REGULATION (EU) No 1258/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 November 2013

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],

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) On 7 January 2010, the Commission adopted a report pursuant to Article 16 of Regulation (EC) No 273/2004 of the European Parliament and of the Council [3] on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors.

(2) In that report, the Commission recommended further analysing ways to strengthen the control of the trade of acetic anhydride, a scheduled substance in category 2 of Annex I to Regulation (EC) No 273/2004, pursuant to Article 2(a) of that Regulation, in order to better prevent the diversion of acetic anhydride for the illicit production of heroin.

(3) In its Conclusions of 25 May 2010 on the functioning and implementation of the EU drug precursors legislation, the Council invited the Commission to propose legislative amendments after carefully assessing their potential impact on Member States' authorities and economic operators.

(4) This Regulation clarifies the definition of a scheduled substance: in this regard, the term 'pharmaceutical preparation', which stems from the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988, is deleted as it is already covered by the relevant terminology of Union legal acts, namely 'medicinal products'. Moreover, the term 'other preparations' is deleted as it duplicates the term 'mixtures' already used in that definition.

(5) A definition of the term 'user' should be introduced for persons possessing substances for purposes other than placing them on the market and it should be clarified that persons using scheduled substances in category 1 of Annex I to Regulation (EC) No 273/2004 for other purposes than placing them on the market are obliged to obtain a licence.

(6) 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 to Regulation (EC) No 273/2004. For substances scheduled in a new subcategory 2A of Annex I to that Regulation, in addition to operators users should also be subject to a registration requirement.

(7) Where fees are levied for obtaining a licence or registration, Member States should consider adjusting such fees in order to safeguard the competitiveness of microenterprises.

(8) It should be made clear 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.

(9) A European database on drug precursors ('the European database') should be created to simplify the reporting by Member States with regard to seizures and stopped shipments, where possible in an aggregated and anonymised manner and in the least intrusive manner as regards the processing of personal data, taking into account the state of the art of privacy-enhancing technologies and the principle of data limitation. The European database should also serve as a European register of operators and users holding a licence or registration which will facilitate verification of the legitimacy of commercial transactions involving scheduled substances, and should enable operators to provide the competent authorities with information about their transactions involving scheduled substances.

(10) Regulation (EC) No 273/2004, as amended by this Regulation, envisages the processing of information, including the processing of personal data, for the purposes of enabling the competent authorities to monitor the placing on the market of drug precursors and to

[1] OJ C 76, 14.3.2013, p. 54.

[2] Position of the European Parliament of 23 October 2013 (not yet published in the Official Journal) and decision of the Council of 15 November 2013.

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

prevent the diversion of scheduled substances. The processing of personal data should be carried out in a manner compatible with the purpose of that Regulation and in accordance with Directive 95/46/EC of the European Parliament and of the Council [1] and Regulation (EC) No 45/2001 of the European Parliament and of the Council [2] and, in particular, with Union requirements relating to data quality, proportionality, purpose limitation, and rights to information, access, rectification of data, erasure and blocking, organisational and technical measures and international transfers of personal data.

(11) The processing of personal data for the purposes of Regulation (EC) No 273/2004, as amended by this Regulation, and any delegated and implementing acts adopted pursuant thereto should respect the fundamental right to respect for private and family life recognised by Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms as well as the rights to respect for private and family life, and the right to the protection of personal data recognised, respectively, by Articles 7 and 8 of the Charter of Fundamental Rights of the European Union. The delegated and implementing acts should also ensure that any processing of personal data takes place in accordance with Directive 95/46/EC and Regulation (EC) No 45/2001.

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

(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 [3].

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

(15) In order to achieve the objectives of Regulation (EC) No 273/2004, as amended by this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to specify the requirements and conditions for the granting of the licence and registration, for listing operators and users having obtained a licence or registration in the European database, for obtaining and using customer declarations, for the documentation and labelling of mixtures containing scheduled substances, for the provision of information by the operators on transactions involving scheduled substances, and for information to be provided by Member States on the implementation of the monitoring measures laid down in Regulation (EC) No 273/2004, and in order to amend the Annexes thereto. Such delegated acts should also determine the categories of personal data which can be processed by Member States and operators pursuant to Regulation (EC) No 273/2004, the categories of personal data which can be stored in the European database and the safeguards for the processing of personal data. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure the simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(16) It is also important that the Commission seek the opinion of the European Data Protection Supervisor when preparing delegated acts relating to the processing of personal data.

(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 [4]. 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 and on how to provide the information about transactions of operators with scheduled substances to a European database.

(18) Since the objective of this Regulation, namely to strengthen the rules for registration of operators placing on the market or possessing scheduled substances of category 2 of Annex I to Regulation (EC) No 273/2004, in particular acetic anhydride, in order to prevent its diversion towards the illicit production of drugs, cannot be sufficiently achieved by the Member States because traffickers gain from national differences in registration and move their illicit business where drug precursors are easiest to divert, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level, 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

[1] 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 (OJ L 281, 23.11.1995, p. 31).

