REGULATION (EU) No 1259/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 November 2013

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

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,

Acting in accordance with the ordinary legislative procedure ([1]),

Whereas:

(1) On 7 January 2010, the Commission adopted a report, pursuant to Article 32 of Council Regulation (EC) No 111/2005 ([2]), on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors.

(2) Trade in medicinal products is not controlled in the existing Union control system for drug precursors, since they are currently excluded from the definition of scheduled substances.

(3) The Commission report pointed out that medicinal products containing ephedrine and pseudoephedrine were diverted into the illicit drug manufacture outside the Union, as a substitute for 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 customs territory of the Union in order to prevent their diversion for the illicit manufacture of narcotic drugs or psychotropic substances.

(4) In its Conclusions of 25 May 2010 on the functioning and implementation of 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.

(5) 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 ('the United Nations Convention'), 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.

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

(7) Medicinal products and veterinary medicinal products ('medicinal products') containing ephedrine or pseudoephedrine should be controlled without impeding their legitimate trade. To that end, a new category (Category 4) should be added to the Annex to Regulation (EC) No 111/2005 listing medicinal products containing certain scheduled substances.

(8) The export of medicinal products listed in Category 4 of the Annex to Regulation (EC) No 111/2005, as amended by this Regulation, should be preceded by an export authorisation, and a pre-export notification sent by the competent authorities in the Union to the competent authorities of the country of destination.

(9) Member States' competent authorities should be given the powers to stop or seize those medicinal products where there are reasonable grounds for suspecting that they are intended for the illicit manufacture of narcotic drugs or psychotropic substances, when they are exported, imported or in transit.

(10) With a view to enabling Member States to react more quickly with regard to new trends in drug precursors' diversion, their possibilities to act in cases of suspicious transactions involving non-scheduled substances should be clarified. To that end, Member States should be able to empower their competent authorities to obtain information on any orders for or operations involving non-scheduled substances, or to enter business premises to obtain evidence of suspicious transactions involving such substances. In addition, competent authorities should prevent the introduction into, or the departure from, the customs territory of the Union of non-scheduled substances, where it can be demonstrated

([1]) 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.

([2]) 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).

that such substances will be used in the illicit manufacture of narcotic drugs or psychotropic substances. Such non-scheduled substances should be considered as proposed for inclusion in the voluntary monitoring list of non-scheduled substances.

(11) Member States' competent authorities should share between themselves and with the Commission, through the European database on drug precursors ('the European database'), established under Regulation (EC) No 273/2004 of the European Parliament and of the Council ([1]), information on seizures and stopped shipments in order to improve the overall level of information on trade in drug precursors, including medicinal products. The European database should be used to simplify the reporting by Member States with regard to seizures and stopped shipments. It should also serve as a European register of operators holding a licence or registration which will facilitate verification of the legitimacy of their transactions involving scheduled substances, and should enable operators to provide the competent authorities with information about their export, import or intermediary activities involving scheduled substances. That European register should be regularly updated and the information it contains should be used by the Commission and Member States' competent authorities only for the purpose of preventing the diversion of drug precursors onto the illegal market.

(12) Regulation (EC) No 111/2005 provides for the processing of data. Such processing may also cover personal data and should be carried out in accordance with Union law.

(13) The processing of personal data for the purposes of Regulation (EC) No 111/2005, 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 right 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.

(14) Member States and the Commission should process personal data only in a manner compatible with the purposes of Regulation (EC) No 111/2005, as amended by this Regulation, and the delegated and implementing acts adopted pursuant thereto. 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 ([2]) and Regulation (EC) No 45/2001 of the European Parliament and of the Council ([3]).

(15) 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 ([4]).

(16) 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).

(17) In order to achieve the objectives of Regulation (EC) No 111/2005, as amended by this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to set out the conditions for granting licences and registration and for determining cases where a licence or a registration is not required, 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 and by the Commission to allow them to monitor export, import or intermediary activities of operators, to determine the lists of the countries of destination to which exports of scheduled substances of Categories 2 and 3 of the Annex to Regulation (EC) No 111/2005 are to be preceded by a pre-export notification, to determine simplified pre-export notification procedures and to establish the common criteria to be applied by the competent authorities, to determine simplified export authorisation procedures and to establish the common criteria to be applied by the competent authorities, and to adapt the Annex to Regulation (EC) No 111/2005 in order to respond to new trends in diversion of drug precursors and to follow any amendment to the tables

([1]) 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).

([2]) 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).

([3]) 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).

([4]) 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).

in the Annex to the United Nations Convention. 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 a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(18) In order to ensure uniform conditions for the implementation of Regulation (EC) No 111/2005, as amended by this Regulation, implementing powers should be conferred on the Commission, namely to establish a model for licences, the procedural rules on the provision of information that is required by the competent authorities to monitor export, import or intermediary activities of operators, and the measures to ensure the effective monitoring of trade between the Union and third countries in drug precursors, in particular with regard to the design and use of export and import authorisation forms, for the purpose of preventing the diversion of drug precursors. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ([1]).

