EUROPEAN
COMMISSION

Brussels, 31.1.2013
COM(2013) 39 final

2013/0021 (NLE)

Proposal for a

COUNCIL DECISION

on submitting 4-methylamphetamine to control measures

EXPLANATORY MEMORANDUM

The Council Decision 2005/387/JHA[1] on the information exchange, risk-assessment and control of new psychoactive substances provides for a three-step procedure that may lead to submission of a new psychoactive substance to control measures in the Union.

On 24 September 2012 and pursuant to Article 6 of the above-mentioned Council Decision, the Council formally requested a risk assessment on the psychoactive substance 4-methylamphetamine, to be carried out by the extended Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA).

The main results of the risk assessment are the following:

(1) 4-methylamphetamine is a synthetic ring-methylated derivative of the controlled substance amphetamine which provokes physical effects that can be compared to those produced by other stimulant substances such as amphetamine.

(2) Acute health problems and adverse effects related to the use of 4-methylamphetamine can occur and have been documented. The patterns of use appear to follow those associated with amphetamine.

(3) Between 2010 and 2012, 21 fatalities in four Member States have been reported where 4-methylamphetamine alone or in combination with other substances has been detected in post-mortem samples. In some cases 4-methylamphetamine was the predominant drug detected.

(4) 4-methylamphetamine has no known, established or acknowledged medical value or use. However, it is used as an analytical reference standard and in scientific research.

Pursuant to Article 8(1) of the Council Decision, within six weeks from the date on which it receives the Risk Assessment Report, the Commission shall either present to the Council an initiative to have the new psychoactive substance subjected to control measures, or shall present a report justifying why it deems it not necessary to present such an initiative.

Although the scientific evidence concerning the overall risks and patterns of use of 4-methylamphetamine is still limited at this stage, there are grounds for subjecting the substance to control across the Union. The main reason is that, according to the available information from the Risk Assessment Report, the substance poses risks to health, as highlighted above. These risks are heightened by the fact that 4-methylamphetamine is often sold as amphetamine or in combination with amphetamine or other substances, and that most users are unaware that they are consuming this specific substance.

Furthermore, taking into account that organised crime appears to be involved in the manufacture, trafficking and supply of 4-methylamphetamine and given the similarity of this substance with amphetamine, the possibility that 4-methylamphetamine develops as an alternative to amphetamine further justifies subjecting the substance to control measures.

The objective of this proposal for a Council Decision is to call upon Member States to submit 4-methylamphetamine to control measures and criminal penalties as provided under their legislation by virtue of their obligations under the 1971 United Nations Convention on Psychotropic Substances.

[1] OJ L 127, 20.5.2005, p. 32.

2013/0021 (NLE)

Proposal for a

COUNCIL DECISION

on submitting 4-methylamphetamine to control measures

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances[2], and in particular Article 8 (3) thereof,

Having regard to the initiative of the Commission,

Whereas:

(1) A Risk Assessment Report on 4-methylamphetamine was drawn up on the basis of Article 6 of Decision 2005/387/JHA by a special session of the extended Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction, and was subsequently received by the Commission on 29 November 2012.

(2) 4-methylamphetamine is a synthetic ring-methylated derivative of amphetamine which has predominantly been seized in powder and paste form in samples containing amphetamine and caffeine, but which has also appeared in tablet and liquid form. It has emerged on the illicit amphetamine market where it is sold and used as amphetamine. There has been one report of the substance being detected in a commercial product sold on the internet. The main chemical precursor for the synthesis of 4-methylamphetamine is 4-methylbenzyl methyl ketone (4-methyl-BMK), which appears to be commercially available on the internet and is not controlled under the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

(3) 4-methylamphetamine's specific physical effects have been rarely reported by users as they are typically unaware that they have taken the substance. However, the few reports that are available suggest that it has stimulant-type effects. Limited available data related to humans suggest that the adverse effects of 4-methylamphetamine include hyperthermia, hypertension, anorexia, nausea, perspiration, gastric distress, coughing, vomiting, headache, palpitations, insomnia, paranoia, anxiety and depression. Current data is not sufficient to determine the relative dependence-producing potential of this substance.

(4) The acute toxicity of 4-methylamphetamine is similar to that of other stimulants, according to the limited data sources available. Certain evidence suggests that in combination with other substances, including amphetamine and caffeine, there may be a higher risk of overall enhanced toxicity.

(5) There have been a total of 21 fatalities registered in four Member States where 4-methylamphetamine alone or in combination with one or more substances, especially amphetamine, has been detected in post-mortem samples. While it is not possible to determine

[2] OJ L 127, 20.5.2005, p. 32.

with certainty the role of 4-methylamphetamine in these fatalities from the available information, in some cases the substance was the predominant drug detected, with levels comparable to those found in certain cases of death caused by the consumption of amphetamine.

(6) 4-methylamphetamine has been detected in 15 Member States, while one Member State has reported the manufacture of the substance on its territory. Prevalence specific to 4-methylamphetamine is difficult to estimate. There is no information on specific demand for the substance from user groups. It is not commercially marketed through internet shops.

(7) The available information suggests that it is produced and distributed by the same organised crime groups that are involved in the manufacture and trafficking of the controlled drug amphetamine.

(8) 4-methylamphetamine has no known, established or acknowledged medical value or use in the Union and there is no marketing authorisation for the substance in the Union. Apart from its use as an analytical reference standard and in scientific research, there are no indications that it may be used for any other legitimate purpose.

(9) 4-methylamphetamine is currently not under assessment and has not been under assessment by the United Nations system. Eight Member States control the substance under drug control legislation by virtue of their obligations under the 1971 United Nations Convention on Psychotropic Substances. Two other Member States apply the generic definition in their national legislation to the product while one Member State controls it under its medicines legislation.

(10) Although the Risk Assessment Report reveals that limited scientific evidence is available on the characteristics and risks of 4-methylamphetamine and points out that further studies are required on the overall health and social risks associated with the substance, the available evidence provides sufficient grounds for subjecting the substance to control measures across the Union. This is because of the health risks that the substance poses, as documented in its detection in several cases of fatalities, especially when used in combination with other substances, because of its strong resemblance in terms of appearance and effects with amphetamine and the fact that users may unknowingly consume this substance. These risks as well as the limited medical value or use of 4-methylamphetamine, justify a decision to subject it to control measures across the Union.

(11) Since ten Member States already control 4-methylamphetamine, placing it under control across the Union may help avoid problems in cross-border law enforcement and judicial cooperation.

(12) Union-wide control measures may help prevent 4-methylamphetamine developing as an alternative to amphetamine in the illicit drug markets,

HAS ADOPTED THIS DECISION:

Article 1

The new psychoactive substance 4-methylamphetamine is hereby submitted to control measures.

Article 2

Member States shall take the necessary measures, in accordance with their national law, and not later than one year from the date this decision is published, to submit 4-methylamphetamine to control measures and criminal penalties as provided for under their legislation by virtue of their obligations under the 1971 United Nations Convention on Psychotropic Substances.

Article 3

This Decision shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels,

For the Council
The President