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Legal responses to new synthetic drugs 2000–2004

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Contribution to the evaluation of the EU action plan on drugs (2000–2004)

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Contents • Table des matières

1. Introduction

The paper has been written to inform the Commission's contribution to the EU Action Plan on Drugs 2000-2004.

The subject matter was chosen with regard to two aspects. Firstly, the political priority attributed to the problems of new synthetic drugs, as shown by the two references to them in the EU Action Plan. Secondly, the resources available. The Reitox National Focal Point Annual Reports, sections 1.2 (Legal framework) and 1.3 (Laws implementation), and the Legal Correspondent network that is responsible for updating the ELDD, were once again consulted. Replies were received from all Member States except Austria. After obtaining permission from the Member States, the European Commission provided copies of the answers received[1] to its questionnaire of December 2002 intended to examine the feasibility of a pan-European generic approach to drug classification, in which countries outlined the systems involved. Nine of these were summarised in the Room Document "Results of the questionnaire on the generic and emergency list approach to synthetic drugs". Programme P3 of EMCDDA, in charge of implementing the Joint Action on New Synthetic Drugs, also provided the answers received to a different questionnaire on the targets to be covered in the Early Warning System workshop of November 2002. The Annual Council reports to the Presidency under the Joint Action 97/396/JHA, Art. 5(3), on the implementation of Decisions taken under that Joint Action, were not available. Finally, another paper in this series, "Legislative Activity", has been drafted at the same time by consulting the first two sources in order to create a list of all legislative instruments reported as drug-related in the last five years, which had been (approximately) indexed by topic and attributed to Actions or Sections of the EU Action Plan. A draft of this paper was also sent to the P3 and P4 Scientific Sub-Committee members for their views.

As the terms laws, regulations, decrees, orders, etc may be used by different countries or translated in different ways, this paper refers to "laws" as a general term to cover all different types of national legal text unless otherwise stated. Parliamentary and governmental resolutions, and prosecutorial circulars, directives and guidelines were also included where reported, in their role as documents of the parliament / government designed to bring about a change in the implementation of the drug legislative framework. However, major court decisions, though sometimes reported as affecting the legal framework, have been excluded, as they were not the action of the [elected] legislature.

The study has been limited to the national laws of the countries, thus excluding legislative instruments of the EU or the international framework. This study is also limited to the period 1999-2004, so it does not include a detailed examination of the laws before this date, which may already be sufficient to address the issue, and therefore did not require alterations during the period. (The study did, however, include a request of significant alterations made before 1999 in order to gauge the impact of synthetic drugs on the legal systems.) Lack of legislative activity should therefore not necessarily be interpreted as lack of relevant or effective activity by the Member State. On the other hand, where legislative activity has taken place in line with the EU Action Plan, this paper does not claim the EU Action Plan to be the cause of that legislation.

[1] Of the 15 countries addressed in this report, answers to the Commission questionnaire were not received by EMCDDA from Germany and Italy.

Nevertheless, the main aim of this paper is to highlight visible data where there is clear legislative activity, as a positive indicator of where Member States considered that legislation was necessary, and to highlight how Member States have decided to tackle this issue.

This study aims to identify what legal activity might be attributed to, or in the spirit of, those Actions in the EU Action Plan which clearly refer to the problems of synthetic drugs.

2. Outline of classification systems used in the Member States

Before examining the legislative changes in detail, it may help to understand the context to examine the different methods of classification of substances that are used by Member States. This looks not only at the formal system used, but also the legal procedure involved in putting a new substance under control, and the time that such a procedure might take. As the following shows, such a wide range of methods and procedures should be borne in mind in future requests to the Member States that concern their control systems.

The systems of classification used in Member States are various. All use the **individual list**, whereby the chemical definitions of the substances are named individually. This may be supplemented by an alternative control system, developed by the Member States as a rapid response to control the threat of a new synthetic drug. These may be:

- the **generic system** (inclusion of a definition applying to a family of substances);
- the **emergency list** (fast but temporary listing of individual substances);
- and what we will term a **"rapid" system**, which differs from the emergency list in that it is permanent[2].

Of the 15, two countries (Ireland and the UK) use the generic system. (According to the Commission questionnaire results, most other Member States reported that such a wide interpretation of substances would infringe primary legislation or basic legal principles). Five[3] countries possess a type of emergency list, or rapid classification system. Member States' responses in this manner vary from a system using the state's powers to pass urgent legislation on any topic, to a system embedded in the drug law designed specifically to react rapidly to the threat of a new drug. In 1999 Sweden enacted a complementary system using a new legal framework, whereby substances that are not yet recognised as drugs may be controlled (this is detailed below) – thus effectively more rapid as not requiring the scientific evaluation. Italy can use general legal powers to request researchers to give priority to a request to evaluate a substance, but this is not really a separate system, only a power to speed up one stage of the procedure.

