



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 23.05.1997  
COM(97) 249 final

**COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE  
EUROPEAN PARLIAMENT ON THE CONTROL OF NEW SYNTHETIC DRUGS  
(DESIGNER DRUGS)**

# **COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT ON THE CONTROL OF NEW SYNTHETIC DRUGS (DESIGNER DRUGS)**

## **I. INTRODUCTION**

Every year, large amounts of new synthetic drugs are produced in Member States of the European Union. The consumption of these drugs is on the rise, particularly among very young people. This development poses a serious threat to their health and lives and it is a source of great distress to our citizens. They expect urgent action at all levels to reverse this trend.

Firm action in this area is also needed to maintaining the credibility of the considerable efforts the European Union is undertaking in combatting the cultivation and production of narcotic drugs throughout the world.

The sharp increase of illicit production, trafficking and use of these new synthetic drugs in Europe can be attributed to several factors which make them different from more traditional plant-based drugs. These include:

- the ingredients needed for their production are all available within the EU, meaning that they can be produced locally, close to the areas of consumption.
- they are relatively easy to prepare, with precursors freely available in the market and requiring only a rather unsophisticated infrastructure such as abandoned warehouses or even mobile homes;
- they are cheaper than cocaine or other plant based drugs which are the other “more traditional” main stimulants in illicit markets and have a longer-lasting effect;
- they are seen as fashionable and part of youth culture in some countries. There is no strong link with theft or violent crime;
- the public health risk is frequently underestimated in public perception. It is not always easy to recognize the difference with similar, licit products which are often used functionally, e.g. in certain professions to increase endurance.

They do, however, also have features in common with plant-based drugs, notably the analogous threat they can pose to human health and the danger they represent, particularly to young people.

The Community action programme on the prevention of drug dependence already contributes to improving public awareness and developing appropriate health and social responses to this threat. In particular, this programme currently gives support to transnational pilot projects aiming to build up a system to recognise trends in drugs consumption among the young, to assess prevalence of drug use in particular settings such as Techno-scenes and to develop transnational exchange of data.

The European Commission, acting together with the Presidency of the Council of Ministers and the European Parliament, has on several occasions highlighted this problem and called for priority action at the level of the European Union. The fight against drugs became a central theme during the Irish Presidency and the Dublin European Council clearly pointed out the need to suppress domestic production and trafficking of synthetic drugs within our Member States.

This Communication represents the Commission's contribution to following up that instruction.

## **II. NATURE OF THE PROBLEM**

The world-wide nature of the problem is reflected in the increasing attention directed to it in the relevant international organisations within the United Nations family : World Health Organisation, International Narcotics Control Board, Commission on Narcotic Drugs.

There exists a major international legal instrument for tackling the problem at world level, in the shape of the 1971 United Nations Convention on Psychotropic Substances.

Ratified and implemented by 146 nations, and subsequently enhanced by the relevant provisions of the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, the 1971 Convention offers the essential international framework for the scheduling and interdiction of the main synthetic drugs identified at that time as posing a danger to health. It contains an updating mechanism, but recent experience has shown that this mechanism, requiring a world-wide international consensus, is slow to mobilise - and certainly not flexible or rapid enough to keep pace with the appearance on the market of new synthetic drugs often deliberately designed to circumvent the Convention's provisions.

The European Union and its Member States are, however, equipped -especially since the entry into force of the TEU - with a range of instruments and possibilities to react quickly and effectively among themselves to address the moving target represented by new synthetic drugs.

Synthetic drugs, like plant-based drugs, are dependent upon certain precursor chemicals. Of the 22 substances controlled through EC legislation in implementation of the 1988 United Nations Convention, 8 are directly relevant to synthetic drugs <sup>1</sup> and others need to be added.

Furthermore, with regard to end products (i.e. the synthetic drugs themselves, as opposed to their precursor chemicals) all EU Member States have introduced in their legislation the control of the psychotropic substances placed under control by the 1971 UN Convention (see ANNEX I). This Convention provides for the control of classified substances on the basis of their strict chemical definition.

Since, however, the amphetamine-type stimulants are very similar in chemical structure, they lend themselves easily to minor structural modifications to lead to a different end-product. These modifications can be motivated by various factors :

- (i) the deliberate effort to circumvent legislation on precursors or,
- (ii) the possible use and availability of non-listed precursors;
- (iii) the deliberate manufacturing of amphetamine-type stimulants not covered by national law or international convention, and sometimes referred to as "designer drugs".

