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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: Draft 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

DRAFT

COUNCIL IMPLEMENTING DECISION (EU) 2018/...

of ...

**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 the information exchange, risk-assessment and control of new psychoactive substances¹, and in particular Article 8(3) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament²,

¹ OJ L 127, 20.5.2005, p. 32.

² OJ C , , p. .

Whereas:

- (1) In accordance with Article 6 of Decision 2005/387/JHA, 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 by a special session of the extended Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction and was submitted to the Commission and to the Council on 14 November 2017.
- (2) 5F-MDMB-PINACA is a synthetic cannabinoid. It has similar effects to those of THC, which is responsible for the major psychoactive effects of cannabis, but 5F-MDMB-PINACA has additional life-threatening toxicity. The high potency of 5F-MDMB-PINACA on the one hand, and the fact that it can account for a large or unknown variable proportion of smoking mixtures on the other, means that it constitutes a significant poisoning risk.
- (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, cases of detection are likely to be underreported since 5F-MDMB-PINACA is not routinely screened for. In most cases, 5F-MDMB-PINACA was seized as herbal or plant material and as powder, but it has also been seized, though to a lesser extent, in liquid form, in blotter form and in other unspecified physical forms. More than 1770 seizures of herbal material have been made within the Union.

- (4) Two Member States have reported 28 deaths associated with 5F-MDMB-PINACA. In at least 20 of those cases, 5F-MDMB-PINACA was either the cause of death or was likely to have contributed to the death. In addition, two Member States reported 35 cases of acute non-fatal intoxication associated with 5F-MDMB-PINACA. Due to the nature of 5F-MDMB-PINACA, both non-fatal intoxications and deaths caused by 5F-MDMB-PINACA are likely to be underdetected and underreported.
- (5) There is no 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 that 5F-MDMB-PINACA is produced by chemical companies in China.
- (6) 5F-MDMB-PINACA is typically sold in small and wholesale amounts in head shops, branded as a so-called legal-high, as smoking mixtures or as powder, as well as on the internet, branded as a so-called legal replacement for cannabis. It is also likely to be sold directly on the illicit drug market. Since the packaging of such products rarely state the ingredients, most users are unaware that they are using 5F-MDMB-PINACA, or even synthetic cannabinoids in general.
- (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 can 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 grounds 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. 5F-MDMB-PINACA is currently under assessment by the United Nations system and has been reviewed at the 39th meeting of the WHO Expert Committee on Drug Dependence held from 6 to 10 November 2017 in Geneva. That does not preclude the Union from 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 5F-MDMB-PINACA 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 poses.

- (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, which implements Decision 2005/387/JHA.
- (13) 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.
- (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 of publication of this Decision], Member States shall take the necessary measures, in accordance with their national law, to subject 5F-MDMB-PINACA 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 date 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
