

**COMMON POSITION (EC) No 59/2003****adopted by the Council on 29 September 2003****with a view to the adoption of a Regulation (EC) No .../2003 of the European Parliament and of the Council of ... on drug precursors**

(2003/C 277 E/03)

(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 <sup>(1)</sup>,

Having regard to the Opinion of the European Economic and Social Committee <sup>(2)</sup>,

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

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 <sup>(4)</sup>.
- (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 <sup>(5)</sup>.
- (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 <sup>(6)</sup>. 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.

- (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 thirty-fifth 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 substance' 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.

<sup>(1)</sup> OJ C 20 E, 28.1.2003, p. 160.

<sup>(2)</sup> OJ C 95, 23.4.2003, p. 6.

<sup>(3)</sup> Opinion of the European Parliament of 11 March 2003 (not yet published in the Official Journal), Council Common Position of 29 September 2003 and Decision of the European Parliament of ... (not yet published in the Official Journal).

<sup>(4)</sup> OJ L 326, 24.11.1990, p. 56.

<sup>(5)</sup> 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).

<sup>(6)</sup> OJ L 370 19.12.1992, p. 76. Directive as last amended by Commission Directive 2001/8/EC (OJ L 39, 9.2.2001, p. 31).

- (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.
- (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 <sup>(1)</sup>.
- (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.
- (18) Council Directive 92/109/EEC, Commission Directives 93/46/EEC <sup>(2)</sup>, 2001/8/EC <sup>(3)</sup> and 2003/.../EC <sup>(4)</sup> and Commission Regulations (EC) No 1485/96 <sup>(5)</sup> and (EC) No 1533/2000 <sup>(6)</sup> should be repealed,
- HAVE ADOPTED THIS REGULATION:
- Article 1*
- Scope and objectives**
- This Regulation establishes harmonised measures for the intra-Community 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.
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- <sup>(1)</sup> OJ L 184, 17.7.1999, p. 23.
- <sup>(2)</sup> 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).
- <sup>(3)</sup> 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).
- <sup>(4)</sup> OJ L ...
- <sup>(5)</sup> 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).
- <sup>(6)</sup> 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.

*Article 2***Definitions**

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

- (a) 'scheduled substance' means any substance listed in Annex I, including mixtures and natural products containing such substances. This excludes medicinal products as defined by 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<sup>(1)</sup>, pharmaceutical preparations, mixtures, natural products and other preparations containing scheduled substances that are compounded in such a way that they cannot be easily used or extracted by readily applicable or economically viable means;
- (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;
- (c) 'placing on the market' means any supply, whether in return for payment or free of charge, of scheduled substances in the Community; or the storage, manufacture, production, processing, trade, distribution or brokering of these substances for the purpose of supply in the Community;
- (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.

*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.

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

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

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.

5. Without prejudice to Article 14, the competent authorities may either limit the validity of the licence to a period not exceeding three years or may oblige the operators to demonstrate at intervals not exceeding three years that the conditions under which the licence was granted are still fulfilled. The licence shall mention the operation or operations for which it is valid, as well as the substances concerned. Special licences within the meaning of paragraph 2 shall be granted in principle for an unlimited duration but may be suspended or revoked by the competent authorities under the conditions of paragraph 4, third sentence.

6. Without prejudice to Article 6, operators engaged in the placing on the market of scheduled substances of category 2 of Annex I shall be required to register and update with the competent authorities without delay the addresses of the premises at which they manufacture or from which they trade in these substances, before placing them on the market. Pharmacies, dispensaries of veterinary medicine, certain types of public authorities or the armed forces may be made subject to a special registration. Such registrations shall be considered valid only for the use of precursors within the scope of the official duties of the operators concerned.

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

<sup>(1)</sup> OJ L 311, 28.11.2001, p. 67. Directive as amended by Directive 2002/98/EC (OJ L 33, 8.2.2003, p. 30).

#### Article 4

##### Customer declaration

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

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 twelve months;
- (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.

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 must always accompany category 1 substances being moved within the Community and must be presented on request to the authorities responsible for checking vehicle contents during transport operations.

#### 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 under 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.

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.

#### Article 6

##### Exemptions

The obligations under 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.