It is chemically possible to obtain a large number of structures altered in this way, in which however the basic composition of the amphetamine remains unchanged. Some such derivatives currently popular in Europe thus fall outside the scope of the 1971 UN Convention on Psychotropic Substances. Although in theory this problem could be tackled through regular modification of any of the lists of the 1971 UN Convention, such a process can be expected to take 2-3 years. Thus an important lacuna can exist between the moment when new synthetic drugs are introduced in the illicit market and when they are added to one of the lists of the UN Convention. During this intervening period, and unless other defences are mounted, there is a risk that the new synthetic drugs can circulate freely since the criminal law of several Member States does not allow control to be legally exercised on substances which are not (yet) put under a list of controlled substances.

### **III. SOME RESPONSES AT NATIONAL LEVEL**

In countries affected by the problem of synthetic drugs, three different categories of response appear to have been adopted, in addition to the control system based on the strict chemical definition of the substances (the control "by name" of the substance) which is foreseen in the 1971 UN Convention on Psychotropic Substances :

---

<sup>1</sup> phenyl-2-propanone (P2P), ephedrine, pseudoephedrine, safrole, isosafrole, piperonal, 3,4 methylenedioxy-P2P and phenylacetic acid.

(i) the “generic approach” :

some Member States (United Kingdom, Ireland) have introduced in their misuse of drugs legislation the use of generic definitions for various families of drugs to catch those new synthetic drugs which do not appear on the Schedules of the UN Conventions. In Germany, a new bill which would introduce the generic approach is being discussed at the interministerial level and with the Länder before being presented at Parliament.

The use of generic definitions has the advantage of criminalising by anticipation a great number of groups of synthetic drugs that could eventually appear on the market. Although it can not cover all the potential drugs of abuse which may eventually be produced on the basis of a single molecular structure, it makes it more difficult for clandestine laboratories to produce synthetic drugs which remain outside of the scope of criminal law;

(ii) the “emergency list” approach

other Member States (Germany, The Netherlands) have introduced into their legislation an urgency procedure to control legally, on a provisional basis, new substances which appear on the market before the full introduction of these new drugs into the relevant schedule. This system allows for a quick reaction to the abuse of and trafficking in “new” synthetic drugs and can give rise to the use of criminal sanctions;

(iii) the “analogue” approach :

this is the system preferred by the US Drugs Enforcement Agency and is set out in the 1986 amendment to the Controlled Substances Act (CSA) in the form of the *Controlled Substance Analogue Enforcement Act*.

This Act provides that criminal sanctions apply to the activity of manufacturing and distributing “controlled substance analogues” intended for human consumption. These substances are considered “analogues” if they produce substantially the same psychoactive effect as controlled substances and have chemical structures substantially similar to those of controlled substances. These substances are therefore prohibited unless it is concluded in a court of law that the assumptions were unfounded. It is important to note that there is no list of controlled substance analogues. Since the introduction of the 1986 amendment, the DEA have observed a decrease in the production and distribution of analogues and attribute this, in particular, to the analogue statute which has had the effect of making the trafficking of new synthetic drugs too risky and uncertain to be worth the effort for the profit involved.

#### **IV. ELEMENTS FOR A RESPONSE AT THE LEVEL OF THE EUROPEAN UNION**

##### **THE DUBLIN EUROPEAN COUNCIL**

Heads of State and Government, meeting in Dublin in December 1996, identified the issue of synthetic drugs as needing priority attention both within the European Union and between the Union and third countries, particularly the Central and Eastern European countries. In doing so, they specifically endorsed the report on drugs they had received from the Council, and the Joint Action of 17 December 1996 concerning the approximation of the laws and practices of the Member States in the field of drugs.

The report in question stated clearly that synthetic drugs was an area "where insufficiencies exist" and "needed to be tackled at three levels: (a) legislation; (b) practical cooperation against production and trafficking, including improved cooperation between national authorities and the chemical industry; and (c) international cooperation".

As for the Joint Action, it states in its Article 5 that there is a need for more convergence in Member States legislation in the area of synthetic drugs and provides that the Member States "*shall endeavour to draft convergent legislation to the extent necessary to make up legal ground or fill legal vacuums as regards synthetic drugs. In particular they shall promote the establishment of a rapid information system to enable such drugs to be identified as substances liable to be prohibited as soon as they appear anywhere in a Member State*".

