the term 'mixtures' already used in the definition.

(5) Rules on suspending or revoking a registration should be introduced in order to match the existing rules for suspending or revoking a licence.

(6) Medicinal products containing ephedrine or pseudoephedrine should therefore be controlled without impeding their legitimate trade.

(7) To this end, any export of medicinal products containing ephedrine or pseudoephedrine should be preceded by a pre-export notification sent by the competent authorities in the Union to the competent authorities of the country of destination.

(8) Member States' competent authorities should be given the powers to stop or seize those products when there are reasonable grounds for suspecting that they are intended for the illicit drug manufacture, when they are exported, imported or in transit.

(9) With a view to enabling Member States to react more quickly with regard to new emerging trends in drug precursors' diversion, their possibilities to act in cases of suspicious transactions involving non-scheduled substances should be clarified.

(10) The European Database on drug precursors should be used to simplify the reporting by Member States with regard to seizures and stopped shipments, to establish a European register of operators holding a licence or a registration, which will facilitate verification of the legitimacy of their transactions involving scheduled substances and to enable operators to provide the competent authorities with information about their export, import or intermediary activities involving scheduled substances.

(11) Regulation (EC) No 111/2005 envisages the processing of data. Such processing of data may also cover personal data which should be carried out in accordance with Union Law.

(11a) The processing of personal data for the purposes of this Regulation respects the fundamental rights guaranteed namely by Article 8 (respect of private life) of the European Convention of Human rights (ECHR) and by Articles 7 (respect of private life) and 8 (protection of personal data) of the Charter of Fundamental Rights of the Union.

(11b) Member States and the Commission should process personal data only in a way compatible with the purposes of the present Regulation.Those data should be processed in accordance with Union legislation concerning the protection of individuals with regard to the processing of personal data, in particular Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

(11c) The delegated and implementing acts to be adopted should respect the fundamental rights guaranteed namely by Article 8 (respect of private life) of the European Convention of Human rights (ECHR) and by Articles 7 (respect of private life) and 8 (protection of personal data) of the Charter of Fundamental Rights of the Union. They should also ensure that any processing of personal data takes place in accordance namely with Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

(12) Regulation (EC) No 111/2005 confers powers on the Commission in order to implement some of its provisions, to be exercised in accordance with the procedures laid down in Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[4] as amended by Council Decision 2006/512/EC[5].

(13) As a consequence of the entry into force of the Lisbon Treaty, those powers need to be aligned to Articles 290 and 291 of the Treaty on the Functioning of the European Union (the Treaty).

(14) In order to achieve the objectives of Regulation (EC) No 111/2005, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in order to lay down provisions determining cases where a licence is not required and to set out further conditions for granting licences, to establish the conditions for exemptions 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, to establish the criteria to determine how the licit purposes of the transaction may be demonstrated, to determine the information that is required by the competent authorities to monitor export, import or intermediary activities of operators, to determine the countries of destination to which exports of scheduled substances

4 OJ L 184, 17.7.1999, p. 23.
5 OJ L 200, 22.7.2006, p. 11.

of Category 2 and 3 of the Annex should be preceded by a pre-export notification, to determine simplified pre-export procedures and to establish the common criteria thereof, to determine the countries of destination to which exports of scheduled substances listed in Category 3 of the Annex should be subject to an export authorisation, to determine simplified export authorisation procedures and to establish the common criteria thereof, and to introduce additional substances into the Annex to this Regulation, as well as other amendments necessary to respond to new trends of drug precursor diversion. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level.

(14a) These acts should guarantee a systematic and consistent control and monitoring of operators.

(15) The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

(16) In order to ensure uniform conditions for the implementation of Regulation (EC) No 111/2005, implementing powers should be conferred on the Commission, namely to establish a model for licences. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers.[6]

(17) Since this Regulation is based on the common commercial policy, the examination procedure should be used for the adoption of the implementing acts.

(18) Regulation (EC) No 111/2005 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

[6] OJ L 55, 28.2.2011, p. 13.