The system may partly depend on the State's ability to classify new drugs. In 14 of the 15 countries, the primary drug control law outlines the standard procedure that permits the state to add new substances to the list of control – in Portugal, the drug law mentions no procedure and thus relies on the standard national procedure for amending any primary legislation. In nine countries[4], classification requires adding

[2] The generic system and the emergency list have already been defined, in the Commission's Room Document on the results of the questionnaire on the generic and emergency list approach to synthetic drugs, with the help of the Commission's Communication to the Council and European Parliament on the control of new synthetic drugs (COM/97/0249 final). The rapid system is a new term proposed by the author of this paper, resulting from analysis of the different systems in use in the 15 countries.

[3] Belgium, Germany, Luxembourg, Netherlands, Sweden

[4] Denmark, Greece, Spain, Italy, Netherlands, Portugal, Finland, Sweden, UK

substances to a list (Schedule, Table…) annexed to the main drug law; in five countries[5], it means to add them to lists established in separate decrees. In Ireland, substances are not usually added to the annex of the main drug law, which would involve a long procedure to change the primary legislation, but "declared" to be a controlled drug for the purposes of the law; thus, equivalent to being added to that list.

The nature of the list, or the procedure of its alteration (in this case, by addition of a new substance), may affect the speed of its alteration, and thus the need for a "fast" classification system. Lists which are alterable simply by the signature of a minister, either as they are Ministerial orders, or because that is the procedure established in the main drug law, can be altered quicker than lists where either their nature (a parliamentary law – for which parliament's approval is necessary to change) or the procedure that has been actually set out ("this amendment must be agreed by parliament") contain more steps. For final approval:

- **seven** systems need approval of a Minister[6],
- **three** need approval of two Ministers[7],
- **five** need approval of government[8],
- and **five** need approval of parliament[9] (which may include signature by the Head of State).

When considering both the emergency and rapid systems, it was found that of these systems, the two in Germany and Netherlands are emergency-list, as they expire after one year if not renewed/confirmed; and the three in Belgium, Luxembourg and Sweden are rapid control systems, as they remain permanent (in Sweden a substance may be transferred from the "Goods Dangerous to Health" to the "Narcotic" classification, but there is no time limit for this). Those in Belgium and Luxembourg work due to a general procedure for urgent legislation, and those in Germany, Netherlands and Sweden were specifically established in (or in the case of Sweden, complementary to) the drug law. In Luxembourg, use of the rapid system has effectively become the norm for classifying new drugs, whereas in Belgium it is used rarely. In Italy, though not really a separate system, the procedure whereby the Minister of Health uses his general power to ask researchers to prioritise a request has been used on a number of occasions to classify synthetic substances.

Art. 2.7 of the 1971 UN Convention on Psychotropic Substances requests that a CND decision to put a substance under control should become effective within 180 days of its communication to the Parties. EU Council Decisions to control substances, taken under the Joint Action of 16 June 1997 concerning the information exchange, risk assessment and the control of new synthetic drugs similarly give a deadline for their implementation – usually three months (about 90 days). From the above, it becomes clear that the systems of classification under domestic systems may have an effect on the ability to implement the decision within this deadline.

[5] Belgium, Germany, France, Luxembourg, Austria
[6] Germany (emergency system), Spain, France, Luxembourg (rapid system), Netherlands (emergency system), Austria, Finland
[7] Denmark, Greece, Italy
[8] Belgium (both systems), Germany, Sweden (both systems)
[9] Ireland, Luxembourg (standard system), Netherlands (standard system), Portugal, UK.

The Legal Correspondents reported theoretical times for implementation as follows:

Table 1: Estimates of minimum time taken to put a substance under control using a given system

	Individual list system	**Emergency / Rapid system**
Belgium	Minimum 6 months	Minimum 2 months
Denmark	1 day to sign, 10 days to enter into force	N/A
Germany	Minimum 2 months	Minimum 1 week (temporary)
Greece	1-2 months	N/A
Spain	Two of the last three took 4.5 months from start to finish	N/A
France	Minimum 3 months	N/A
Ireland	About 1.5 months	Generic system also used
Italy	1-2 months after scientific results are made available	N/A
Luxembourg	No longer used	1-2 months
Netherlands	About a month	1-2 weeks (temporary)
Austria	[Estimate not given]	[Estimate not given]
Portugal	1-6 months	N/A
Finland	2 weeks	N/A
Sweden	If UN – automatic. Otherwise – minimum 2 days, normally a month	Prohibition of Goods Dangerous to Health – 2-3 days
UK	1.5 – 2 months	Generic system also used

(Note that these are not fully comparable, as some may have included the period for scientific evaluations, or the time between final approval of the law and its official publication.)