Thus the European Council has given clear guidance on how it wishes to see the problem addressed. The Commission considers that this invitation to ensure an appropriate and swift control on new synthetic drugs and their chemical precursors should be followed up by means of a number of initiatives, which could be taken on a step by step basis.

As a first and early step, the Commission favours action on three fronts:

- chemical precursors (starting material): Proposals for amending the existing Directive and Regulation will be presented by the Commission by October 1997.
- new synthetic drugs (end-products): the creation of an early warning system for synthetic drugs, including a mechanism for risk assessment .
- a commitment by Member States to criminalise production and trafficking of new synthetic drugs declared dangerous.

There is also a case for an examination at EU level of whether at a later stage additional instruments might enhance the effectiveness of the fight against the illicit trafficking in and use of synthetic drugs, based perhaps on a discussion of the relative merits of the "emergency list" approach, the "generic approach" or the "analogue approach" mentioned under chapter III above.

## ACTION FORESEEN ON PRECURSOR OF NEW SYNTHETIC DRUGS

An effective way of approaching the problem of new synthetic drugs consists in ensuring a better monitoring of the trade in the chemical substances which are the basic ingredients used in manufacturing new synthetic drugs.

It is not possible to monitor this trade under the classical methods of control such as those provided for under the present Community legislation on precursors. The nature of the chemicals involved and the particular conditions under which new synthetic drugs can be manufactured impede the use of these strict control mechanisms.

This is the reason why a broad consensus exists at the international level to look for other monitoring mechanisms such as a "special surveillance list", that would be more flexible for both trade and public authorities and thus would be really efficient, given this specific context. This is in particular the approach the US.DEA follows, more stringent mechanisms being unrealistic in this case.

Technical work is currently in progress in the competent Community fora. They will result in formal proposals by the Commission, to be presented to the Council next October, after further discussions with the Member states and the relevant trade and chemical industries organisations.

These proposals will address the following aspects:

- list of new products to be monitored,
- new methods for the monitoring of the products concerned,
- ways and means of adapting rapidly in the future the list of these products.

They will concern amendment of the existing directive concerning manufacture and placing on the market of the chemical substances concerned within the EU and amendment of the regulation concerning the international trade.

Moreover, when a common position has been adopted within the Council on this question, the Commission intends to ask for a negotiation mandate vis-à-vis the Central and Eastern European Countries on the territory of which new synthetic drugs are produced. In parallel, the Phare programme resources will be used to continue to help these countries to prepare and to adapt their own legislation on precursors, namely in view of their accession to the EU.

Finally, some efforts will have to be made in short term, in order to allow the EU to speak with one voice within the international meetings that should take place from next July, in view of the preparation of the 1998 UN General Assembly Special Session which will be devoted to drugs and in which precursors will occupy a large place.

The Commission will do the necessary work in order to ensure that the necessary coordination is done within the Council and that it results in a concrete Community position on this topic, thus allowing the EU to maintain a leading and constructive role in these international fora.

Details of this action are described in Annex II. The input of Member States experts in this process will be very important for achieving the objectives for action described in this Annex.

### CREATION OF AN EARLY WARNING SYSTEM

An effective early warning system for new synthetic drugs appearing in the Member States should build on existing information gathering bodies and avoid duplication. In addition to national sources, the two most appropriate such bodies at EU level are the Europol Drugs unit (EDU) for information coming from the law enforcement agencies, and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), by means of the national focal points of REITOX, for information coming from the health and social services.

To this can be added data concerning chemical precursors diverted into the illicit manufacture of synthetic drugs which will continue to be examined by the Drugs Precursors Committee set up under Regulation 3677/90 and Directive 92/109 to which the early warning system will provide an added value.

All this relevant information will need to be assessed by experts in order to evaluate the risks posed by these new substances.

The Commission believes that this assessment would best be carried out in the framework of a Technical Committee to be set up, which would involve representatives from not only Member States but also from the existing relevant agencies (EMCDDA; the Agency for the Evaluation of Medicinal Products; and the Europol Drugs Unit). The Commission would seem to be the right institution to chair such a committee, as well as contributing to its work on the basis of information on synthetic drugs coming from the existing Community instruments related to (i) the international control and intra-Community surveillance of chemical precursors, (ii) the Community action programme on the prevention of drug dependence, (iii) the Community framework research and development programme.

