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Subject:	Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 273/2004 on drug precursors

Delegations will find attached a revised compromise text on the above proposal, prepared by the Presidency. Changes compared to doc. 6246/13 are indicated in bold/underline, deletions by […].

2012/0261 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Amending Regulation (EC) No 273/2004 on 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 114**(1)** thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the European Data Protection Supervisor[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Pursuant to Article 16 of Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors[3], the Commission adopted on 7 January 2010 a report to the Council and the European Parliament on the implementation and functioning of the existing EU legislation on drug precursors[4].

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1 OJ C , , p. .

2 OJ C…p….

3 OJ L 47, 18.2.2004, p. 1.

4 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) In that report, the Commission recommended further analysing ways to strengthen the control of the trade of acetic anhydride (scheduled substance in Category 2) in order to better prevent the diversion of acetic anhydride for the illicit production of heroin.

(3) In its Conclusions on the functioning and implementation of the EU drug precursor's legislation of 25 May 2010, the Council invited the Commission to propose legislative amendments after assessing their potential impacts on competent authorities and economic operators.

(4) The definition of scheduled substances should 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) A definition of the term 'user' should be introduced for companies possessing substances for purposes other than placing them on the market.

(6) It should be clarified that companies using scheduled substances in category 1 for other purposes than placing them on the market are obliged to obtain a licence.

(7) More detailed rules on registration should be introduced to ensure uniform conditions of registration in all Member States for scheduled substances in category 2 of Annex I. For substances scheduled in a new subcategory 2A of Annex I, not only operators but also users should be subject to a registration requirement.

(8) In order to safeguard the competitiveness of microenterprises, no fees should be imposed on them for obtaining a registration or a licence.

(9) Explicit provisions should be foreseen to clarify that Member States have the possibility to act with regard to suspicious transactions involving non-scheduled substances in order to enable them to react more quickly with regard to new trends in the illicit production of drugs.

(10) A European database on drug precursors should be created to simplify the reporting by Member States with regard to seizures and stopped shipments, to create a European register of operators and users holding a license or a registration which will facilitate verification of the legitimacy of commercial transactions involving scheduled substances, and to enable operators to provide the competent authorities with information about their legal transactions involving scheduled substances.

(11) Regulation (EC) No 273/2004 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) Acetic anhydride, currently scheduled in category 2 of Annex I, should be included in a new subcategory 2A of Annex I to allow increased control of its trade. The remaining substances of category 2 should be listed as subcategory 2B.

(13) Regulation (EC) No 273/2004 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[5] as amended by Council Decision 2006/512/EC[6].

(14) 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.

(15) In order to achieve the objectives of Regulation (EC) No 273/2004, 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 to specify the requirements and conditions for the granting of the licence and registration, for obtaining and using customer declarations, for the documentation and labelling of mixtures, for provision of information by the operators on transactions involving scheduled substances, for listing operators and users having obtained a licence or registration in the European register and in order to amend the

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

Annexes. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

(16) 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.

(17) In order to ensure uniform conditions for the implementation of Regulation (EC) No 273/2004, implementing powers should be conferred on the Commission. 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[7].

(18) The examination procedure should be used for the adoption of the implementing acts in order to set up details on how customer declarations should be provided in electronic form; to set up details on how to provide the information about transactions of operators with scheduled substances to a European database.

(19) Since the objectives of this Regulation, namely to strenghen the rules for registration of operators placing on the internal market or possessing scheduled substances of category 2, in particular acetic anhydride, in order to prevent its diversion towards the illicit production of drugs, cannot be sufficiently achieved by Member States because traffickers gain from national differences in registration and move their illicit business where drug precursors are easiest to divert and can therefore be better achieved at the level of the Union, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

Regulation (EC) No 273/2004 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

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7 OJ L 55, 28.2.2011, p. 13.

Article 1

Regulation (EC) No 273/2004 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 I** 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[8] and of Article 1(2) of Directive 2001/82/EC of the European Parliament and the Council[9];

(b) the following point (h) is inserted:

"(h) 'user' means any natural or legal person, who is not an operator, and who possesses a scheduled substance and is engaged in the processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, transformation or any other utilisation of scheduled substances."

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8 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).

9 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).

(2) Article 3 is amended as follows:

(a) paragraphs 2 and 3 are replaced by the following:

"2. Operators and users shall be required to obtain a licence from the competent authorities before they may possess or place on the market scheduled substances of category 1 of Annex I. Special licences may be granted by the competent authorities to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or armed forces. Such special licences shall only be valid for the use of scheduled substances of category 1 of Annex I within the scope of the official duties of the operators concerned.

3. Any operator holding a licence referred to in paragraph 2 shall supply scheduled substances of category 1 of Annex I only to operators or users who hold such a licence and have signed a customer declaration as provided for in Article 4(1)."