However, we considered the situation in practice, tracking the last four substances requested to be controlled by international organisations (CND and EU). The number of days between the international request and the actual control are shown in Table 2:

Table 2: Number of days between international request and actual control of a substance

	4-MTA	GHB	2C-B	PMMA
Should be within (days):	90	180	180	90
Time taken (days):				
Belgium	60	Already	323	54
Denmark	81	Already	10	70
Germany	Already	263	Already	Already
Greece	Already	Already	Already	Already
Spain	145	269	269	142
France	1040	407	407	57
Ireland	Not controlled	Already	Already	Already
Italy	54	Already	Already	279
Luxembourg	80	Not controlled	186	53
Netherlands	138	498	Already	229
Austria	568	932	Not controlled	Not controlled
Portugal	351	1065	1065	533
Sweden	75	Already	385	116
Finland	76	173	173	Not controlled
United Kingdom	868	750	Already	Already

"Already" indicates that the substance was already under control in that country.
(Source: Legal Correspondents Network, for document prepared by EMCDDA for HDG)

In response to the questionnaire, no country reported problems in classifying the substances requested by the EU – in the case of the UK there was debate about whether or not 4-MTA was already classified under the generic system, and this was finally solved by listing it as a new substance – yet it can be seen that in practice, various factors act to cause sometimes considerable delays to the legislative process. Given the complexity of the 15 different processes, it was not attempted to identify these factors for this study.

It should be noted that the procedure is not always identical for substances identified by the different bodies. In Germany, s.1(4) of the BtMG states that the Minister of Health and Social Security does not need the consent of the Bundesrat in order to list substances controlled by the UN. This exemption does not apply to substances controlled by the EU. In Sweden, substances controlled by the UN automatically enter into force on the date that the UN requests them to take effect, so there is no delay. Conversely, those to be controlled according to an EU Council Decision must follow the procedure on technical regulations and standards according to directive 98/34/EC. It is of interest to note that, in Germany and Sweden, the differences in procedures would lengthen times to control substances identified by the EU, yet the EU gives a shorter deadline than the UN in its instructions for implementation.

3. Mapping of laws to Action Plan, by Action

As mentioned above, with the increase in synthetic drugs occurring in the late 80s – early 90s, it is possible that Member States would not report major alterations of their legal systems during the period of the EU Action Plan 2000-2004, as there is the likelihood that necessary alterations would have been made earlier. In Ireland, for example, controls for ecstasy-type drugs (phenethylamine derivatives) were introduced in 1987, and France created the national system for the evaluation of drug dependence in 1990. Germany introduced its emergency classification procedure in 1992. Portugal passed a new law on the control of drugs in 1993, as did Austria in 1998. In Belgium, the Royal Decree on psychotropic substances of 1998 organised substances into schedules of the 1971 UN Convention, and in the Netherlands, the Coordination Centre for Assessment and Monitoring of New Drugs, to advise the Minister for Health, Welfare and Sport was established in 1998. On top of these, adjustments were made in a number of countries following the Joint Action 97/396/JHA "concerning the information exchange, risk assessment and the control of new synthetic drugs", that established the Early Warning System.

Nevertheless, the EU Action Plan 2000-2004 refers to synthetic drugs in two particular Actions, and so this study has looked particularly for legislative changes that may have taken place in these fields.

Action 3.1.1.4 – prevention and synthetic drug users

Firstly, under the heading of prevention and demand reduction, Action 3.1.1.4 requests "Member States and the Commission further to develop innovative approaches to the prevention of the abuse of synthetic drugs, taking into account the specificities of synthetic drug users". Six countries reported changes. In France, Article 53 of the law No. 2001-1062 of 15 November 2001 regarding day-to-day security (*LSQ*) has supplemented the law No. 95-73 of 21 January 1995 giving guidelines and programming regarding security (*LOPS*). The new article 23-I of the *LOPS* confers a new legal framework on the gathering currently known as "rave parties". The organisers of these gatherings are now required to declare their plans to the prefect of the *département* within which a rave party is planned. The decree No. 2002-887 of 3 May 2002 (on rave party organisation) defines the details of this system and provides for a differentiated regime, depending whether the organisers subscribe or not to an engagement to adhere to the good practices fixed by order. This law is apparently facing some difficulties in implementation, regarding the definition of what is/is not a rave party.