(19) The delegated and implementing acts adopted pursuant to Regulation (EC) No 111/2005, as amended by this Regulation, should guarantee a systematic and consistent control and monitoring of operators.

(20) 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 ([2]).

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

HAVE ADOPTED THIS REGULATION:

Article 1

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

(1) in the title of the Regulation and in Article 1, in points (d) and (e) of Article 2, in Article 10(1), in the first paragraph of Article 17, in the first paragraph of Article 20 and in Article 25, the noun 'Community' is replaced by the noun 'Union'. In point (e) of Article 2, in point (d) of Article 13(1), in the first subparagraph of Article 14(1), in Article 14(2), in Article 18 and in the first paragraph of Article 22, the term 'Community customs territory' is replaced by the term 'customs territory of the Union'. In the first subparagraph of Article 12(1), the term 'Customs territory from the Community' is replaced by the term 'customs territory of the Union';

(2) in Article 2:

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

'(a) "scheduled substance" means any substance listed in the Annex 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 (**), except medicinal products and veterinary medicinal products listed in the Annex;

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

'(c) "import" means any entry of scheduled substances having the status of non-Union goods into the customs territory of the Union, including temporary storage, the placing in a free zone or free warehouse, the placing under a suspensive procedure and the release for free circulation within the meaning of Council Regulation (EEC) No 2913/92 (*);

([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).

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

(*) 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).';

(*) Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1).';

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

'(j) "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) the first paragraph of Article 3 is replaced by the following:

'All imports, exports or intermediary activities involving scheduled substances, with the exception of substances listed in Category 4 of the Annex, shall be documented by the operator by way of customs and commercial documents, such as summary declarations, customs declarations, invoices, cargo manifests, transport and other shipping documents.';

(4) Article 5 is replaced by the following:

'Article 5

Operators shall ensure that labels are affixed on any packaging containing scheduled substances, except substances listed in Category 4 of the Annex, indicating their name as stated in the Annex, or, in the case of a mixture or a natural product, its name and the name of any scheduled substance, except substances listed in Category 4 of the Annex, as stated in the Annex, contained in the mixture or in the natural product. Operators may, in addition, affix their customary labels.';

(5) in Article 6:

(a) paragraph 1 is replaced by the following:

'1. Unless otherwise provided, operators established in the Union, 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 competent authority of the Member State in which the operator is established shall issue the licence.

In considering whether to grant a licence, the competent authority shall take into account the competence and integrity of the applicant, in particular the absence of any serious infringement or repeated infringements of legislation in the field of drug precursors and the absence of a record of any serious criminal offence.

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

(b) the following paragraph 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).';

(6) Article 7 is replaced by the following:

'Article 7

1. Unless otherwise provided, operators established in the Union, 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 competent authority in the Member State in which the operator is established shall issue the registration.

In considering whether to grant a registration, the competent authority shall take into account the competence and integrity of the applicant, in particular the absence of any serious infringement or repeated infringements of legislation in the field of drug precursors and the absence of a record of any serious criminal offence.

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.

2. The competent authority may suspend or revoke the registration where 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.';

(7) Article 8 is replaced by the following:

'*Article 8*

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

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 can be monitored by the competent authorities and the risk of diversion be minimised.';

(8) Article 9 is replaced by the following:

'*Article 9*

1. Operators established in the Union shall notify the competent authorities immediately of any circumstances, such as unusual orders and transactions involving scheduled substances, which suggest that such substances intended for import, export or intermediary activities might be diverted for the illicit manufacture of narcotic drugs or psychotropic substances.

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

(a) the name of the scheduled substance;

(b) the quantity and weight of the scheduled substance;

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

That information shall only be collected for the purposes of preventing the diversion of scheduled substances.

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 the procedural rules on the provision of such information, including, where appropriate, in electronic form to the European database on drug precursors established under Regulation (EC) No 273/2004 of the European Parliament and of the Council (*) ("the European database"). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).

(*) 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).';

(9) in Article 10, the following paragraphs are added:

'4. In order to respond rapidly to new diversion trends, the competent authorities of the Member States and the Commission may propose to add a non-scheduled substance to the list referred to in paragraph 2(b) in order to temporarily monitor its trade. Detailed arrangements and criteria for the inclusion or deletion from that list shall be specified in the guidelines referred to in paragraph 1.