The Committee, having conducted its risk assessment on the basis of the information from different sources (law enforcement, health and social services) should make its recommendation for action at the level of the Council, including, where appropriate and agreed, action to ban and criminalise the production and trafficking of the dangerous substances identified.

## CO-OPERATION WITH CENTRAL AND EASTERN EUROPEAN COUNTRIES

Co-operation between EU Member States and the Central and Eastern European countries in fighting against illicit drugs trafficking, in particular synthetic drugs, received special attention at the seminar and meeting of the Council's Drugs and Organised Crime Working Group with the countries of Central and Eastern Europe and the Baltic States which took place on 23-24 October, 1996. This gave rise to a number of useful recommendations which should be followed up:

- Development of a network of law enforcement focal points for synthetic drugs and drug precursors between Member States of the European Union, the countries of Central and Eastern Europe and the Baltic States, making use of the existing list of contact points maintained in connection with the European Community legislation on the control of precursors;
- Combatting misuse of synthetic drugs and precursors by:
  - the building of a network of expertise from the European Union and associated countries to facilitate the enhancement of the knowledge necessary to tackle the problem, as well as the rapid exchange of information (profiling, production methods, etc.) and the adoption of the necessary legal provisions;
  - the surveillance of non-listed precursors used in illicit production, involving co-operation by law enforcement and other appropriate authorities. To this extent the importance of voluntary agreement and concluding Memoranda of Understanding with the trade were underlined.
- In the field of precursors, adaptation of the relevant PHARE project to ensure that the pre-accession procedures presently underway (adaptation of legislation to EU standards, ie Regulation 3677/90 and Directive 92/109) reflect any possible amendment of the EU legislation to cover chemicals diverted for the illicit manufacture of new synthetic drugs.

## CO-OPERATION WITH OTHER KEY EU PARTNERS

Given the global and growing nature of this synthetic drugs problem, as reflected in the Resolution adopted at the 1995 UN Commission on Narcotic Drugs (CND) and in a number of expert meetings which have taken place within the UN bodies concerned, particularly UNDCP and WHO, it would be appropriate also to share the EU's thinking with its main partners, notably the USA, Canada and Japan.

This could in turn lead to possible joint initiatives with them in international fora, for example at the UN Commission on Narcotic Drugs (CND) in view of the forthcoming UN General Assembly (UNGA) special session on drugs (1998).

## ANNEX I

**Table 1b: Scheduling of individual substances under the 1971 Convention on Psychotropic Substances**  
 (Note: Only the year of the first inclusion of a substance into any of the Schedules of the Psychotropic Convention has been considered)

| Sch. | 1971                               | 1980          | 1981 | 1984        | 1985 | 1986                | 1987       | 1988                   | 1989          | 1990              | 1991       | 1995          |
|------|------------------------------------|---------------|------|-------------|------|---------------------|------------|------------------------|---------------|-------------------|------------|---------------|
| I    | DET                                | eticyclidine  |      |             | DOB  | Cathinone           |            |                        |               | MDE               |            | tryptamine    |
|      | DMHP                               | rolicyclidine |      |             | MDA  | DMA                 |            |                        |               | N-OH-MDA          |            | methcathinone |
|      | DMT                                | tenocyclidine |      |             |      | DOET                |            |                        |               | 4-methyl-aminorex |            |               |
|      | LSI                                |               |      |             |      | MDMA                |            |                        |               |                   |            |               |
|      | mescaline                          |               |      |             |      | MMDA                |            |                        |               |                   |            |               |
|      | parahexyl                          |               |      |             |      | PMA                 |            |                        |               |                   |            |               |
|      | psilocine                          |               |      |             |      | TMA                 |            |                        |               |                   |            |               |
|      | psilocybine                        |               |      |             |      |                     |            |                        |               |                   |            |               |
|      | STP/DOM                            |               |      |             |      |                     |            |                        |               |                   |            |               |
|      | tetrahydrocannabinols <sup>2</sup> |               |      |             |      |                     |            |                        |               |                   |            |               |
| II   | amphetamine                        | mecloqualone  |      |             |      | fenethylone         |            | metamfetamine racemate |               |                   | dronabinol | ziperol       |
|      | dexamphetamine                     |               |      |             |      | levamphetamine      |            |                        |               |                   |            |               |
|      | metamphetamine                     |               |      |             |      | levomethamphetamine |            |                        |               |                   |            |               |
|      | methylphenidate                    |               |      |             |      |                     |            |                        |               |                   |            |               |
|      | phenacyclidine                     |               |      |             |      |                     |            |                        |               |                   |            |               |
|      | phenmetrazine                      |               |      |             |      |                     |            |                        |               |                   |            |               |
| III  | amobarbital                        |               |      | pentazocine |      | entline             | butalbital |                        | buprenorphine |                   |            |               |
|      | cyclobarbital                      |               |      |             |      |                     |            |                        |               |                   |            |               |

<sup>2</sup>Dronabinol (delta-9-tetrahydrocannabinol) was transferred from Schedule I to Schedule II in 1991.

