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Regulation on drug precursors in the European Union

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Both of the European Drugs Strategies of 2000–2004 and of 2005–2012 focus on reducing supply and demand of drugs or psychotropic substances. One of the most important parts of the above mentioned policy is monitoring precursor chemicals frequently used in illicit manufacture of narcotic drugs. Control system of precursors contains measures preventing diversion of precursor consignments from licit trade to illicit manufacture of drugs or psychotropic substances. All governments, as well as the European Community joined the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, in order to do everything to minimize threats caused by traffickers and organized crime. Prevention of precursor diversion is based on the adequate existing legislation system. Below brief history of the conventions involved and a review of UN regulations are given. The process of the European legal framework is shown in this article.

Background

The *Single Convention on Narcotic Drugs* is the international treaty against illicit manufacture and trafficking of narcotic drugs. The Single Convention was adopted in New York in 1961. It came into force in 1964 ratified by 40 states.[1] This agreement consolidated previous treaties controlled opium, coca and derivatives, broadening its control on cannabis and any drugs with similar effects. The Commission on Narcotic Drugs and World Health Organisation were empowered to add, remove and transfer drugs among the treaty's four schedules of controlled substances. The International Narcotic Control Board (INCB) was put in charge of administering controls on drug production, international trade and dispensation. The United Nations Office on Drugs and Crime (UNODC) was delegated the Board's day-to-day work of monitoring states parties and working with national authorities to ensure implementation of Single Convention. This treaty was supplemented by the *Convention on Psychotropic Substances* (1971) controlling LSD, Extasy and other psychoactive pharmaceuticals. After decades of efforts to implement the 1961 and 1971 Conventions, trends in drug

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abuse and illicit traffic were rapidly spreading worldwide. The international community had to realize that the existing drug control system is inadequate to counter with spreading clandestine production and illicit traffic in drugs. This new initiative was complement existing conventions. *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances* was signed at Vienna in 1988 (The 1988 Convention). It focuses on stopping organized crime by providing international cooperation and establishes a system for placing precursors to scheduled drugs under international control. The Chemical Action Task Force in its final report to the G-7 Economic Summit in 1992 stated: "…. regulation of legitimate commerce to deny traffickers the chemicals they need is one of our most valuable tools in the battle against drug criminals."

About precursors

Table 1. Substances scheduled in Tables I and II of the 1988 Convention

Substances included in Table I	Substances included in Table II
Acetic anhydride** (acetic oxide)	Acetone (2-propanone)
N-Acetylanthranilic-acid (benzoic acid,2-(acetylamino)-)	Anthranilic acid (2-aminobenzoic acid)
Ephedrine ([R-(R*,S*)]-[1-(methylamino)ethyl]-benzenemethanol)	Ethyl ether (1,1'-oxybis[ethanel])
Ergometrine (ergoline-8-carboxamide,9,10-didehydro-N-(2-hydroxy-1-methylethyl)-6-methyl-,[8β(S)])	Hydrochloric acid (hydrohloric acid)*
Ergotamine (ergotaman-3',6',18'-trione,12'-hydroxy-2'-methyl-5'-(phenylmethyl)-,(5))	Methyl ethyl ketone (2-butanone)
Isosafrole (1,3,-benzodioxole,5-(1-propenyl)-)	Phenylacetic acid (benzeneacetic acid)
Lysergic acid (8β)-9,10-didehydro-6-methylergoline-8-carboxylic acid)	Piperidine (piperidine)
3,4-Methylenedioxyphenyl-2-propanone (2-propanone,1-[3,4(methylenedioxy)phenyl]-)	Sulphuric acid (sulfuric acid)*
Norephedrine (R*,S*)-(1-aminoethyl)benzenemethanol	Toluene (benzene, methyl-)
1-Phenyl-2-propanone (1-phenyl-2-propanone)	
Piperonal (1,3-benzodioxole-5-carboxaldehyde)	
Potassium permanganate* *(permanganic acid(HMnO4), potassium salt)	
Pseudoephedrine ([S-(R˝*,R*]-[1-(methylamino)ethyl]-benzenemethanol)	
Safrole (1,3-benzodioxole,5-(2-propenyl)-)	

The salts of the substances listed in these Tables whenever the existence of such salts is possible.
* The salts of hydrochloric acid and sulphuric acid are specifically excluded from Table II.
** After revision held in 1992 Acetyc anhydride and Potassium permanganate were transferred into Table II.