In Ireland, in August 2002 the Report of the Benzodiazepine Committee and its Good Practice Guidelines for Clinicians were published (Health and Children 2002). The Committee was set up by the Minister in June 2000 to 'examine the current prescribing and use of benzodiazepines; to consider recommendations on good prescribing and dispensing practice, paying particular attention to the management of drug misusers'. It is not a legal instrument, but the recommendations of the committee may be used to influence or amend legislation. (However, no changes in law have occurred since its publication.)

Luxembourg has acted to tighten the prescription controls of drugs that may be abused, notably Ritalin (1999) and Rohypnol (2000). Furthermore substances evaluated by the Joint Action mechanisms, for which an EU control decision has been taken by the EU Council, have been put under national control within very short delays by the procedure described above.

In the Netherlands, pill testing at dance parties finished in 1999. However, pill testing facilities continue to work at offices of drug care agencies (approx. 25 nationwide), under an agreement with the General Public

Prosecutor based on the expediency principle. The national agency (DIMS) located at the Trimbos Institute is licensed by the inspectorate for health care to possess, transport, analyse etc scheduled substances. In 2001, the Medicines Act was changed so that unauthorised traffic of GHB became an economic offence punishable by up to six years in prison. Since November 2002, however, GHB is scheduled on List II of the Dutch Opium Act.

In Sweden, in 1999 a new control system was implemented by the Act on Prohibition of Certain Goods Dangerous to Health (1999:42). This Act applies to goods that, "by reason of their innate characteristics, entail a danger to human life or health, or can be used or assumed to be used for the purpose of intoxication or other influence." It does not demand strongly addictive properties or euphoric effects (necessary for control under the Narcotic Drugs Punishment Act), making it possible to control a substance at an earlier stage – correspondingly, punishments for violations are less severe. The main focus for establishing the act was the increase of new synthetic drugs, but also other substances can be covered. However, it may not apply to drugs under narcotic or doping control, or medical products approved within the EU.

To facilitate the mission given to the National Institute of Public Health to guard and investigate the need of control of substances, the Ordinance on Prohibition of certain Goods Dangerous to Health (1999:58) says that "if, in the course of their activities, the National Police Board or the Customs Administration observes anything that suggests that a new substance is being utilized for the purpose of misuse, or that changes occur in the pattern of misuse of known substances, it shall report this to the National Institute of Public Health without delay." The Social Services Act (2001:453) similarly asks the Social Welfare Committees (within the municipalities) to without delay inform the National Institute of Public Health if it in the course of its activity has observed anything to suggest that new preparations are being employed for abuse, or that changes are occurring in the abuse pattern of known preparations.

In the UK, a revised version of the Misuse of Drugs Regulations came into effect on 1st February 2002. One of the major changes was that all benzodiazepine drugs listed in the Act would now be subject to a possession offence. Previously, most benzodiazepines, when in the form of a medicinal preparation, had been exempted from the offence of possession. The change was a consequence of earlier decisions by the United Nations concerning the import and export restrictions on the trade in these drugs. Besides this, in April 2002, the UK Home Office issued a 'Safer Clubbing' guide to club owners with information on harm reduction measures in an attempt to reduce drug-related deaths. The brochure, aimed at club managers, licensing authorities and promoters includes tips on how to prevent drugs being brought into and used in clubs as well as emphasizing that the licensing authorities need to ensure that clubs provide adequate supplies of drinking water, prevent overcrowding, ensure proper air conditioning and ventilation, prevent overheating, and maintain venues complying with health and safety regulations. The guide implies that those who do not follow this guidance will not retain their licence.

Action 4.1.1.4 – composition, production and trafficking of synthetic drugs, etc

Under the heading of supply reduction, Action 4.1.1.4 requests "Member States, with the assistance of Europol, to further consider the possibilities of combining forensic and law enforcement information, with a view to identifying the production and trafficking of synthetic drugs, the composition of such drugs, and those involved in their production and trafficking. To that extent, Member States' forensic laboratories should exchange information on the analysis of samples taken from synthetic drug seizures". Four countries reported legislative changes that are relevant to this. In Belgium, the Royal Decree of 29 June

2003 on transmission of information to the Belgian (Reitox) Focal Point makes anonymous transmission of data from certain laboratories to the Focal Point possible. Furthermore, it authorizes the Institute of Public Health to retain reference samples as pure as possible of different substances, to create a collection of reference samples at national level. Pill testing is implemented but only in the form of a pilot (scientific) project - it is not regulated by law.