**Table 1b: Scheduling of individual substances under the 1971 Convention on Psychotropic Substances**

(Note: Only the year of the first inclusion of a substance into any of the Schedules of the Psychotropic Convention has been considered)

| Sch. | 1971                      | 1980 | 1981              | 1984             | 1985 | 1986                         | 1987            | 1988 | 1989     | 1990      | 1991 | 1995       |
|------|---------------------------|------|-------------------|------------------|------|------------------------------|-----------------|------|----------|-----------|------|------------|
|      | glutethimide              |      |                   |                  |      |                              |                 |      |          |           |      |            |
| III  | pentobarbital             |      |                   |                  |      |                              |                 |      |          |           |      |            |
|      | secobarbital <sup>3</sup> |      |                   |                  |      |                              |                 |      |          |           |      |            |
| IV   | amfepramone               |      | benzphetamine     | alprazolam       |      | etilamfetamine               | allobarbitol    |      | pemoline | midazolam |      | aminorex   |
|      | barbital                  |      | mazindol          | bromazepam       |      | fencamfamin                  | butobarbital    |      |          |           |      | brotizolam |
|      | ethchlorvynol             |      | phendimetrazine   | canazepam        |      | fenproporex                  | seclutabarbital |      |          |           |      | mesocarb   |
|      | ethinamate                |      | phentermine       | chlordiazepoxide |      | mefenorex                    | vinylbital      |      |          |           |      |            |
|      | lfeftamine                |      |                   | clobazam         |      | propylhexedrine <sup>4</sup> |                 |      |          |           |      |            |
|      | meprobamate               |      |                   | clonazepam       |      | pyrovalerone                 |                 |      |          |           |      |            |
|      | methaqualone <sup>5</sup> |      |                   | clorazepate      |      |                              |                 |      |          |           |      |            |
|      | methylphenobarbital       |      |                   | clotiazepam      |      |                              |                 |      |          |           |      |            |
|      | methypylon                |      |                   | cloxazolam       |      |                              |                 |      |          |           |      |            |
|      | phenobarbital             |      |                   | delorazepam      |      |                              |                 |      |          |           |      |            |
|      | pipradrol                 |      |                   | diazepam         |      |                              |                 |      |          |           |      |            |
|      |                           |      |                   | estazolam        |      |                              |                 |      |          |           |      |            |
|      |                           |      | ethyl loflazepate |                  |      |                              |                 |      |          |           |      |            |

<sup>3</sup>Secobarbital was transferred from Schedule III to Schedule II in 1988.

<sup>4</sup>Propylhexedrine was deleted from Sch. IV in 1991.

<sup>5</sup>Methaqualone was transferred from Schedule IV to Schedule II in 1978.

**Table 1b: Scheduling of individual substances under the 1971 Convention on Psychotropic Substances**

(Note: Only the year of the first inclusion of a substance into any of the Schedules of the Psychotropic Convention has been considered)

| Sch. | 1971 | 1980 | 1981       | 1984                       | 1985 | 1986 | 1987 | 1988 | 1989 | 1990 | 1991 | 1995 |
|------|------|------|------------|----------------------------|------|------|------|------|------|------|------|------|
| IV   |      |      |            | fludiazepam                |      |      |      |      |      |      |      |      |
|      |      |      |            | flunitrazepam <sup>6</sup> |      |      |      |      |      |      |      |      |
|      |      |      |            | flurazepam                 |      |      |      |      |      |      |      |      |
|      |      |      |            | halazepam                  |      |      |      |      |      |      |      |      |
|      |      |      |            | haloxazolam                |      |      |      |      |      |      |      |      |
|      |      |      |            | ketazolam                  |      |      |      |      |      |      |      |      |
|      |      |      |            | loprazolam                 |      |      |      |      |      |      |      |      |
|      |      |      |            | lorazepam                  |      |      |      |      |      |      |      |      |
|      |      |      |            | lormetazepam               |      |      |      |      |      |      |      |      |
|      |      |      |            | medazepam                  |      |      |      |      |      |      |      |      |
|      |      |      |            | nimetazepam                |      |      |      |      |      |      |      |      |
|      |      |      |            | nitrazepam                 |      |      |      |      |      |      |      |      |
|      |      |      |            | nordazepam                 |      |      |      |      |      |      |      |      |
|      |      |      |            | oxazepam                   |      |      |      |      |      |      |      |      |
|      |      |      |            | oxazolam                   |      |      |      |      |      |      |      |      |
|      |      |      |            | pinazepam                  |      |      |      |      |      |      |      |      |
|      |      |      | prazepam   |                            |      |      |      |      |      |      |      |      |
|      |      |      | temazepam  |                            |      |      |      |      |      |      |      |      |
|      |      |      | tetrazepam |                            |      |      |      |      |      |      |      |      |
|      |      |      | triazolam  |                            |      |      |      |      |      |      |      |      |