Chemicals or substances that are used in the manufacture of other substances are called precursors. They are used in products such as pharmaceuticals, plastics, cosmetics, dyes etc. Precursor chemicals have also used for the manufacture of illicit drugs in clandestine laboratories. Precursors are the base materials for making specific drugs they are therefore required to be controlled or monitored. Appendix to the 1988 Convention identifies 23 substances to be controlled in two tables. Class I precursors in Table I are essential components of illicit substances such as methamphetamine, MDMA, cocaine, heroin and LSD. Class II chemicals in Table II are mostly solvents and reagents used in clandestine manufacturing processes.[2] Generally Table I chemicals are more critical to the production of controlled substances than are those in the Table II, therefore provisions concerning these substances are more rigorous. Table I substances are mainly used in the pharmaceutical industry, while the majority of Table II substances are mainly applicated in industry and commerce.

Summary of key elements in the 1988 Convention

Article 12 – Substances frequently used in manufacture of narcotic drugs or psychotropic substances.[2]

Development and implementation of regulations and administrative system – Parties should take the measures to prevent diversion of substances listed in Table I and Table II and should cooperate with each other.

Notification of substances – Parties to the convention must notify INCB if they have information that may help to the inclusion or deletion of a substance in Table I or Table II.

Monitoring system for domestic transactions – Parties should take the measures to monitor the manufacture and distribution of substances in Table I and Table II.

Mandatory control – Parties to the convention shall

- monitor international trade in substances listed in Table I and Table II in cooperation with manufacturers, importers, exporters, wholesalers and retailers in order to detect suspicious transactions; seize any substance in Table I or Table II when there is an evidence that is used in clandestine production of narcotic drugs or psychotropic substances;
- notify other parties regarding suspicious import, export and transit of substances in Table I and Table II;
- require that import and export of substances in Table I and II be properly labelled and documented. Documents must be kept for at least two years and be available for inspection.

Pre-export notification – Exporting countries must provide specified information on every export transaction of substances listed in Table I prior to such export when the importing country makes a formal request to the Secretary General of the United Nations.

Confidentiality – When requested parties must keep confidential any information procured about any trade, business, commercial or professional secret or trade process.

Annual reports – Each party shall submit annual reports to INCB including the quantity of seized substances in Table I and II and substances not in Tables, which have been used significantly in the production of narcotic drugs and psychotropic substances, the methods of diversion, illicit manufacture and the licit trade and use of those substances.

Exemptions – This article shall not apply to pharmaceutical preparation, not to other preparations containing substances in Table I and II that are compounded in such a way that such substances cannot be easily used or recovered by readily applicable means.

Offences and sanction – Each party shall adopt measures by establish criminal offences under its domestic law when committed internationally the manufacture, transport, distribution of equipment materials or of substances listed in Tables if those are to be used in or for illicit cultivation, production, or manufacture of narcotic drugs and psychotropic substances.

Implementation in EU

Table 2. Scheduled substances in legislation of the European Union

Category I	Category II	Category III
1-Phenyl-2-propanone	Acetic anhydride	Hydrochloric acid
N-acetylanthranilic acid	Phenylacetic acid	Sulphuric acid
Isosafrol (cis + trans)	Anthranilic acid	Toluene
3,4-Methylenedioxyphenylpropan-2-one	Piperidine	Ethyl ether
Piperonal	Potassium permanganate	Acetone
Safrole		Methylethylketone
Ephedrine		
Pseudoephedrine		
Norephedrine		
Ergometrine		
Ergotamine		
Lisergic acid		

The stereisomeric forms of the substances listed in this Category not being cathine, whenever the existence of such forms is possible.
The salts of the substances listed in these Categories whenever the existence of such forms is possible.