5. If voluntary monitoring by the industry is considered insufficient to prevent the use of a non-scheduled substance for the illicit manufacture of narcotic drugs or psychotropic substances, the Commission may add the non-scheduled substance to the Annex by means of delegated acts in accordance with Article 30b.';

(10) in Article 11:

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

'1. All exports of scheduled substances listed in Categories 1 and 4 of the Annex and exports of scheduled substances listed in Categories 2 and 3 of the Annex to certain countries of destination shall be preceded by a pre-export notification sent from the competent authorities in the 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 of this Regulation to determine the lists of the countries of destination for export of scheduled substances listed in Categories 2 and 3 of the Annex 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. 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.';

(11) 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.';

(12) in Article 13(1), the following subparagraph is added:

'An application for an export authorisation for exports of scheduled substances listed in Category 4 of the Annex shall contain the information set out in points (a) to (e) of the first subparagraph.';

(13) 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.';

(14) in Article 20, the second paragraph is replaced by the following:

'However, where the substances referred to in the first paragraph are unloaded or transhipped, under temporary storage, stored in a free zone of control type I or a free warehouse, or placed under the external Union transit procedure, such import authorisation shall not be required.';

(15) in Article 26:

(a) paragraph 1 is replaced by the following:

'1. Without prejudice to 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 into the customs territory of the Union or their departure from it, where there are reasonable grounds for suspecting that such substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.';

(b) the following paragraphs are inserted:

'3a. The competent authorities of each Member State shall prohibit the introduction of consignments of non-scheduled substances into the customs territory of the Union or their departure from it where there is sufficient evidence that those substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.

The competent authority shall immediately inform the competent authorities of the other Member States and the Commission thereof, using the procedure referred to in Article 27.

Those substances shall be considered as proposed for inclusion in the list of non-scheduled substances referred to in point (b) of Article 10(2).

3b. Each Member State may adopt the measures necessary to enable its competent authorities to control and monitor suspicious transactions involving 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 involving non-scheduled substances.';

(16) the title of Chapter V is replaced by the following:

'DELEGATED AND IMPLEMENTING ACTS';

(17) 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, in particular with regard to the design and use of export and import authorisation forms, for the purpose of preventing the diversion of drug precursors. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).';

(18) Article 29 is deleted;

(19) Article 30 is replaced by the following:

'*Article 30*

1. The Commission shall be assisted by the Drug Precursors Committee. 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.

(*) 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).';

(20) the following Articles are inserted:

'*Article 30a*

The Commission shall be empowered to adopt delegated acts in accordance with Article 30b of this Regulation in order to adapt the Annex hereto to new trends in diversion of drug precursors, in particular substances which can be easily transformed into scheduled substances, and to follow any 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 power to adopt delegated acts referred to 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 10(5), Article 11(1) and (3), Articles 19 and 30a and Article 32(2) 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 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 10(5), Article 11(1) and (3), Articles 19 and 30a and Article 32(2) 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 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 10(5), Article 11(1) and (3), Articles 19 and 30a and Article 32(2) 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.';

(21) Article 32 is replaced by the following:

'*Article 32*

1. The competent authorities in each Member State shall communicate to the Commission in electronic form via the European database 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 30b in order to specify the conditions and requirements concerning the information to be provided under paragraph 1 of this Article.

3. On the basis of the information referred to in paragraph 1 of this Article, 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.

4. The Commission shall submit by 31 December 2019 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';

(22) the following Article is inserted:

'*Article 32a*

The competent authorities of the Member States and the Commission shall use the European database under the conditions for its use for the following functions:

(a) to facilitate the communication of information pursuant to Article 32(1) as well as the reporting to the International Narcotics Control Board pursuant to Article 32(3);

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

(c) to enable operators to provide the competent authorities with information about their export, import or intermediary activities according to Article 9(2), in electronic form.';

(23) Article 33 is replaced by the following:

'*Article 33*

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 of the European Parliament and of the Council (*) and under the supervision of the supervisory authority of the Member State referred to in Article 28 of that Directive.

2. 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 of the European Parliament and of the Council (**) and under the supervision of the European Data Protection Supervisor.

3. No special categories of data within 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 or 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 manner incompatible with the purposes set out in Article 32a.

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

(*) 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).

(**) 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).';

(24) in the Annex:

(a) the title is replaced by the following:

'List of scheduled substances';

(b) before the first table, the following subtitle is inserted:

'Category 1';

(c) in Category 1, the CN Code for Norephedrine is replaced by the following:

'2939 44 00';

(d) 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';

(e) the following category is added:

'Category 4

Substance	CN designation (if different)	CN Code
Medicinal products and veterinary medicinal products containing ephedrine or its salts	Containing ephedrine or its salts	3003 40 20 3004 40 20
Medicinal products and veterinary medicinal products containing pseudo-ephedrine or its salts	Containing pseudoep-hedrine (INN) or its salts	3003 40 30 3004 40 30'

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
The President
M. SCHULZ

For the Council
The President
V. LEŠKEVIČIUS