<sup>6</sup>Flunitrazepam was transferred from Schedule IV to Schedule III in 1995.

**- ACTION AGAINST PRECURSORS OF NEW SYNTHETIC DRUGS -**

**1. The issue**

Compared with other types of drugs and psychotropic substances, the emergence and development of new synthetic drugs (NSDs) poses a special problem because their chemical structure changes frequently and because many types of precursors (themselves very variable) can be used for making them.

Since almost all of these chemical substances are used for legal purposes, action is needed to prevent them from being diverted to the illicit manufacture of synthetic drugs. This could be done by drawing up suitable monitoring measures that would reconcile the legitimate interests of business with the imperatives of action to combat synthetic drugs.

In view of the very changeable nature of this phenomenon and the wide range of basic chemical substances that can be used, a targeted response is required. And as NSDs can be very simple to produce, with "recipes" available on the Internet or in specialist publications, there is also the question of whether it is wise to make public the list of precursors to be monitored.

The NSDs affecting the European Union are mostly produced in certain Member States and in a number of Central and Eastern European countries. The response in terms of controls on precursors therefore has to cover both the commercial use of these products inside the Community and trade with non-member countries.

A uniform response across the entire Union is essential, since supplies to traffickers would otherwise quickly be diverted to Member States where there was no monitoring mechanism.

The threat of NSDs is not confined solely to Europe. Meetings of experts are therefore under way at international level. In particular, mention should be made of the two meetings already held under the auspices of the United Nations from 12 to 16 February 1996 in Vienna and from 25 to 29 November 1996 in Shanghai. In addition the Commission, together with the US Drug Enforcement Administration, organized an international conference on precursors from 11 to 14 February 1997 in Prague, at which the substances used to produce NSDs received considerable attention.

The extraordinary UN General Assembly to be held in 1998 on the fight against drugs will boost the effort to tackle the problem. Several preparatory meetings are already scheduled, starting in July, and it is vital for the Community to define a common position on the issue fairly quickly in order to be able to make a positive contribution to the debate so that real progress can be made in the fight against new synthetic drugs.

## **2. Current legislation on precursors**

Community legislation on precursors involves a two-pronged approach to cover the internal and the external aspects.

On the internal side, the basic legislation is Council Directive 92/109/EEC, amended by Commission Directive 93/46/EEC and supplemented by Commission Regulation 1485/96. The scope of the Directive covers the production and marketing of the 22 internationally scheduled substances (1988 Vienna Convention). In outline, the mechanisms that apply on the internal front are:

- transactions leading to the marketing of classified substances (both substances produced in the Community and those put into free circulation are covered) must be documented; this includes a declaration by the customer on their use;
- documents must be kept available for inspection by the authorities and classified substances must be labelled;
- operators producing or marketing category I substances must be licensed and authorization is required to be supplied with, possess or handle them;
- cooperation between the public authorities and operators is required.

The external arrangements are based on Council Regulation (EEC) No 3677/90, as amended by Regulation (EEC) No 900/92. Implementing rules have been adopted by the Commission. The aim is to regulate exports of the 22 scheduled substances, imposing obligations as regards:

- commercial documents, commercial records and the labelling of substances;
- the licensing and registering of operators;
- cooperation between public authorities and economic operators; and
- the issuing of export authorizations.

