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► **B** REGULATION (EC) No 273/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 February 2004

on drug precursors

(Text with EEA relevance)

(OJ L 47, 18.2.2004, p. 1)

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**REGULATION (EC) No 273/2004 OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL**

of 11 February 2004

on drug precursors

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE
EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and
in particular Article 95 thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Economic and Social
Committee ⁽²⁾,

Acting in accordance with the procedure laid down in Article 251 of the
Treaty ⁽³⁾,

Whereas:

- (1) 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', was concluded by the Community by Council
Decision 90/611/EEC ⁽⁴⁾.
- (2) The requirements of Article 12 of the United Nations Convention
in respect of trade in drug precursors (i.e. substances frequently
used in the illicit manufacture of narcotic drugs and psychotropic
substances) have been implemented, as far as trade between the
Community and third countries is concerned, by Council
Regulation (EEC) No 3677/90 of 13 December 1990 laying
down measures to be taken to discourage the diversion of
certain substances to the illicit manufacture of narcotic drugs
and psychotropic substances ⁽⁵⁾.
- (3) Article 12 of the United Nations Convention envisages adoption
of appropriate measures to monitor the manufacture and
distribution of precursors. This requires the adoption of
measures relating to the trade in precursors among Member
States. Such measures were introduced by Council Directive
92/109/EEC of 14 December 1992 on the manufacture and the
placing on the market of certain substances used in the illicit
manufacture of narcotic drugs and psychotropic substances ⁽⁶⁾.
To better ensure that harmonised rules are applied at the same
time in all Member States, a regulation is considered to be more
adequate than the current Directive.

⁽¹⁾ OJ C 20 E, 28.1.2003, p. 160.

⁽²⁾ OJ C 95, 23.4.2003, p. 6.

⁽³⁾ Opinion of the European Parliament of 11 March 2003 (not yet published in
the Official Journal), Council common position of 29 September 2003 (OJ C
277 E, 18.11.2003, p. 31) and position of the European Parliament of 16
December 2003 (not yet published in the Official Journal).

⁽⁴⁾ OJ L 326, 24.11.1990, p. 56.

⁽⁵⁾ OJ L 357, 20.12.1990, p. 1. Regulation as last amended by Commission
Regulation (EC) No 1232/2002 (OJ L 180, 10.7.2002, p. 5).

⁽⁶⁾ OJ L 370 19.12.1992, p. 76. Directive as last amended by Regulation (EC)
No 1882/2003 of the European Parliament and of the Council (OJ L 284,
31.10.2003, p. 1).

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- (4) In the context of the enlargement of the European Union, it is important to replace Directive 92/109/EEC by a regulation, as each modification of that Directive and its Annexes would trigger national implementation measures in 25 Member States.
- (5) By decisions taken at its 35th session in 1992, the United Nations Commission on Narcotic Drugs included additional substances in the tables of the Annex to the United Nations Convention. Corresponding provisions should be laid down in this Regulation in order to detect possible cases of illicit diversion of drug precursors in the Community and to ensure that common monitoring rules are applied in the Community market.
- (6) The provisions of Article 12 of the United Nations Convention are based on a system of monitoring trade in the substances in question. Most trade in these substances is entirely lawful. The documentation of consignments and labelling of these substances should be sufficiently explicit. It is furthermore important, whilst providing competent authorities with the necessary means of action, to develop, within the spirit of the United Nations Convention, mechanisms based on close cooperation with the operators concerned and on the development of intelligence gathering.
- (7) The measures applicable to sassafras oil are currently interpreted in different ways in the Community, since in some Member States it is regarded as a mixture containing Safrole and is therefore controlled, while other Member States regard it as a natural product not subject to controls. Inserting a reference to natural products in the definition of 'scheduled substances' will resolve this discrepancy and therefore allow controls to be applied to sassafras oil; only natural products from which scheduled substances can be extracted easily should be covered by the definition.
- (8) Substances commonly used in the illicit manufacture of narcotic drugs or psychotropic substances should be listed in an Annex.
- (9) It should be ensured that the manufacture or use of certain scheduled substances listed in Annex I is subject to possession of a licence. In addition, the supply of such substances should be permitted only where the persons to whom they are to be supplied are holders of a licence and have signed a customer declaration. The detailed rules concerning the customer declaration should be laid down in Annex III.
- (10) Measures should be adopted to encourage operators to notify the competent authorities of suspect transactions involving scheduled substances listed in Annex I.
- (11) Measures should be adopted in order to guarantee better control of intra-Community trade in scheduled substances listed in Annex I.