[2] 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 (OJ L 8, 12.1.2001, p. 1).

[3] Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).

[4] 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 (OJ L 55, 28.2.2011, p. 13).

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 that objective.

(19) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and delivered an opinion on 18 January 2013 ([1]).

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

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 273/2004 is amended as follows:

(1) Article 1 is replaced by the following:

'*Article 1*

Scope and objectives

This Regulation establishes harmonised measures for the intra-Union control and monitoring of certain substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances with a view to preventing the diversion of such substances.';

(2) in Article 2:

(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 but excluding mixtures and natural products 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, medicinal products as defined in point 2 of Article 1 of Directive 2001/83/EC of the European Parliament and of the Council (*) and veterinary medicinal products as defined in point 2 of Article 1 of Directive 2001/82/EC of the European Parliament and of the Council (**);

(*) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(**) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).';

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

'(c) "placing on the market" means any supply, whether in return for payment or free of charge, of scheduled substances in the Union; or the storage, manufacture, production, processing, trade, distribution or brokering of these substances for the purpose of supply in the Union;';

(c) the following points are added:

'(h) "user" means a natural or legal person other than an operator 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;

(i) "natural product" means an organism or a part thereof, in any form, or any substances which occur in nature as defined in point 39 of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (*).

(*) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).';

(3) in Article 3:

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

'2. Operators and users shall obtain a licence from the competent authorities of the Member State in which they are established before they may possess or place on the market scheduled substances of category 1 of Annex I. The competent authorities may grant special licences to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or armed forces. Such special licences shall be valid only 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 shall supply scheduled substances of category 1 of Annex I only to operators or users who also hold a licence and have signed a customer declaration as provided for in Article 4(1).';

(b) paragraphs 5, 6 and 7 are replaced by the following:

'5. Without prejudice to paragraph 8, the competent authorities may either limit the validity of the licence to a period not exceeding three years or

([1]) Not yet published in the Official Journal.

may oblige the operators and users 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 scheduled substances concerned. The competent authorities shall, in principle, grant special licences for an unlimited duration but may suspend or revoke them where there are reasonable grounds for believing that the holder is no longer a fit and proper person to hold a licence, or that the conditions under which the licence was granted are no longer fulfilled.

6. Operators shall obtain registration from the competent authorities of the Member State in which they are established before placing on the market scheduled substances of category 2 of Annex I. From 1 July 2015 users shall obtain a registration from the competent authorities of the Member State in which they are established before possessing scheduled substances of subcategory 2A of Annex I. The competent authorities may grant special registrations to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or the armed forces. Such special 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.

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

6b. When considering whether to grant registration, the competent authorities shall take into account, in particular, the competence and integrity of the applicant. They shall refuse registration 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. They may suspend or revoke registration where 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 registration was granted are no longer fulfilled.

6c. The competent authorities may require operators and users to pay a fee for the application for a licence or for registration.

Where a fee is levied, competent authorities shall consider adjusting the level of the fee depending on the size of the enterprise. Such a fee shall be levied in a non-discriminatory manner and shall not exceed the cost of processing the application.

7. The competent authorities shall list the operators and users that have obtained a licence or a registration in the European database referred to in Article 13a.

8. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for:

(a) granting the licence, including, where relevant, the categories of personal data to be provided;

(b) granting registration, including where relevant the categories of personal data to be provided;

(c) listing operators and users in the European database referred to in Article 13a, in accordance with paragraph 7 of this Article.

The categories of personal data referred to in points (a) and (b) of the first subparagraph of this paragraph shall not include special categories of data as referred to in Article 8(1) of Directive 95/46/EC of the European Parliament and of the Council (*).

(*) 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 (OJ L 281, 23.11.1995, p. 31).';

(4) in Article 4:

(a) paragraph 1 is replaced by the following:

'1. Without prejudice to paragraph 4 of this Article, and to Articles 6 and 14, any operator established within the Union who supplies a customer with a scheduled substance of category 1 or 2 of Annex I shall obtain a declaration from the customer which shows the specific use or uses of the scheduled substances. The operator shall obtain a separate declaration for each scheduled substance. That 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) paragraph 3 is replaced by the following:

'3. An operator supplying scheduled substances of category 1 of Annex I shall stamp and date a copy of the declaration, certifying it to be a true copy of the original. Such copy shall always accompany those substances being moved within the Union and shall be presented on request to the authorities responsible for checking vehicle contents during transport operations.

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.';

(5) in Article 5, the following paragraph 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 scheduled substances.';

(6) in Article 7, the following 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 scheduled substances.';

(7) Article 8 is replaced by the following:

'Article 8

Notification of the competent authorities

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 that 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 with relevant information in summary form 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 of this Article including, where relevant, the categories of personal data to be processed for that purpose and the safeguards for processing such personal data.