### 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.

2. Operators shall provide the competent authorities in summary form with such information about their transactions involving scheduled substances as is specified in implementing measures adopted pursuant to Article 14.

### Article 9

#### Guidelines

1. In order to facilitate cooperation between the competent authorities, the operators, and the chemical industry, in particular as regards non-scheduled substances, the Commission shall, in accordance with the procedure referred to in Article 15(2), draw up and update guidelines to assist the chemical industry.

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 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;
- (b) to enter operators' business premises in order to obtain evidence of irregularities;
- (c) where necessary, to detain consignments that fail to comply with this Regulation.

2. The competent authorities shall respect confidential business information.

### 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<sup>(1)</sup>, 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.

### 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 each year communicate to the Commission all information on the implementation of the monitoring measures laid down in this Regulation, in particular as regards substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances and methods of diversion and illicit manufacture.

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

### Article 14

#### Implementation

Where necessary, the following measures for the implementation of this Regulation shall be adopted in accordance with the procedure referred to in Article 15(2):

- (a) Determination of the requirements and conditions for the granting of the licence as provided for in Article 3 and the details pertaining to the licence;

<sup>(1)</sup> 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).

- (b) Determination, whenever necessary, of the conditions which shall apply to the documentation and labelling of mixtures and preparations containing substances listed in Annex I, as provided for in Articles 5 to 7;
- (c) Any amendments to Annex I made necessary by amendments to the tables in the Annex to the United Nations Convention;
- (d) Amendments to the thresholds set in Annex II;
- (e) Determination of the requirements and conditions for customer declarations referred to in Article 4, as well as the detailed rules concerning their use. This shall include rules on how to provide customer declarations in electronic form, where appropriate;
- (f) Other measures needed for the efficient implementation of this Regulation.

#### Article 15

##### Committee

1. The Commission shall be assisted by the committee set up by Article 10 of Regulation (EEC) No 3677/90.
2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

#### Article 16

##### Information about measures adopted by Member States

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

The Commission shall communicate this information to the other Member States. It shall evaluate the implementation of the Regulation three years after its entry into force.

#### Article 17

##### Repeals

1. Council Directive 92/109/EEC, Commission Directives 93/46/EEC, 2001/8/EC and 2003/.../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 ... (\*), except for Articles 9, 14 and 15, which shall enter into force on the day of the 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 ... (\*).

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

Done at ...

For the European Parliament  
The President

For the Council  
The President

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(\*) 18 months after the date of publication in the *Official Journal of the European Union*.

## ANNEX I

## SCHEDULED SUBSTANCES WITHIN THE MEANING OF ARTICLE 2(a)

## Category 1

Substance	CN designation (if different)	CN code <sup>(1)</sup>	CAS No <sup>(2)</sup>
1-Phenyl-2-propanone	Phenylacetone	2914 31 00	103-79-7
N-acetylanthranilic acid	2-Acetamidobenzoic acid	2924 23 00	89-52-1
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		ex 2939 49 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 <sup>(3)</sup> 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.

## Category 2

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

## Category 3

Substance	CN designation (if different)	CN code <sup>(1)</sup>	CAS No <sup>(2)</sup>
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.

<sup>(1)</sup> OJ L 290, 28.10.2002, p. 1.

<sup>(2)</sup> 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.

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

## 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



## 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  
(individual transactions)

I/We,

Name: .....

Address: .....

.....

Reference number of Authorisation/Licence/Registration: .....  
(delete as appropriate)issued on ..... by .....  
(name and address of the authority)and without time limit/valid until .....  
(delete as appropriate)

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: .....  
(in block capitals)

Position: ..... Date: .....