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- (12) All transactions leading to the placing on the market of scheduled substances of categories 1 and 2 of Annex I should be properly documented. Operators should notify the competent authorities of any suspect transactions involving the substances listed in Annex I. However, exemptions should apply to transactions involving substances of category 2 of Annex I where the quantities involved do not exceed those indicated in Annex II.
- (13) A significant number of other substances, many of them traded legally in large quantities, have been identified as precursors to the illicit manufacture of synthetic drugs and psychotropic substances. To subject these substances to the same strict controls as those listed in Annex I would present an unnecessary obstacle to trade involving licences to operate and documentation of transactions. Therefore, a more flexible mechanism at Community level should be established whereby the competent authorities in the Member States are notified of such transactions.
- (14) The introduction of a cooperation procedure is provided for in the European Union action plan against drugs approved by the European Council of Santa Maria da Feira on 19 and 20 June 2000. In order to support cooperation between the competent authorities of the Member States and the chemicals industry, in particular with regard to substances which, although not referred to in this Regulation, might be used in the illicit manufacture of synthetic drugs and psychotropic substances, guidelines should be drawn up aimed at helping the chemical industry.
- (15) It is appropriate to make provision for the Member States to lay down rules on penalties applicable for infringement of the provisions of this Regulation. Given that the trade in drug precursors may lead to the illicit manufacture of synthetic drugs and psychotropic substances, Member States should be free to choose the most dissuasive penalties available under their national legislation.
- (16) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽¹⁾.
- (17) Since the objectives of this Regulation, namely the harmonised monitoring of the trade in drug precursors and the avoidance of its diversion to the illicit manufacture of synthetic drugs and psychotropic substances, cannot be sufficiently achieved by the Member States and can therefore, by reason of the international and changeable nature of such trade, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. 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.

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

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- (18) Council Directive 92/109/EEC, Commission Directives 93/46/EEC ⁽¹⁾, 2001/8/EC ⁽²⁾ and 2003/101/EC ⁽³⁾ and Commission Regulations (EC) No 1485/96 ⁽⁴⁾ and (EC) No 1533/2000 ⁽⁵⁾ should be repealed,

HAVE ADOPTED THIS REGULATION:

▼ M2*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.

▼ B*Article 2***Definitions**

For the purposes of this Regulation the following definitions shall apply:

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- (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 ⁽⁶⁾ 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 ⁽⁷⁾;

⁽¹⁾ Commission Directive 93/46/EEC of 22 June 1993 replacing and modifying the Annexes to Council Directive 92/109/EEC on the manufacture and placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances (OJ L 159, 1.7.1993, p. 134).

⁽²⁾ Commission Directive 2001/8/EC of 8 February 2001 replacing Annex I to Council Directive 92/109/EEC on the manufacture and placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances (OJ L 39, 9.2.2001, p. 31).

⁽³⁾ Commission Directive 2003/101/EC of 3 November 2003 amending Council Directive 92/109/EEC on the manufacture and placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances (OJ L 286, 4.11.2003, p. 14).

⁽⁴⁾ Commission Regulation (EC) No 1485/96 of 26 July 1996 laying down detailed rules for the application of Council Directive 92/109/EEC, as regards customer declarations of specific use relating to certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances (OJ L 188, 27.7.1996, p. 28). Regulation as amended by Regulation (EC) No 1533/2000 (OJ L 175, 14.7.2000, p. 75).