4. Operators shall not disclose any personal data collected pursuant to this Regulation other than to the competent authorities.';

(8) in Article 9, paragraph 1 is replaced by the following:

'1. The Commission shall draw up, and keep up to date, guidelines to facilitate cooperation between the competent authorities, the operators, and the chemical industry, in particular as regards non-scheduled substances.';

(9) in Article 10:

(a) points (b) and (c) of paragraph 1 are replaced by the following:

'(b) to enter operators' and users' business premises in order to obtain evidence of irregularities;

(c) where necessary, to detain and seize consignments that fail to comply with this Regulation.';

(b) 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 involving non-scheduled substances, and 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 involving non-scheduled substances;

(c) where necessary, to detain and seize consignments to prevent the use of specific non-scheduled substances for the illicit manufacture of narcotic drugs or psychotropic substances.

3. The competent authorities shall respect confidential business information.';

(10) Articles 13 to 16 are 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 referred to in Article 13a 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 specifying the conditions and requirements concerning the information to be provided under paragraph 1 of this Article.

3. A summary of the communications made pursuant to paragraph 1 of this Article 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.

Article 13a

European database on drug precursors

1. The Commission shall establish a European database on drug precursors with the following functions:

(a) to facilitate the communication of information, where possible in an aggregated and anonymised manner, pursuant to Article 13(1), the synthesis and analysis of that information at the Union level, and the reporting to the International Narcotics Control Board pursuant to Article 13(3);

(b) to create a European register of operators and users, which have been granted a licence or registration;

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

Personal data shall be included in the European database only after the adoption of the delegated acts referred to in Articles 3(8) and 8(3).

2. The Commission and the competent authorities shall take all necessary measures to ensure the security, confidentiality and accuracy of personal data contained in the European database and to ensure that the rights of data subjects are protected in accordance with Directive 95/46/EC and Regulation (EC) No 45/2001 of the European Parliament and of the Council (*).

3. Information obtained pursuant to this Regulation, including personal data, shall be used in accordance with the applicable law on personal data protection and shall not be retained for longer than necessary for the purposes of this Regulation. The processing of special categories of data as referred to in Article 8(1) of Directive 95/46/EC and in Article 10(1) of Regulation (EC) No 45/2001 shall be prohibited.

4. The Commission shall make publicly available, in a clear, comprehensive and understandable manner, information concerning the European database in accordance with Articles 10 and 11 of Regulation (EC) No 45/2001.

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 laws, regulations and administrative provisions transposing Directive 95/46/EC and under the supervision of the supervisory authority of the Member State referred to in Article 28 of that Directive.

2. Without prejudice to Article 13 of Directive 95/46/EC, personal data obtained or processed pursuant to this Regulation shall be used solely for the purpose of preventing the diversion of scheduled substances.

3. The processing of personal data by the Commission, including for the purpose of the European database, shall be carried out in accordance with Regulation (EC) No 45/2001 and under the supervision of the European Data Protection Supervisor.

4. Member States and the Commission shall not process personal data in a manner incompatible with the purposes set out in Article 13a.

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, where appropriate, in electronic form to a European database;

(c) procedural rules for granting licences and registrations and for listing operators and users in the European database, as referred to in Article 3(2), (6) and (7).

2. Those implementing acts 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 (**). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (***).

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

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 precursors and to follow any amendment to the tables in the Annex to the United Nations Convention.

Article 15a

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Articles 3(8), 4(4) and 5(7), the second paragraph of Article 7, Articles 8(3) and 13(2) and Article 15 shall be conferred on the Commission for a period of five years from 30 December 2013. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-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 power referred to in Articles 3(8), 4(4) and 5(7), the second paragraph of Article 7, Articles 8(3) and 13(2) and Article 15 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the 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 to the Council.

5. A delegated act adopted pursuant to Articles 3(8), 4(4) and 5(7), the second paragraph of Article 7, Articles 8(3) and 13(2) and Article 15 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two 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 two months at the initiative of the European Parliament or of the Council.

Article 16

Information about measures adopted by Member States

1. Member States shall inform the Commission of the measures they adopt 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, by 31 December 2019, submit a report to the European Parliament and to the Council on the implementation and functioning of this Regulation, and in particular on the possible need for additional action to monitor and control suspicious transactions with non-scheduled substances.

(*) 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 (OJ L 8, 12.1.2001, p. 1).

(**) 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 (OJ L 22, 26.1.2005, p. 1).

(***) 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 (OJ L 55, 28.2.2011, p. 13).';

(11) in Annex I:

(a) the title is replaced by the following:

'List of scheduled substances';

(b) in category 1, the CN code for Norephedrine is replaced by the following:

'2939 44 00';

(c) in category 1, the following substance is added to the list of substances:

'Alpha-phenylacetoacetonitrile, CN code 2926 90 95, CAS No 4468-48-8';

(d) the text of category 2 is replaced by the text of the Annex to this Regulation;

(12) in Annex III, the text 'authorisation/' is 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 Strasbourg, 20 November 2013.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	V. LEŠKEVIČIUS

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.			

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.			

(1) OJ L 290, 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.