Control procedures and requirements governing trade between European Community and third countries are laid down in Council Regulation No 3677/90 and was implemented and amended by Community Regulation No 3769/92. Regulations define "scheduled substances" listed in three Tables in the Annex.[3,4] Precursors listed in Table II of the Convention were divided into two parts in Category 2 and Category 3. The commonly used solvents and potassium permanganate were transferred into Category 3. Regulation of substances listed in Category 3 is less strict than those in Category 2.

Import and export provisions

Category 1: the authority of the member state must issue individual export authorizations. The "Customs Export Declaration" is to be lodged in the authority. Decision shall be taken within 15 working days.

Category 2: Export processes are similar as in case of substances of Category 1 when exports are intended for any third country identified, or to an operator established in a country listed in Annex 2. In other cases exports of substances in Category 2 may be authorized on the basis at the request of the operators by issuing of an open authorization.

Category 3: Exports to non-targeted countries is unrestricted, there are circumstances, however that require open export authorization.

Documentation, records, labelling

Documentation: All export; import and transit operations of scheduled substances shall be properly documented:

- the name of the scheduled substance as given in Annex to the Regulations;
- the quantity and weight of the substance, if a mixture, the quantity and weight of it and the weight of percentage of the substance listed;
- name and address of the exporter, importer, distributor and consignee.

Records: Operators must keep detailed records of all transactions of scheduled precursors for three years from the end of the calendar year in which the operation took place.

Labelling: Labels must show the correct names of substances listed in Annex to the Regulation.

Licenses and registration

Category 1: An operator must obtain a license from the member state for import, export or transit operations.

Category 2: Operators engaged in import, export or transit substances in Category 2 are required to register the addresses of the premises where manufacture, or from which they trade these substances.

Category 3: The exports of these substances are required to register the addresses of the premises. Registration of substances in Category 3 is not necessary if the sum of these substances exported during previous year does not exceed the thresholds given in Annex I.

Intra-community trade

This directive applies to manufacture or placing on the market of chemicals in Categories 1 and 2. Category 2 chemicals have prescribed thresholds. There are no controls over intra-community trade in Category 3 chemicals. Commercial documents must contain information see below:

- the name of scheduled substances;
- the quantity and the weight of the substance;
- the name and address of the supplier, distributor and consignee;
- the end-user declaration.

Effects of the Convention

Some of the precursors listed have become difficult for traffickers to obtain as lot of states implement the provisions of the Convention. Traffickers have found new chemicals and new methods to make precursors or final drugs. To stop this phenomenon INCB and UNDCP have established a list of non-scheduled substances used in illicit drug manufacture. In 1998 the limited international surveillance list of non-scheduled substances was created. Twenty- seven substances were identified from an initial list of 500 substances. The European Commission has developed guidelines on legislative obligations as well as voluntary controls in a document *Chemical Control in the European Community – Guidelines for the Chemical Trade*.[5] It identifies indicators of suspicious transactions to help suppliers recognize suspected orders and suggest someone to be responsible as the main contact between the company and competent authorities. As a result of the new trends in trafficking it would be necessary to introduce more strict control provisions. At the United Nations General Assembly Special Session on the world drug problems held in New York in 1998 a draft resolution[6] was accepted. It contained

further strengthening on the control of precursor chemicals. Under the draft resolution on control of precursors states will be requested to:

1. improve the monitoring of trade in precursor chemicals through the regular exchange of information among exporting, importing and transit countries; encourage the rapid and timely exchange of information to prevent diversions;
2. informing importing countries of proposed imports before they take place, prior to precursors used in illicit manufacture of amphetamines and amphetamine-type stimulants and the key chemicals (acetic anhydride, potassium permanganate) used in illicit processing of heroin and cocaine;
3. promote the adoption of national legislation to comply strictly with the 1988 Convention to establish an international monitoring system in precursors;
4. develop effective mechanisms to obtain data on the licit manufacture and trade in precursors;
5. promote technical assistance programmes in field of police, customs other investigations and facilitate universal cooperation in the control of precursors;
6. adopt civil, penal and administrative measures for punishing the unlawful conduct between individuals or companies and criminals;
7. collect information on non-scheduled chemicals that have been used in illicit drug manufacture and trafficking and inform INCB so that it can maintain an up-to-date list.