⁽⁵⁾ Commission Regulation (EC) No 1533/2000 of 13 July 2000 amending Regulation (EC) No 1485/96 laying down detailed rules for the application of Council Directive 92/109/EEC, as regards customer declarations of specific use relating to certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

⁽⁶⁾ 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).

⁽⁷⁾ 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).

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- (b) ‘non-scheduled substance’ means any substance which, although not listed in Annex I, is identified as having been used for the illicit manufacture of narcotic drugs or psychotropic substances;

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- (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;

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- (d) ‘operator’ means any natural or legal person engaged in the placing on the market of scheduled substances;
- (e) ‘International Narcotics Control Board’ means the Board established by the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol;
- (f) ‘special licence’ means a licence that is granted to a particular type of operator;
- (g) ‘special registration’ means a registration that is made for a particular type of operator;

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- (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 ⁽¹⁾.

▼ B*Article 3***Requirements for the placing on the market of scheduled substances**

1. Operators wishing to place on the market scheduled substances of categories 1 and 2 of Annex I shall be required to appoint an officer responsible for the trade in scheduled substances, to notify the competent authorities of the name and contact details of that officer and to notify them immediately of any subsequent modification of this information. The officer shall ensure that the trade in scheduled substances conducted by the operator takes place in compliance with this Regulation. The officer shall be empowered to represent the operator and to take the decisions necessary for performing the tasks specified above.

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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.

⁽¹⁾ 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).

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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).

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4. When considering whether to grant a licence, the competent authorities shall take into account in particular the competence and integrity of the applicant. The licence 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 licence 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 licence, or that the conditions under which the licence was granted are no longer fulfilled.

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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 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.

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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 ⁽¹⁾.

▼ B*Article 4***Customer declaration****▼ M2**

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.

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2. As an alternative to the above declaration for an individual transaction, an operator who regularly supplies a customer with a scheduled substance of category 2 of Annex I may accept a single declaration in respect of a number of transactions involving this scheduled substance over a period not exceeding one year, provided that the operator is satisfied that the following criteria have been met:

- (a) the customer has been supplied by the operator with the substance on at least three occasions in the preceding 12 months;

⁽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).

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- (b) the operator has no reason to suppose that the substance will be used for illicit purposes;
- (c) the quantities ordered are consistent with the usual consumption for that customer.

This declaration shall conform to the model set out in point 2 of Annex III. In the case of legal persons, the declaration shall be made on headed notepaper.

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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.

▼B*Article 5***Documentation**

1. Without prejudice to Article 6, operators shall ensure that all transactions leading to the placing on the market of scheduled substances of categories 1 and 2 of Annex I are properly documented in accordance with paragraphs 2 to 5 below. This obligation shall not apply to those operators who hold special licences or are subject to special registration pursuant to Article 3(2) and (6) respectively.

2. Commercial documents such as invoices, cargo manifests, administrative documents, transport and other shipping documents shall contain sufficient information to identify positively:

- (a) the name of the scheduled substance as given in categories 1 and 2 of Annex I;
- (b) the quantity and weight of the scheduled substance and, where a mixture or natural product is concerned, the quantity and weight, if available, of the mixture or natural product as well as the quantity and weight, or the percentage by weight, of any substance or substances of categories 1 and 2 of Annex I which are contained in the mixture;
- (c) the name and address of the supplier, distributor, consignee, and, if possible, of other operators directly involved in the transaction, as referred to in Article 2(c) and (d).

3. The documentation must also contain a customer declaration as referred to in Article 4.

4. Operators shall keep such detailed records of their activities as are required to comply with their obligations under paragraph 1.

5. The documentation and records referred to in paragraphs 1 to 4 shall be kept for at least three years from the end of the calendar year in which the transaction referred to in paragraph 1 took place, and must be readily available for inspection by the competent authorities upon request.