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

<p>CUSTOMER DECLARATION OF SPECIFIC USE(S) OF THE SCHEDULED CATEGORY 2 SUBSTANCE (multiple transactions)</p>	
<p>I/We,</p>	
<p>Name: .....</p>	
<p>Address: ..... .....</p>	
<p>Registration reference number: .....</p>	
<p>issued on ..... by ..... (name and address of the authority)</p>	
<p>and without time limit/valid until ..... (delete as appropriate)</p>	
<p>intend to order from</p>	
<p>Name: .....</p>	
<p>Address: ..... .....</p>	
<p>the following substance</p>	
<p>Description: ..... .....</p>	
<p>Combined nomenclature (CN) code: ..... Quantity: .....</p>	
<p>The substance will be used solely for ..... .....</p>	
<p>and represents a quantity that is normally considered sufficient for ..... months (up to a maximum of 12 months)</p>	
<p>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.</p>	
<p>Signature: .....</p>	<p>Name: ..... (in block capitals)</p>
<p>Position: .....</p>	<p>Date: .....</p>

## STATEMENT OF THE COUNCIL'S REASONS

### I. INTRODUCTION

The Commission submitted the above-mentioned proposal to the Council on 10 September 2002.

The European Parliament delivered its Opinion at first reading on 11 March 2003, adopting three amendments to the initial proposal.

In the light of the outcome of the European Parliament's first reading, on 27 May 2003 the Commission submitted an amended proposal.

The Economic and Social Committee delivered its Opinion on 26 February 2003 <sup>(1)</sup>.

Under the codecision procedure (Article 251 TEC), on 29 September 2003 the Council, having regard to Parliament's first reading, adopted its common position on the draft Regulation.

### II. OBJECTIVE

The objective of the proposed Regulation is to transform the existing Directive 92/109/EEC <sup>(2)</sup> into a Regulation in order to simplify legislation and thus facilitate legitimate trade in precursors in the internal market, avoiding at the same time the diversion of these chemicals to the manufacturing of illegal drugs.

### III. ANALYSIS OF THE COMMON POSITION

#### 1. General

In its common position the Council shares the proposal's objective, which is to establish harmonised measures for the intra-Community control and monitoring of certain substances frequently used for the illicit manufacture of narcotic drugs and psychotropic substances with a view to preventing the diversion of such substances.

#### 2. EP Amendments

The Council took the following positions on the amendments adopted by the European Parliament:

- *Amendment No 1* has been accepted by the Council and included as a new Recital 4 in the common position.
- *Amendment No 2* has not been incorporated into the common position since the list of non-scheduled substances is examined by the Committee referred to in Article 15 four times a year and modified when necessary. The Council shares the Commission's view that the proposed amendment would not lead to an improvement of the current system.
- The Council has not accepted the first part of *Amendment No 3*, whereby each Member State should inform the Commission annually of its implementation measures. However, the EP's concern that such information be provided regularly is addressed by the requirement for Member States to notify the Commission of any amendments to their implementation measures (Article 16). The second part of this Amendment has been accepted by the Council.

#### 3. New elements introduced by the Council

The main points of the common position which differ from the Commission's proposal are as follows:

##### *Recital 4*

This new Recital explicitly states that in the context of the EU enlargement it is important to transform the existing Directive into a Regulation, as each modification of the Directive and its annexes would trigger national implementation measures in 25 Member States.

<sup>(1)</sup> OJ C 95, 23.4.2003, p. 6.

<sup>(2)</sup> OJ L 370, 19.12.1992, p. 76.

*Recital 15*

The common position adds a new recital, Recital 15, to clarify that Member States which currently provide for strict controls and penalties under national legislation are not required to downgrade such legislation under this Regulation.

*Article 2 — Definitions*

- Under (c), 'processing' has been included in the definition of 'placing on the market' in order to include processing within the scope of the Regulation. Processing was included in the definition of 'operator' in Directive 92/109/EEC;
- Under (f) and (g) definitions have been added for 'special licence' and 'special registration' to reflect additions to Article 3(2), (5) and Article 5.