The new regulation

In 2004 the European Parliament adopted a new regulation No 273/2204 on drug precursors. The aim of the regulation was to harmonize measures for the intra-community control and monitoring of certain substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances. In the regulation operators have lots of obligations:[7,8]

1. to notify the authorities immediately of any circumstances which suggest that such substance might be diverted for the illicit production;
2. to appoint an officer responsible for the trade and to notify the authorities of the name and details of this officer;
3. to declare the addresses of the premises at which they manufacture or from which they trade in these substances;
4. to obtain special license for possession of scheduled substances;
5. to ask customer to sign an end-user declaration - the use made of the substance in Category 1 and 2;

6. to supply scheduled substances with costumer declaration and with license of possession of substances in Category 1;
7. to label properly consignments of scheduled substances representing the name, quantity and weight of the substance and name and address of the supplier and customer.

To prevent creating unnecessary barriers to trade the requirements for scheduled substances of Category 2 are less restrictive where the quantities involved do not exceed those indicated in Annex 2. Referred to in Article 15 of the Regulation the Commission will draw up and keep updated at all times the list of products that should be monitored.

The same year another Regulation (No 111/2005) was adopted laying down rules for the monitoring of trade between the Community and third countries in drug precursors. According the assessment of European Action Plan on Drugs 2000–2004 this act has to fulfil new requirements:[9,10]

1. to extend monitoring requirements to operators based within the community facilitating trade between third countries;
2. to strengthen monitoring requirements of suspected customs procedures;
3. to intensify control procedures and requirements for export of most sensitive drug precursors (Category1);
4. to reduce administrative gates for exports of high volume substances (less sensitive ones);
5. import control mechanisms for the main synthetic drug precursors of amphetamine-type stimulants through individual consignment based controls should be further strengthened;
6. uniform application of these provisions within the Community should be ensured.

Monitoring system of scheduled substances involves the correct documentation and labelling containing the name, the quantity and the weight of the substance in case of a mixture or a natural, the percentage of any scheduled precursor and the term “DRUG PRECURSORS”, the names and addresses of the exporter, importer, and consignee. The documentation shall be kept for three years of the end of calendar year in which the operation took place. Operators established in the Community engaged in any kind of activity of scheduled substances in Category 1 shall hold a license, while operators doing any transactions in Scheduled substances listed in Category 2 and exporting of scheduled substance in Category 3 shall register the addresses of the premises.

Information system is determined in the regulation: The operators transmit all relevant information to the competent authorities and notify them of all transactions involving scheduled substances and provide the competent authorities with all data about their export import or intermediary activities. To strengthen cooperation among

the competent authorities of the states, operators and the chemical industry, the Commission draws up and updates guidelines about how to recognise and report suspected transactions.

Operators shall obtain export and import authorizations for all transactions of substances in Category 1 and 2 and export authorization are needed for substances in Category 3 where pre-export notification is required.

Both of 273/2004 and 111/2005 rules entered into force on 18 August 2005 by a new regulation No 1277/2005 of United Commission giving a unified legal frame of them.