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6. The documentation may also be kept in the form of reproductions on an image medium or other data media. It must be ensured that the data stored:

- (a) match the documentation in appearance and content when made readable, and
- (b) are readily available at all times, can be made readable without delay and can be analysed by automated means for the duration of the period specified in paragraph 5.

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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.

▼B*Article 6***Exemptions**

The obligations according to Articles 3, 4 and 5 shall not apply to transactions involving scheduled substances of category 2 of Annex I where the quantities involved do not exceed those indicated in Annex II over a period of one year.

*Article 7***Labelling**

Operators shall ensure that labels are affixed to scheduled substances of categories 1 and 2 of Annex I before they are supplied. The labels must show the names of the substances as given in Annex I. Operators may in addition affix their customary labels.

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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.

*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.

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

▼ B*Article 9***Guidelines****▼ M2**

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.

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2. The guidelines shall provide in particular:

- (a) information on how to recognise and notify suspect transactions;
- (b) a regularly updated list of non-scheduled substances to enable the industry to monitor on a voluntary basis the trade in such substances;
- (c) other information which may be deemed useful.

3. The competent authorities shall ensure that the guidelines and the list of non-scheduled substances are regularly disseminated in a manner deemed appropriate by the competent authorities in accordance with the objectives of the guidelines.

*Article 10***Powers and obligations of competent authorities**

1. In order to ensure the correct application of Articles 3 to 8, each Member State shall adopt the measures necessary to enable its competent authorities to perform their control and monitoring duties, and in particular:

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

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- (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.

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.

▼B*Article 11***Cooperation between the Member States and the Commission**

1. Each Member State shall designate the competent authority or authorities responsible for ensuring the application of this Regulation and shall inform the Commission thereof.

2. For the purposes of applying this Regulation and without prejudice to Article 15, the provisions of Council Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters ⁽¹⁾, and in particular those on confidentiality, shall apply *mutatis mutandis*. The competent authority or authorities designated under paragraph 1 of this Article shall act as competent authorities within the meaning of Article 2(2) of Regulation (EC) No 515/97.

*Article 12***Penalties**

The Member State shall lay down the rules on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.

▼M2*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.

⁽¹⁾ OJ L 82, 22.3.1997, p. 1. Regulation as amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

▼ **M2***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 ⁽¹⁾.

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.

⁽¹⁾ 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).

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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 ⁽¹⁾. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽²⁾.
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.

⁽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).

⁽²⁾ 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).

▼ M2*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.

*Article 17***Repeals**

1. Council Directive 92/109/EEC, Commission Directives 93/46/EEC, 2001/8/EC and 2003/101/EC and Commission Regulations (EC) No 1485/96 and (EC) No 1533/2000 are hereby repealed.
2. References to the repealed directives or regulations shall be construed as being made to this Regulation.
3. The validity of any register established, any licences granted and any customer declarations issued under the repealed directives or regulations shall not be affected.

*Article 18***Entry into force**

This Regulation shall enter into force on 18 August 2005, except for Articles 9, 14 and 15, which shall enter into force on the day of publication of this Regulation in the *Official Journal of the European Union*, in order to permit the adoption of the measures provided for in those Articles. Such measures shall enter into force at the earliest on 18 August 2005.

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

▼ B

ANNEX I

▼ M2

List of scheduled substances

▼ B

CATEGORY 1

Substance	CN designation (if different)	CN code ⁽¹⁾	CAS No ⁽²⁾
1-phenyl-2-propanone	Phenylacetone	2914 31 00	103-79-7
N-acetylanthranilic acid	2-acetamidobenzoic acid	2924 23 00	89-52-1
▼ <u>M2</u>			
Alpha-phenylacetoacetone nitrile		2926 90 95	4468-48-8
▼ <u>B</u>			
Isosafrol (cis + trans)		2932 91 00	120-58-1
3,4-methylenedioxyphenylpropan-2-one	1-(1,3-Benzodioxol-5-yl)propan-2-one	2932 92 00	4676-39-5
Piperonal		2932 93 00	120-57-0
Safrole		2932 94 00	94-59-7
Ephedrine		2939 41 00	299-42-3
Pseudoephedrine		2939 42 00	90-82-4
Norephedrine		► <u>M2</u> 2939 44 00 ◀	14838-15-4
Ergometrine		2939 61 00	60-79-7
Ergotamine		2939 62 00	113-15-5
Lysergic acid		2939 63 00	82-58-6