(b) paragraph 5 is replaced by the following:

"5. Without prejudice to paragraph 9, the competent authorities may either limit the validity of the licence to a period not exceeding three years or may oblige the operators to demonstrate at intervals not exceeding three years that the conditions under which the licence was granted are still fulfilled. The licence shall mention the operation or operations for which it is valid, as well as the substances concerned. Special licences within the meaning of paragraph 2 shall be granted in principle for an unlimited duration but may be suspended or revoked by the competent authorities under the conditions of paragraph 4, third sentence."

(c) paragraph 6 is replaced by the following:

"6. […] Operators shall be required to obtain a registration from the competent authorities before placing on the market scheduled substances of category 2 of Annex I. Furthermore, users, 18 months after the date of publication, shall be required to obtain a registration from the competent authorities before possessing scheduled substances of subcategory 2A of Annex I. Special registrations may be

granted by competent authorities to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or the armed forces. Such registrations shall be considered valid only for the use of scheduled substances of category 2 of Annex I within the scope of the official duties of the operators or users concerned."

(d) the following paragraphs 6a and 6b are inserted:

"6a. Any operator holding a registration referred to in paragraph 6 shall supply scheduled substances of subcategory 2A of Annex I only to other operators or users who hold such a registration and have signed a customer declaration as provided for in Article 4(1).

6b. When considering whether to grant a registration, the competent authorities shall take into account in particular the competence and integrity of the applicant. The registration is to be refused if there are reasonable grounds for doubting the suitability and reliability of the applicant or of the officer responsible for the trade in scheduled substances. The registration may be suspended or revoked by the competent authorities whenever there are reasonable grounds for believing that the holder is no longer a fit and proper person to hold a registration, or that the conditions under which the registration was granted are no longer fulfilled."

(e) […] paragraph 7 is replaced by the following:

7. The competent authorities may require operators and users to pay a fee for the application for a licence or a registration. Such fees shall be levied in a non-discriminatory way and shall not exceed the cost of processing the application.

[…]

(f) the following paragraphs 8 and 9 are added:

"8. The competent authorities shall enter operators and users having obtained a licence referred to in paragraph 2 or a registration referred to in paragraph 6 in a European Database on drug precursors to be developed by the Commission as provided for in Article 13a.

9. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning:

(a) the requirements and conditions for the granting of the licence referred to in paragraph 2;

(b) the requirements and conditions for the granting of the registration referred to in paragraph 6.

(c) the requirements and conditions for listing operators and users having obtained a licence or registration in a European Database on drug precursors referred to in paragraph 8."

(3) Article 4 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. Without prejudice to paragraph 4, Articles 6 and 14, any operator established within the Community who supplies a customer with a scheduled substance of categories 1 or 2 of Annex I shall obtain a declaration from the customer which shows the specific use or uses of the scheduled substances. A separate declaration shall be required for each scheduled substance. This declaration shall conform to the model set out in point 1 of Annex III. In the case of legal persons, the declaration shall be made on headed notepaper."

(b) the following paragraph 4 is added:

"4. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for obtaining and using customer declarations."

(4) In Article 5, the following paragraph 7 is added:

"7. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for the documentation of mixtures containing substances listed in Annex I."

(5) In Article 7, the following second paragraph is added:

"The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for the labelling of mixtures containing substances listed in Annex I."

(6) Article 8 is replaced by the following:

"1 Operators shall notify the competent authorities immediately of any circumstances, such as unusual orders or transactions involving scheduled substances to be placed on the market, which suggest that such substances might be diverted for the illicit manufacture of narcotic drugs or psychotropic substances. To this end, operators shall provide any available information allowing the competent authorities to verify the legitimacy of the relevant order or transaction.

2. Operators shall provide the competent authorities in summary form with relevant information about their transactions involving scheduled substances.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for operators to provide information as referred to in paragraph 2."

(7) In Article 9, paragraph 1 is replaced by the following:

"In order to facilitate cooperation between the competent authorities, the operators, and the chemical industry, in particular as regards non-scheduled substances, the Commission shall draw up and update guidelines. ."

(7a) Article 10, paragraph 1, letter (b) is replaced byu the following:

"(b) to enter business premises in order to obtain evidence of irregularities;"

(8) In Article 10, paragraph 2 is replaced by the following:

"2. 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 non-scheduled substances or operations involving non-scheduled substances;

(b) to enter […] business premises in order to obtain evidence of suspicious transactions with non-scheduled substances;

(c) where necessary, to detain consignments […] to prevent the use of specific non-scheduled substances for illicit production of drugs.

3. The competent authorities shall respect confidential business information."

(8a) Article 13 is replaced by the following:

"Article 13

Communications from Member States

1. To permit any necessary adjustments to the arrangements for monitoring trade in scheduled substances and non-scheduled substances, 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."

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a in order to specify the conditions and requirements concerning the information to be provided under paragraph 1.

