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### COVER NOTE

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From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	18 December 2017
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2017) 766 final
Subject:	Proposal for a COUNCIL IMPLEMENTING DECISION on subjecting the new psychoactive substance methyl 2-[[1-(5-fluoropentyl)-1 <i>H</i> -indazole-3- carbonyl]amino]-3,3-dimethylbutanoate (5F-MDMB-PINACA) to control measures

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Delegations will find attached document COM(2017) 766 final.

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Encl.: COM(2017) 766 final



EUROPEAN  
COMMISSION

Brussels, 18.12.2017  
COM(2017) 766 final

2017/0346 (NLE)

Proposal for a

**COUNCIL IMPLEMENTING DECISION**

**on subjecting the new psychoactive substance methyl 2-*[[1-(5-fluoropentyl)-1*H*-indazole-3-carbonyl]amino]-3,3-dimethylbutanoate (5F-MDMB-PINACA) to control measures***

## **EXPLANATORY MEMORANDUM**

### **1. CONTEXT OF THE PROPOSAL**

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

On 4 July 2017, a joint report of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and Europol drawn up in accordance with Article 5 of Council Decision 2005/387/JHA was issued. On 15 September 2017, following the request made by the Commission and seven Member States and pursuant to Article 6(1) of the above-mentioned Council Decision, the Council requested an assessment of the risks caused by the use, manufacture and trafficking of the new psychoactive substance methyl 2-[[1-(5-fluoropentyl)-1*H*-indazole-3-carbonyl]amino]-3,3-dimethylbutanoate (5F-MDMB-PINACA, 5F-ADB) the involvement of organised crime and the possible consequences of control measures introduced on this substance.

The risks of 5F-MDMB-PINACA were assessed by the Scientific Committee of the EMCDDA, acting in compliance with the provisions of Article 6(2), (3) and (4) of the Council Decision. The risk assessment report was submitted to the Commission and to the Council on 14 November 2017. The main results of the risk assessment are the following:

- 5F-MDMB-PINACA is a synthetic cannabinoid. It shows similar effects to THC, which is responsible for the major psychoactive effects of cannabis, but with additional life-threatening toxicity. The high potency of 5F-MDMB-PINACA and the large and variable content of the substance in smoking mixtures constitute a high risk of poisoning.
- 5F-MDMB-PINACA has been available in the European Union since at least September 2014 and has been detected in 25 Member States. 28 deaths associated with 5F-MDMB-PINACA have been reported by two Member States. In at least 20 deaths 5F-MDMB-PINACA was the cause of death or is likely to have contributed to the death.

Pursuant to Article 8(1) of Council Decision 2005/387/JHA, within six weeks from the date of receipt of the risk assessment report, the Commission shall present to the Council either an initiative to subject the new psychoactive substances to control measures across the Union, or a report explaining its views on why such an initiative is not deemed necessary. According to the judgment of the Court of Justice of 16 April 2015 in Joined Cases C-317/13 and C-679/13, the European Parliament must be consulted before an act based on Article 8(1) of Council Decision 2005/387/JHA is adopted.

Based on the findings of the risk assessment report, the Commission considers that there are grounds for subjecting this substance to control measures across the Union. According to the risk assessment report, the acute toxicity of 5F-MDMB-PINACA is such that it can cause severe harms to the health of individuals.

### **2. OBJECTIVE OF THE PROPOSAL**

The objective of this proposal for a Council Implementing Decision is to call upon the Member States to subject 5F-MDMB-PINACA to control measures and criminal penalties as

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<sup>1</sup> OJ L 127, 20.5.2005, p. 32.

provided under their legislation by virtue of their obligations under the 1971 United Nations Convention on Psychotropic Substances.

Proposal for a

## COUNCIL IMPLEMENTING DECISION

**on subjecting the new psychoactive substance methyl 2-[[1-(5-fluoropentyl)-1*H*-indazole-3-carbonyl]amino]-3,3-dimethylbutanoate (5F-MDMB-PINACA) 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 information exchange, risk-assessment and control of new psychoactive substances<sup>2</sup>, and in particular Article 8(3) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament<sup>3</sup>,

Whereas:

- (1) A risk assessment report on the new psychoactive substance methyl 2-[[1-(5-fluoropentyl)-1*H*-indazole-3-carbonyl]amino]-3,3-dimethylbutanoate (5F-MDMB-PINACA) was drawn up in compliance with 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 (EMCDDA), and was subsequently submitted to the Commission and to the Council on 14 November 2017.
- (2) 5F-MDMB-PINACA is a synthetic cannabinoid. It shows similar effects to THC, which is responsible for the major psychoactive effects of cannabis, but with additional life-threatening toxicity. The high potency of 5F-MDMB-PINACA and the large and variable content of the substance in smoking mixtures constitute a high risk of poisoning.
- (3) 5F-MDMB-PINACA has been available in the Union since at least September 2014 and has been detected in 25 Member States. Due to the nature of 5F-MDMB-PINACA, detections are likely to be under-reported since the substance is not routinely screened for. In most cases, the substance was seized as herbal/plant material and powder, but it was also seized, though to a lesser extent, as liquid, blotter and in other unspecified physical forms. More than 1770 seizures of herbal material have been made within the European Union.
- (4) 28 deaths associated with 5F-MDMB-PINACA have been reported by two Member States. In at least 20 deaths 5F-MDMB-PINACA was the cause of death or is likely to have contributed to the death. In addition, 35 acute non-fatal intoxications associated with 5F-MDMB-PINACA were reported by two Member States. Due to the nature of 5F-MDMB-PINACA, both non-fatal intoxications and deaths are likely to be under-detected and under-reported.

<sup>2</sup> OJ L 127, 20.5.2005, p. 32.

<sup>3</sup> OJ C , , p. .

- (5) There is no specific information on the involvement of organised crime in the manufacture, distribution (trafficking) and supply of 5F-MDMB-PINACA within the Union. The available data suggest 5F-MDMB-PINACA is produced by chemical companies in China.
- (6) 5F-MDMB-PINACA is typically sold in small and wholesale amounts branded as "legal-high" smoking mixtures and as powder in head shops as well as on the internet as "legal" replacements for cannabis. It may also be sold directly on the illicit drug market. Because these products rarely state the ingredients, most users will be unaware that they are using synthetic cannabinoids in general and 5F-MDMB-PINACA in particular.
- (7) 5F-MDMB-PINACA has no recognised human or veterinary medical use in the Union nor, it appears, elsewhere. There are no indications that 5F-MDMB-PINACA may be used for any other purpose aside from as an analytical reference standard and in scientific research.
- (8) The risk assessment report reveals that many of the questions related to 5F-MDMB-PINACA that are posed by the lack of data on the risks to individual health, risks to public health, and social risks, could be answered through further research. However, the available evidence and information on the health and social risks that the substance poses provides sufficient ground for subjecting 5F-MDMB-PINACA to control measures across the Union.
- (9) 5F-MDMB-PINACA is not listed for control under the 1961 United Nations Single Convention on Narcotic Drugs or under the 1971 United Nations Convention on Psychotropic Substances. The substance is currently under assessment by the United Nations system and has been reviewed at the 39<sup>th</sup> meeting of the WHO Expert Committee on Drug Dependence (ECDD) held from 6 to 10 November 2017 in Geneva. This does not preclude the Union taking a decision to submit the substance to control measures.
- (10) Given that 14 Member States control 5F-MDMB-PINACA under national drug control legislation and four Member States control 5F-MDMB-PINACA under other legislation, subjecting this substance to control measures across the Union would help avoid the emergence of obstacles in cross-border law enforcement and judicial cooperation, and would help protect from the risks that its availability and use can pose.
- (11) Decision 2005/387/JHA confers implementing powers upon the Council with a view to giving a quick and expertise-based response at 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 subject 5F-MDMB-PINACA to control measures across the Union.
- (12) Denmark is bound by Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision.
- (13) Ireland is bound by Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision.
- (14) The United Kingdom is not bound by Decision 2005/387/JHA and is therefore not taking part in the adoption and application of this Decision and is not bound by it or subject to its application,

HAS ADOPTED THIS DECISION:

*Article 1*

The new psychoactive substance methyl 2-{{1-(5-fluoropentyl)-1*H*-indazole-3-carbonyl}amino}-3,3-dimethylbutanoate (5F-MDMB-PINACA) shall be subjected to control measures across the Union.

*Article 2*

By [*one year from the date this Decision is published*] at the latest Member States shall take the necessary measures, in accordance with their national law, to subject the new psychoactive substance referred to in Article 1 to control measures and criminal penalties, as provided for under their legislation, in compliance 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*.

This Decision shall apply in accordance with the Treaties.

Done at Brussels,

*For the Council  
The President*