The stereoisomeric forms of the substances listed in this category not being cathine ⁽³⁾, whenever the existence of such forms is possible.

The salts of the substances listed in this category, whenever the existence of such salts is possible and not being the salts of cathine.

⁽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.

⁽³⁾ Also named (+)-norpseudoephedrine, CN code 2939 43 00, CAS No 492-39-7.

▼ M2

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.

▼ M2

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.

▼ B

CATEGORY 3

Substance	CN designation (if different)	CN code ⁽¹⁾	CAS No ⁽²⁾
Hydrochloric acid	Hydrogen chloride	2806 10 00	7647-01-0
Sulphuric acid		2807 00 10	7664-93-9
Toluene		2902 30 00	108-88-3
Ethyl ether	Diethyl ether	2909 11 00	60-29-7
Acetone		2914 11 00	67-64-1
Methylethylketone	Butanone	2914 12 00	78-93-3

The salts of the substances listed in this category, whenever the existence of such salts is possible and not being the salts of hydrochloric acid and sulphuric acid.

⁽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.

▼B*ANNEX II*

Substance	Threshold
Acetic anhydride	100 l
Potassium permanganate	100 kg
Anthranilic acid and its salts	1 kg
Phenylacetic acid and its salts	1 kg
Piperidine and its salts	0,5 kg

▼ **B**

ANNEX III

1. Model declaration relating to individual transactions (category 1 or 2)

CUSTOMER DECLARATION OF SPECIFIC USE(S) OF THE SCHEDULED CATEGORY 1 OR 2 SUBSTANCE <i>(individual transactions)</i>	
I/We,	
Name:	
Address:	
.....	
Reference number of ► ⁽¹⁾	◀ licence/registration:
<i>(delete as appropriate)</i>	
issued on.....	by
<i>(name and address of the authority)</i>	
.....	
and without time limit/valid until	
<i>(delete as appropriate)</i>	
have ordered from	
Name:	
Address:	
.....	
the following substance	
Description:	
.....	
Combined nomenclature (CN) code:	Quantity:
The substance will be used solely for	
.....	
I/We hereby certify that the substance referred to above will not be re-sold or otherwise supplied to any other customer unless the latter furnishes a declaration of use in accordance with this model or, for category 2 substances, a declaration relating to multiple transactions.	
Signature	Name:
<i>(in block capitals)</i>	
Position:	Date:

► ⁽¹⁾ **M2**

▼ B

2. Model declaration relating to multiple transactions (category 2)

CUSTOMER DECLARATION OF SPECIFIC USE(S) OF THE SCHEDULED CATEGORY 2 SUBSTANCE <i>(multiple transactions)</i>	
I/We,	
Name:	
Address:	
.....	
Registration reference number:	
issued on..... by	
<i>(name and address of the authority)</i>	
.....	
and without time limit/valid until	
<i>(delete as appropriate)</i>	
intend to order from	
Name:	
Address:	
.....	
the following substance	
Description:	
.....	
Combined nomenclature (CN) code: Quantity:	
The substance will be used solely for.....	
.....	
and represents a quantity that is normally considered sufficient for	
<i>(up to a maximum of 12 months)</i>	
I/We hereby certify that the substance referred to above will not be re-sold or supplied to any other customer unless the latter submits a similar declaration of use or a declaration relating to individual transactions.	
Signature: Name:	
<i>(in block capitals)</i>	
Position: Date:	