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NOTE

From:	Presidency
To:	Delegations
No. Cion doc.:	5419/13
Subject:	Draft Council implementing decision on subjecting 4-methylamphetamine to control measures

In its judgement of 16 April 2015 in [Case C-317/13](#) the Court of Justice of the European Union, ruled that the Council should consult the European Parliament before adopting a decision to ban new psychoactive substances following the procedure foreseen in Council Decision [2005/387/JHA](#).

Therefore Council Implementing Decision [2013/129/EU](#) of 7 March 2013 on subjecting 4-methylamphetamine to control measures was annulled by the Court judgement and now needs to be re-adopted, following consultation of the European Parliament.

To this end delegations will find attached the revised text of the above-mentioned proposal, including the amendments proposed by the Council Legal Service.

Changes introduced by the CLS are in **bold** for the new text and ~~strike-through~~ for deleted text.

COUNCIL IMPLEMENTING DECISION

of

on subjecting ~~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 Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances¹, and in particular Article 8(3) thereof,

Having regard to the **proposal** ~~initiative~~ of the European Commission,

Having regard to the opinion of the European Parliament²,

¹ OJ L 127, 20.5.2005, p. 32.

² ***Opinion of XX XX 2015 (OJ / not yet published in the Official Journal).***

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 the controlled drug, 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) The specific physical effects of 4-methylamphetamine have been rarely reported by users, since users are typically unaware that they have taken the substance. However, the few reports that are available suggest that it has stimulant-type effects. Limited data available relating 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 the substance.
- (4) According to the limited data sources available, the acute toxicity of 4-methylamphetamine is similar to that of other stimulants. Certain evidence suggests that a combination of 4-methylamphetamine with other substances, including amphetamine and caffeine, may result in 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 with certainty from the information available the role of 4-methylamphetamine in those fatalities, 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 and it is not commercially marketed through internet shops.
- (7) The information available suggests that 4-methylamphetamine is produced and distributed by the same organised crime groups that are involved in the manufacture and trafficking of 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 is no indication that it may be used for any other legitimate purpose.
- (9) 4-methylamphetamine is not currently 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 of phenethylamine in their national legislation to the product while one Member State controls it under its medicines legislation.

- (10) The risk assessment report reveals that there is limited scientific evidence 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. However, the evidence available provides sufficient grounds for subjecting 4-methylamphetamine to control measures across the Union. As a result of the health risks it poses, as documented in its detection in several reported fatalities, especially when used in combination with other substances; its strong resemblance in terms of appearance and effects with amphetamine; the fact that users may unknowingly consume the substance and its limited medical value or use, 4-methylamphetamine should be subjected to control measures across the Union.
- (11) Since 10 Member States already control 4-methylamphetamine, subjecting it to control measures across the Union may help avoid problems in cross-border law enforcement and judicial cooperation.
- (12) Union-wide control measures may also help prevent 4-methylamphetamine developing as an alternative to amphetamine in the illicit drug markets,
- (13) **Decision 2005/387/JHA confers upon the Council implementing powers with a view to giving a quick and expertise-based response at the Union level to the emergence of new psychoactive substances detected and reported by the Member States, by subjecting those substances to control measures across the Union. As the conditions and procedure for triggering the exercise of such implementing powers have been met, an implementing decision should be adopted in order to put 4-methylamphetamine under control across the Union.**

- (14) This Decision replaces Council Implementing Decision 2013/129/EU of 7 March 2013 on subjecting 4-methylamphetamine to control measures³ which was annulled by the Court of Justice of the European Union ('the Court') by its judgment of 16 April 2015 in Case C-317/13. In that judgment, the Court maintained the effects of Decision 2013/129/EU until the entry into force of new acts intended to replace it. Therefore, as of the day of entry into force of this Decision, Decision 2013/129/EU ceases to produce effects.
- (15) In order to ensure the continuity of control measures across the Union with regard to 4-methylamphetamine, this Decision should be without prejudice to the obligations of the Member States relating to the time limit for the subjecting of that new psychoactive substance to control measures and criminal penalties in their national laws, as set out in Article 2 of Decision 2013/129/EU.
- (16) Denmark is bound by Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision which implements Decision 2005/387/JHA.
- (17) Ireland is bound by Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision which implements Decision 2005/387/JHA.
- (18) The United Kingdom is not bound by Decision 2005/387/JHA and is therefore not taking part in the adoption of this Decision which implements Decision 2005/387/JHA and is not bound by it or subject to its application.

³ *OJ L 72 of 15.3.2013, p.11.*

HAS ADOPTED THIS DECISION:

Article 1

The new psychoactive substance, 4-methylamphetamine, ~~shall be is hereby~~ subjected to control measures across the Union.

Article 2

Decision 2013/129/EU ceases to produce effects from the date of entry into force of this Decision, without prejudice to the obligations of the Member States relating to the time limit for subjecting 4-methylamphetamine to control measures and criminal penalties in their national laws, as set out in Article 2 of Decision 2013/129/EU.

~~By ...*, Member States shall take the necessary measures, in accordance with their national law, to subject 4-methylamphetamine to control measures and criminal penalties, as provided for under their legislation complying with 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 ...,

For the Council

The President

* OJ: please insert the date: one year from the date of entry into force of this Decision.