Article 1

Regulation (EC) No 111/2005 is amended as follows:

(1) Article 2 is amended as follows:

(a) point (a) is replaced by the following:

"(a) 'scheduled substance' means any substance listed in Annex that can be used for the illicit manufacture of narcotic drugs or psychotropic substances , including mixtures and natural products containing such substances. This excludes natural products and mixtures which contain scheduled substances and which are compounded in such a way that the scheduled substances cannot be easily used or extracted by readily applicable or economically viable means and medicinal products within the meaning of Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council[7] and of Article 1(2) of Directive 2001/82/EC of the European Parliament and the Council[8];

(b) point (j) is replaced by the following:

"(j) for the purposes of this Regulation 'natural products' means substances that occur in the nature as defined by Article 3 (39) of modified Regulation 1907/2006/EC of the European Parliament and the Council."

(2) Article 6 is amended as follows:

(a) in paragraph 1, the first subparagraph is replaced by the following:

"1. Unless otherwise provided, 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

7 OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2011/62/EU of the European Council (OJ L 174, 1.7.2011, p. 74).

8 OJ L 311, 28.11.2001, p. 1. Directive as last amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council (OJ L 188, 18.7.2009, p. 14).

(a)(a) in paragraph 1, the third subparagraph is replaced by the following:

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

(b) the following paragraphs 3 is added:

"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).

(3) Article 7 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. Unless otherwise provided, 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 hold a registration. The registration shall be issued by the competent authority in the Member State in which the operator is established. In considering whether to grant a registration, the competent authority shall take into account the competence and integrity of the applicant."

(b) paragraph 2 is replaced by the following:

"2. 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."

(c) The following paragraph 3 is added:

"3. The registration may be suspended or revoked by the competent authorities whenever 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."

(4) In Article 8, paragraph 2 is replaced by the following:

"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[9] can be monitored by the competent authorities and the risk of diversion be minimised."

(5) In Article 9,

(a) The following is added at the end of paragraph 1:

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

- the name of the scheduled substance;

- the quantity and weight of the scheduled substance; and

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

This information will only be collected for the purposes of preventing the diversion of scheduled substances."

(b) Paragraph 2 is replaced by the following:

"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 in accordance with Article 30(2) the procedural rules on the provision of such information, including, (where appropriate,) in electronic form to a European database."

[9] 'Customs territory of the Union' means the customs territory of the Community as referred to in Article 3 of Regulation (EEC) No 2913/92;

(5a) Article 10 is amended as follows:

(a) the following paragraph 4 is added:

"4. In order to respond rapidly to new diversion trends, the competent authorities of the Member States may propose to the Commission adding a non-scheduled substance on the list referred to under paragraph 2(b) in order to temporarily monitor its trade."

(b) the following paragraph 5 is added:

"5. If voluntary monitoring is considered as insufficient, the Commission may add the non-scheduled substance to the Annex to this Regulation in accordance with Article 30a."

(6) Article 11 is amended as follows:

(a) in paragraph 1, the first subparagraph is replaced by the following:

"1. All exports of scheduled substances listed in Category 1 of the Annex, exports of scheduled substances listed in Category 2 and 3 of the Annex to certain countries of destination and all exports of medicinal products containing ephedrine or pseudoephedrine 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 to determine the list of the countries of destination for export of scheduled substances listed in Category 2 and 3 in order to minimise the risk of diversion of scheduled substances."

(b) paragraph 3 is replaced by the following:

"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 and of medicinal products containing ephedrine or pseudoephedrine. 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."

(7) In Article 12(1), the third subparagraph is replaced by the following:

"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 those substances are exported to certain countries of destination. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to determine the list of such countries of destination in order to ensure an appropriate level of control."

[(7a) In Article 12, the following paragraph 3 is added:

"**Exports of medicinal products containing ephedrine or pseudoephedrine shall be subject to an export authorisation"]**

[(7b) In Article 13(1), the following subparagraph is inserted:

"An application for an export authorisation for exports of medicinal products containing ephedrine or pseudoephedrine shall only contain the information sat out in (a) to (d) above"]

(8) Article 19 is replaced by the following:

"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."

(9) Article 26 is amended as follows:

(a) paragraph 1 is replaced by the following:

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

(a)(a) paragraph 2 is replaced by the following:

"2. The competent authorities shall detain or suspend release of the scheduled substances or of those medicinal products containing ephedrine or pseudoephedrine for the time necessary to verify the identification of the scheduled substances or of those medicinal products or compliance with the rules of this Regulation."