About INCB and the latest trafficking trends

INCB not only monitors the implementation by Governments of the provisions of Article 12 of the 1988 Convention, but also initiates and coordinates various practical activities against diversion of and trafficking in precursor chemicals. INCB initiated three international activities: Operation Purple, Operation Topaz and Project Prism. During the years thousands of transactions have been monitored, diversion of numerous consignments had prevented under these operations. In the result of successes achieved in monitoring precursor chemicals traffickers have identified new methods and routes of diversion.[11]

Project Prism involves all measures and activities proposed by Board to Governments against illicit manufacture of amphetamine-type stimulants and of methamphetamine. These measures include licit requirements for the precursors, control of some pharmaceutical preparations, and global use of a modern electronic system of pre-export notifications between exporting and importing countries. Most sensitive substances used in the illicit manufacture of amphetamine-type stimulants are ephedrine, pseudo ephedrine, 3,4-methylenedioxyphenyl-2-propanone (3,4-MDP-2-P), 1-phenyl-2-propanone (P-2-P) and piperonal. According to the annual report published by the INCB trends in the illicit trade of ephedrine seems to be turning to ephedra, the plant material from which ephedrine and pseudo ephedrine are extracted and it is currently not under international control. Lots of shipments of ephedra originated from China were sent to Germany, the Netherlands and Sweden during 2005. Regarding 3,4,-MDP-2-P and P-2-P Europe remained the major manufacturer of the MDMA. The Governments of Belgium, Ireland, the Netherlands and Poland had successes during 2004. Traffickers might turn to piperonal, this widely available substance. It may be proved by the enormous seizure of piperonal (2.5 tons) by Romanian authorities in 2004.

Operation Purple was designed to identify and dismantle trafficking networks involved in the diversion of potassium permanganate that is used in the illicit manufacture of cocaine.

Operation Topaz is the international operation focusing on acetic anhydride, monitoring of its international trade and prevent traffickers from obtaining acetic anhydride. This substance is used in illicit manufacture of heroin. Operation had a significant success in Europe: Belarus, Bulgaria and The Russian Federation reported huge quantities of seizures during 2004.

Significant results have been achieved under Operation Purple and Topaz. The Board attempts to launch a new phase of the combined operations in the near future, named *Project Cohesion*. The new project is based on a regional approach to operational work and time limited regional activities. Combined operation is focusing on exchange of real-time information, intelligence gathering and backtracking investigations.

Problems experienced

1. Despite of the achieved successes of Project Prism and operations in the illicit manufacture of amphetamine-type stimulants, they are still spreading all over the world, and Europe remains the main destination and Asia is the main source of those precursors.
2. Falling number of seizures of MDMA precursors indicate that traffickers have found new manner of diversions.
3. Large number and quantity of seizures of acetic anhydride in Europe during 2004 shows that traffickers have identified new routes for their illicit trade.
4. Total of 127 states had submitted annual reports on substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances. Number of the states parties has failed to submit their annual reports for lot of years, and there are a few countries, which have never submitted this report to the Board.
5. Reports of seizures of precursor chemicals contain not sufficient data and details required by the Board.

Proposals for the future

1. To prevent traffickers from obtaining the precursors Governments should estimate their licit requirements for the precursors and lodge those data to the Board.
2. Against spreading illicit MDMA manufacturing Governments should control pharmaceutical preparations containing scheduled substances in the same way as the

listed precursor. Governments of exporting countries should provide pre-export notifications for exports for ephedrine and pseudo ephedrine.

3. The Board called the Governments failing complies with their reporting obligation to complement deficiencies and to submit the missing reports as soon as possible.
4. Governments effecting seizures should provide the information on non-scheduled substances that have been used in illicit drug manufacture, on the methods of diversion and illicit manufacture, or on stopping shipments.
5. Pre-export notification system assists Governments of exporting and re-exporting countries in ensuring that required pre-export notifications are sent to those importing countries, which have officially requested them. To facilitating the pre-export notification process a new Internet-based on-line system was created for the exchange of these notificitations.
6. The necessary actions to be taken by States to prevent diversion are possible only if States have established an adequate legislative basis that assists them to monitor the movement of precursors. Number of Governments have introduced, further tightened existing controls over the trade in precursor chemicals and provided feedback on the subject. The Council of the European Union adopted a further regulation on precursor control regulating the external trade in precursor control between European Union member States and third countries. It tightens existing controls over exports and introduced import control over all substances listed in Table I.

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