These arrangements are backed up by specific agreements concluded by the Community with certain non-member countries. At present there are agreements with the Andean countries, Mexico and the United States. Negotiations are under way with Canada, the Mercosur countries, Chile and the ASEAN countries. A special clause on combating the diversion of precursors has also been included in most association or economic cooperation agreements concluded with non-member countries.

## **3. The weaknesses of current legislation with regard to the problem of NSDs**

The mechanisms established by the instruments cited above are inadequate to deal with the problem of NSDs. The main shortcomings are:

*(a) Monitoring mechanisms involved*

The current system relates to a limited number of products (22), with strict controls laid down by the Directive and the Regulation. The nature of the controls reflects the diversion methods likely to affect the products in question, depending in particular on their nature, their availability on the market and the type of drug or psychotropic substance they can be used to make.

To control exports, an export authorization (individual or comprehensive) is required, depending on the volume of substances traded or the country of destination. In some cases authorization is granted only if an import authorization is first issued in the destination country. Although simplifications have been introduced wherever possible, using criteria such as the integrity and competence of the applicant, the system nevertheless imposes considerable constraints on the economic operators concerned.

These constraints cannot be extended too far, since any restrictive system will only function well if it is targeted and involves no more than a reasonable number of substances and obligations. It must also be borne in mind that besides these mechanisms, close and fruitful cooperation has been established between the national authorities and operators under the Community legislation. Broadening the constraints rashly would inevitably undermine such cooperation and hence the effectiveness of the entire arrangements to combat the diversion of precursors.

*(b) Type and number of substances subject to monitoring*

The Community legislation currently covers 22 substances, only 8 of which relate to synthetic drugs (including methaqualone and LSD). The international efforts referred to earlier and the work done in the Community committee on precursors have identified many other substances used to manufacture NSDs.

At present there is no agreement or scientifically backed view on which precursors should be subject to monitoring at Community level. The main options range between 6 and 62 new substances. There is, however, a general consensus (among economic operators and monitoring authorities) that it would be inappropriate and impossible in practice to apply to these substances the mechanisms provided for by the current Community legislation.

The Union's main partners, and notably the USA, all take the same view and are working to draw up a "special monitoring list" involving new monitoring methods.

**4. The problems that have to be tackled**

These issues can be grouped under four headings:

- What products should be included to meet current requirements? Is there a lawful use for all the products concerned? Which ones can be lawfully used so widely that monitoring them would be impossible or undesirable?

- What monitoring mechanisms (covering substances themselves and suspect transactions or orders) should be set up so that the system as a whole is manageable and effective and allows uniform arrangements across the entire territory of the Union?
- What mechanisms should be established for adapting the rules in order to respond quickly to the very marked changeability of the precursors used to manufacture NSDs, in particular in response to information obtained through the cooperation of economic operators?
- Would it be wise to make the list of precursors concerned public, especially if, through cooperation with operators, the goal is also to pinpoint new developments as early as possible and detect suspect orders?

## **5. The Commission's approach**

Commission departments are working with national experts in an attempt to define a suitable coherent system to tackle the the problems of NSDs. There are no obvious answers to the questions listed above and some technical work needs to be pursued in greater depth. Contacts with the economic operators concerned also need to be pursued in this direction, both at national and Community level.

It is therefore felt that the Community reaction on the issue of the precursors used for making NSDs should focus on the following points:

(a) Presentation of a proposal to amend the Regulation on the external aspects (legal basis: Article 113 of the Treaty). The monitoring mechanisms for the new substances that will be defined should not include such measures as the issuing of licences and should rest primarily on cooperation with the economic operators concerned, bearing in mind the positive experience of some Member States so far and the legitimate concerns of industry. Explicit provision could be made for monitoring other substances used as precursors, provided that the information so gathered is regularly shared in the Community committee on precursors in order to keep pace with developments on the ground.

(b) Presentation of a proposal to amend the Directive on the internal aspects (legal basis: Article 100a of the Treaty). Both the mechanism applied and the substances covered would have to be the same as in the proposed amendment to the Regulation. A separate instrument is needed to cover the manufacture and placing on the Community market of these substances, in addition to their export.

(c) Rapid decision on the Community position on the issue with an eye to the forthcoming discussions in the United Nations. The only way for the Union and the Member States to exert real influence on the course of the discussions is to put forward a single, united position vis à vis our partners. This is essential to obtain an effective outcome in terms of combating NSDs but also to prevent international agreement on mechanisms that do not suit our needs and are out of line with the approach we want to follow.