3. A summary of the communications made pursuant to paragraph 1 shall be submitted by the Commission to the International Narcotics Control Board in accordance with Article 12(12) of the United Nations Convention and in consultation with the Member States."

(9) The following Article 13a is inserted:

"*Article 13a*

Database

The Commission shall develop a European Database on drug precursors with the following functions:

(a) facilitating the communication of information pursuant to Article 13(1), its synthesis and analysis on the level of the Union, and the reporting to the International Narcotics Control Board pursuant to Article 13(2);

(b) creating a European register of operators and users, which have been granted a licence pursuant to Article 3(2) or registration pursuant to Article 3(6);

(c) enabling operators to provide the competent authorities with information about their transactions according to Article 8(2) in electronic form, as specified in implementing measures adopted pursuant to Article 14."

(10) The following Article 13b is inserted:

"*Article 13b*

Data protection

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[10] and under the supervision of the public independent authority of the Member State referred to in Article 28 of this Directive.

2. The processing of personal data by the Commission, including for the purpose of the European Database provided for in Article 13a, shall be carried out in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council[11] and under the supervision of the European Data Protection Supervisor.

3. Member States and the Commission shall not process personal data in a way incompatible with the purposes set out in Article 13 a of this Regulation."

[10] OJ L 281, 23.11.1995, p. 31.
[11] OJ L 8, 12.1.2001, p. 1.

(11) Articles 14 and 15 are replaced by the following:

"*Article 14*

Implementing Acts

1. The Commission may adopt the following implementing acts:

(a) rules on how to provide customer declarations referred to in Article 4 in electronic form, where appropriate;

(b) rules on how to provide the information referred to in Article 8(2), including in electronic form to a European database, where appropriate.

(c) procedural rules for the granting of licences, the granting of registration and the listing of operators and users in a European Database as referred to in Articles 3.2, 3.6 and 3.8 respectively.

2. The acts referred to in paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 14a(2).

Article 14a

Committee Procedure

1. The Commission shall be assisted by the Drug Precursors Committee established by Article 30 of Council Regulation (EC) No 111/2005[12]. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

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

[12] OJ L 22, 26.1.2005, p.1.

Article 15

Adaptation of Annexes

The Commission shall be empowered to adopt delegated acts in accordance with Article 15a in order to adapt Annexes I, II and III to new trends in diversion of drug precurors and to follow an amendment to the tables in the Annex to the United Nations Convention.

Article 15a

Exercise of delegation

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 Article 3(9), 4(4), 5(7), 7, 8(3), […]15 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 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 Article 3(9), 4(4), 5(7), 7, 8(3), […]15 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 spedified 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 Article 3(9), 4(4), 5(7), 7, 8(3), […]15 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 Parliamant 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."

(12) Article 16 is replaced by the following:

"*Article 16*

Information about measures adopted by Member States

1. Member States shall inform the Commission of the measures it adopts pursuant to this Regulation, and in particular of the measures adopted pursuant to Articles 10 and 12. They shall also notify any subsequent amendments thereof.

2. The Commission shall communicate that information to the other Member States.

3. The Commission shall evaluate the implementation and functioning of this Regulation by [78 months after of the date of entry into force of this amending Regulation]."

(13) Annex I is amended as follows:

(a) the title of Annex I is replaced by the following:

"List of scheduled substances";

(a)(a) **The following substance is added to the list of substances under Category 1:**

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

(b) the text set out for Category 2 is replaced by the text set out in the Annex to this Regulation;

(14) In Annex III, the term "authorisation/" shall be deleted.

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	*For the Council*
The President	*The President*

ANNEX

"CATEGORY 2

SUBCATEGORY 2A

Substance	CN designation (if different)	CN code(1)	CAS No(2)
Acetic anhydride		2915 24 00	108-24-7

The salts of the substances listed in this category, whenever the existence of such salts is possible.

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(1) OJ L290, 28.10.2002, p.1.

(2) The CAS No is the 'chemical abstracts service registry number', which is a unique numeric identifier specific to each substance and its structure. The CAS No is specific to each isomer and to each salt of each isomer. It must be understood that the CAS Nos for the salts of the substances listed above will be different to those given.

SUBCATEGORY 2B

Substance	CN designation (if different)	CN code(1)	CAS No(2)
Phenylacetic acid		2916 34 00	103-82-2
Anthranilic acid		2922 43 00	118-92-3
Piperidine		2933 32 00	110-89-4
Potassium permanganate		2841 61 00	7722-64-7

The salts of the substances listed in this category, whenever the existence of such salts is possible.

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(1) OJ L290, 28.10.2002, p.1.

(2) The CAS No is the 'chemical abstracts service registry number', which is a unique numeric identifier specific to each substance and its structure. The CAS No is specific to each isomer and to each salt of each isomer. It must be understood that the CAS Nos for the salts of the substances listed above will be different to those given.