In France, the SINTES (National information system on synthetic drugs) programme has been started in 1999. In Finland, the Police Act (493/1995) was amended (21/2001) in order to add provisions of unconventional means of preventing and investigating crime, including covert operations and fictitious purchase. The Customs Act was amended in 2003 (774/2003) to give the Customs more extensive rights for monitoring telecommunications and employ other technical surveillance.

In Portugal, Portaria 1112/03 establishes information units to determine the effects of synthetic drugs and includes tests of substances to analyse their composition.

Other legal changes regarding synthetic drugs

Aside from these two specific actions, there have been other matters covered by legislation during the period. In Ireland, several precursor chemicals have been put under control; Norephedrine in 2003, and the stereoisomeric forms of Ephedrine, 3,4-Methylenedioxyphenylpropan-2-one, 1-Phenyl-2propanone, Norephedrine (not being cathine), Isosafrole, Safrole, Piperonal and Pseudoephedrine, in 2004. In Germany, in 2001, synthetic drugs were re-listed to the international standard, removing the need for the scheduling difference between Table 1A (numerical order) and Table 1B (alphabetical order). The same amendment put 12 synthetic drugs permanently under control which had previously been controlled provisionally. In the Netherlands, the Opium Act Directive of January 2001 considers action for breach of environmental legislation by synthetic drugs producers.

In Denmark, no relevant legal changes took place, but following the implementation of the 1997 Joint Action, a close collaboration for information exchange on new synthetic drugs between relevant authorities – a so called national joint action group – was established. In 2002, a database on ecstasy was established which created a new and extended basis for collaborating, detecting, and monitoring new synthetic drugs. In 2003, a joint forum for information exchange among relevant authorities in Denmark, Norway and Sweden – NADIS – was established. Similarly, in Italy, there were no relevant legal changes but projects have been financed targeting the new synthetic drugs and the new trends.

4. Trends observed

When studying the control systems employed by / available to Member States, major differences can be seen between them. Some are able to act on the signature of a Minister within a few days, when others are subject to the maximum legislative process with an amendment to be submitted to both levels of Parliament. Some have introduced rapid methods, either general or specific, to get around the long procedures. Some countries are comfortable with the principle of a temporary control (and thus a temporary criminal offence), others prefer such a control only to be unlimited in time. Only two countries have implemented the generic system of control. Curiously, many countries predict an average of 1-2 months for control yet it was Sweden, whose system already appears to be one of the fastest, which introduced a complementary system to effectively cut that time even further.

With knowledge of the above factors, it became clear that such major differences mean that some states simply cannot react as fast as others to the need to control a substance within a short period of time. Although these different systems are theoretically able to control a substance within the deadlines set by the UN (180 days), a number are only just within the capability to control a substance named by an EU Council Decision (90 days), and it can be seen that, in practice, various factors act to cause sometimes considerable delays to this legislative process. This may undermine the rationale of a fast, pan-European response - the principle is to have the substance under equal control across the EU within 3 months, yet some countries take a year or more to do this - and the effectiveness of the Joint Action. Yet it is the same countries, acting in Council, which pass such a Decision to commit themselves this deadline.

It is of interest to note that, in Germany and Sweden, the differences in procedures would apparently work to shorten times to control those substances named by the UN, yet the EU gives a shorter deadline than the UN in its instructions for implementation (90 days against 180 days).

As noted at the beginning, the Annual Council reports to the Presidency under the Joint Action 97/396/JHA, Art. 5(3), were not available, and it is not clear why. Such reports would have the potential to give a valuable insight into the Joint Action's control system.

In the legal sphere, not a large amount of legal changes have been reported that would answer to the Actions requested by the Action Plan 2000-2004. Only six of the 15 countries reported relevant changes to assist prevention and abuse of synthetic drugs, and not all of these could be described as "innovative" as requested in the Action. In terms of activity regarding the combination of information in order to identify composition, production, and trafficking of synthetic drugs, even fewer legislative changes took place, with such changes reported by only four countries. Five more referred to changes of legislation, or projects, in the general synthetic drugs field.

Thus, the attention to synthetic drugs implied or requested by the Council in the design of the EU Action Plan can not easily be seen to be reflected in the laws reported over the period by the 15 countries. Nevertheless, the caveat at the start of this paper should be borne in mind, that lack of legislation on a topic does not necessarily mean lack of relevant or effective activity on that topic.