(d) In view of the large volume of NSDs being made in the countries of Central and Eastern Europe (most of which are seeking membership of the Union), it is essential, once the Community has decided how it wishes to alter its own system, to launch action under the Phare programme to supplement the measures already taken in respect of these countries in terms of preparing their legislation on precursors. In addition, specific agreements should be concluded with them, along the lines of those concluded with other non-member countries on precursors, in order to reinforce the overall effectiveness of our respective arrangements, since it will be some years before those countries actually become members.

## **6. Timetable for action**

To reconcile the need for a swift reaction to the current challenges and the need to finalize effective measures, proposals for measures on points (a) and (b) ought to be ready by early autumn. The timing ties in with action on point (c), where the Union will have to be ready to put forward the Community position in the appropriate international forums by October.

As far as action on point (d) is concerned, this cannot reasonably begin (request to the Council for a negotiating brief) until the Council has adopted the new legislation. This could be early in 1998 if the Regulation (based on Article 113) is adopted quickly.

# FINANCIAL STATEMENT

- 1 TITLE OF OPERATION**  
Communication from the Commission to the Council and the European Parliament on the control of new synthetic drugs.
- 2 BUDGET HEADING INVOLVED**  
A-2511 Expenditure on meetings of Committees whose consultation is not compulsory in the procedure for drafting Community legislation.
- 3 LEGAL BASIS**  
In discussion in the Council.
- 4 DESCRIPTION OF OPERATION**
  - 4.1 General objective**  
To clarify the Commission's views concerning the surveillance of precursors on synthetic drugs, the creation of an early warning and risk assessment system for synthetic drugs in view of a possible interdiction by the Council. In this framework, the Commission envisages the creation of a Technical Committee for assessing the risk posed by new synthetic drugs. The Committee would be chaired by the Commission.
  - 4.2 Period covered and arrangements for renewal**  
undefinite
- 5 CLASSIFICATION OF EXPENDITURE OR REVENUE**
  - 5.1 Non-compulsory expenditure**
  - 5.2 Non-differentiated appropriations**
- 6 TYPE OF EXPENDITURE OR REVENUE**  
Not relevant

**7 FINANCIAL IMPACT (Part B of the Budget)**

Not relevant

**8 FRAUD PREVENTION MEASURES**

Not relevant

**9 ELEMENTS OF COST-EFFECTIVENESS ANALYSIS**

If the Committee chaired by the Commission and which is mentioned in the Presidency proposal for a joint action on an early warning system for synthetic drugs would be created, its mission would be to assess the possible risks, including the health and social risks, caused by the traffic in and use of synthetic drugs.

**10 ADMINISTRATIVE EXPENDITURE (SECTION III, PART A OF THE BUDGET)**

Actual mobilisation of the necessary administrative resources will depend on the Commission annual decision on the allocation of resources, taking into account the number of staff and additional amounts authorised by the budgetary authority.

**10.1 Effect on the number of posts**

| Type of post                 |   | Staff to be assigned to managing the operation |                        | Source   |                      | Duration |
|------------------------------|---|--|------------------------|--|----------------------|----------|
|                              |   | <u>Permanent posts</u>                         | <u>Temporary posts</u> | Existing resources in the DG or department concerned | Additional resources |          |
| Officials or temporary staff | A | 1  | -----                  | 1  |                      |          |
|                              | B | -----  | -----                  |  |                      |          |
|                              | C | 0,5  | -----                  | 0,5  |                      |          |
| Other resources              |   |  |                        |  |                      |          |
| Total                        |   | 1,5  | -----                  | 1,5  |                      |          |

**10.2 Overall financial impact of additional human resources**

ECU

|   | Amounts | Method of calculation |
|---|---------|-----------------------|
| Officials                                 | -----   | -----                 |
| Temporary staff                           | -----   | -----                 |
| Other resources (indicate budget heading) |         |                       |
| Total                                     | -----   |                       |

**10.3 Increase in other administrative expenditure as a result of the operation**

ECU

| Budget heading | Amounts | Method of calculation   |
|----------------|---------|---|
| A-2511         | 20,000  | 2 Committee meetings/year<br>15 experts per Committee<br>(695 Ecu/expert) |
| Total          | 20,000  |   |

ISSN 0254-1475

COM(97) 249 final

# DOCUMENTS

EN

15 05 06

---

Catalogue number : CB-CO-97-235-EN-C

ISBN 92-78-20109-X

---

Office for Official Publications of the European Communities

L-2985 Luxembourg