(b) the following paragraph 3a is added:

"3a. Each Member State may adopt the measures necessary to enable its competent authorities to control and monitor suspicious transactions with non-scheduled substances, in particular:

(a) to obtain information on any orders for or operations involving non-scheduled substances;

(b) to enter business premises in order to obtain evidence of suspicious transactions with non-scheduled substances."

(10) Article 28 is replaced by the following:

"Article 28

In addition to the measures referred to in Article 26, the Commission shall be empowered to lay down, where necessary, by means of implementing acts, measures to ensure the effective monitoring of trade between the Union 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. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2)."

(11) Article 29 is deleted.

(12) Article 30 is replaced by the following:

"Article 30

1. The Commission shall be assisted by the Drug Precursors Committee (hereinafter referred to as the Committee). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply."

(13) The following Articles 30a and 30b are inserted:

"Article 30a

The Commission shall be empowered to adopt delegated acts in accordance with Article 30b in order to adapt the Annex to new trends in diversion of drug precursors, in particular substances which can be easily transformed into scheduled substances, and to follow an amendment to the tables in the Annex to the United Nations Convention.

Article 30b

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Articles 6(1), 7(2), 8(2), 9(2), 11(1) and (3), 12(1), 19 and 30a shall be conferred on the Commission for a period of five years from the date of entry into force of this Regulation. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the 5 year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of powers referred to in Articles 6(1), 7(2), 8(2), 9(2), 11(1) and (3), 12(1), 19 and 30a may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and the Council.

5. A delegated act adopted pursuant to Articles 6(1), 7(2), 8(2), 9(2), 11(1) and (3), 12(1), 19 and 30a shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council."

(14) Article 32 is amended as follows:,

(a) paragraph 1 is replaced by the following:

"1. The competent authorities in each Member State shall communicate to the Commission in electronic form via the European Database on drug precursors in a timely manner all relevant information on the implementation of the monitoring measures laid down in this Regulation, in particular as regards substances used for the illicit manufacture of narcotic drugs or psychotropic substances and methods of diversion and illicit manufacture, and their licit trade."

(b) the following paragraph 1a is inserted:

1a. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b in order to specify the conditions and requirements concerning the information to be provided under paragraph 1.

(c) paragraph 2 is replaced by the following:

"2. On the basis of the information referred to in paragraph 1, 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."

(d) paragraph 3 is replaced by the following:

"3. The Commission shall evaluate the implementation and functioning of Articles 11 and 26 insofar as they concern medicinal products containing ephedrine or pseudoephedrine and Article 30a by *[OPOCE insert date 5 years after entry into force of this amending Regulation]*".

(15) The following Article 32a is inserted:

"Article 32a

Database

The competent authorities of the Member States and the Commission shall use the European Database on drug precursors established by Regulation (EC) No 273/2004 of the European Parliament and of the Council[10] and under the conditions thereof, with the following functions:

(a) facilitating the communication of information pursuant to Article 32 first subparagraph, as well as the reporting to the International Narcotics Control Board pursuant to Article 32 second subparagraph;

(b) managing a European register of operators, which have been granted a licence pursuant to Articles 6(1) or registration pursuant to Articles 7(1);

(c) enabling operators to provide the competent authorities with information about their export, import or intermediary activities according to Article 9(2)."

(16) Article 33 is replaced by the following:

"Data protection provisions

1. The processing of personal data by the competent authorities in the Member States shall be carried out in accordance with national legislation implementing Directive 95/46/EC and under the supervision of the public independent authority of the Member State referred to in Article 28 of this Directive.

[10] OJ L 86, 24.3.2004, p. 21

2. The processing of personal data by the Commission, including for the purpose of the European Database referred to under Article 32a, shall be carried out in accordance with Regulation (EC) No 45/2001 and under the supervision of the European Data Protection Supervisor.

3. No special categories of data in the meaning of Article 8 §1 of Directive 95/46/EC shall be processed for the purposes of this Regulation.

4. The personal data collected for the purposes of this Regulation shall not be further processed in a way inconsistent with Directive 95/46/EC and Regulation (EC) No 45/2001 and shall not be retained longer than necessary for the purposes for which it was collected.

5. Member States and the Commission shall not process personal data in a way incompatible with the purposes set out in Article 32 a of this Regulation."

(16) The following substance is added to the list of substances under Category 1 in the Annex:

"Alpha-phenylacetoacetonitrile, (CN code) 2926 90 95, (CAS No) 4468-48-8"

Article 2

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

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President