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

- A new paragraph 1 has been added by the Council to provide for the appointment by the operator of a particular person to monitor that trade in scheduled substances is in compliance with the Regulation. This provision enables the competent national authorities to assess whether a particular operator should be granted a licence;
- in paragraph 2 the common position introduces the requirement for operators to hold a licence before they possess scheduled substances, to facilitate more effective control. In addition, the common position allows the competent authorities to exempt certain categories of public authorities and operators from some of the obligations relating to the renewal of licences and the documentation required for transactions. This exemption is provided for through the issue of a special licence and registration. Exemption rules have been included in order to avoid creating an excessive administrative burden for the competent authorities and certain categories of operators. The introduction of exemptions is reflected in amendments to Article 3(5), last sentence, Article 3(6), 2nd sentence, Article 5(1), last sentence and Article 14(1);
- The provisions of paragraph (3) stating that operators may only supply scheduled substances to licence holders and signatories of customer declarations have been transferred from Article 4(3) of the Commission's proposal;
- In paragraph 4 the Council has added a provision stating that competent authorities should refuse to issue a licence if there are reasonable grounds to consider the applicant unsuitable;
- A new paragraph 5 has been inserted to empower the competent authorities either to limit the duration of validity of the licence or to seek proof that the conditions for granting the licence are still valid. This insertion allows stricter enforcement of the Regulation;
- In paragraph 7 the Council allows the competent authorities, in accordance with national practice in some Member States, to request a fee for licence or registration, which shall not exceed the administrative costs incurred.

*Article 5 — Documentation*

- In paragraph 1, operators who hold special licences or are subject to special registration are exempted from the obligation of documenting transactions;
- In paragraph 2 under (b), the common position includes natural products, in accordance with the definition of scheduled substances set out in Article 2(a);
- In paragraph 2 under (c), the Council makes reference to all operators involved in transactions in order to ensure that the whole chain of operators are identified on commercial documents, where this proves possible;
- In paragraph 6, the common position adds the possibility for electronic means of storing documentation.

*Article 6 — Exemptions*

Article 6 has been amended to clarify that the thresholds for category 2 substances cover a one-year period.

*Article 8 — Notification of the Competent Authorities*

The Council considered that implementing measures were necessary to determine the information required from operators on transactions involving scheduled substances. Article 8(2) has therefore been amended accordingly.

*Article 10 — Powers and obligations of Competent Authorities*

In paragraph 1 point (c) has been inserted to specify that competent authorities are empowered to detain consignments that are not in compliance with the Regulation.

*Article 12 — Penalties*

In paragraph 1 the obligation of Member States to notify the Commission on the establishment of rules on penalties or their amendment has been transferred to Article 16.

*Article 14 — Implementation procedure*

The Council considered that implementing measures were necessary in Article 14 to determine the requirements and conditions for the granting of licences. A new paragraph 1 has been introduced to meet this consideration. In addition, in paragraph 5 the Council envisaged the possible establishment of rules on how to provide customer declarations in electronic form. Finally a new paragraph 6 was added to cover other necessary implementing measures.

*Article 16 — Information about measures taken by Member States*

- Paragraph 1 has been amended in order to include the obligation for Member States to inform the Commission about the measures they take with regard to penalties and to performing their control and monitoring duties, and any amendments thereto. This obligation has been transferred from Article 12 of the Commission proposal;
- paragraph 2 has been redrafted to take account of an amendment adopted by the Parliament which imposes on the Commission the obligation to evaluate the implementation of the Regulation three years after its entry into force. Since Article 18 foresees that the Regulation shall enter into force 18 months from its publication in the Official Journal, the Council believes that it is reasonable to evaluate its implementation in five years from its publication approximately.

*Article 17 — Repeal and Recital 18*

Given that a period of 18 months is foreseen before the Regulation enters into force (Article 18), a number of Member States have asked the Commission to propose the immediate amendment of the annexes to the existing Directive 92/109/EEC via a Commission Directive. The adoption of this Directive via comitology is foreseen before the summer recess 2003. This Directive should also be repealed together with all current legal instruments specified in Article 17, when the new Regulation enters into force. Article 17 and the corresponding Recital 18 have therefore been amended accordingly.

*Annex I*

The common position:

- adds a title to Annex I;
- corrects the CN code and CAS number for Norephedrine;
- adds references to stereoisomeric forms of the substances listed in Category 1, wherever possible;
- excludes cathine from the substances included in Category 1; and
- adds technical explanatory notes.

**IV. CONCLUSION**

The Common Position, which has been unanimously adopted by the Council, has been designed to achieve the aim of this Regulation, which is to establish harmonised measures for the control and monitoring of the intra-Community licit trade on drug precursors, preventing the diversion of such chemicals for the illicit manufacture of narcotic drugs and psychotropic substances.

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