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Proposal for a

COUNCIL DECISION

on subjecting the new psychoactive substance methyl 2-[[1-(cyclohexylmethyl)-1*H*-indole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-CHMICA) 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[1] provides for a three-step procedure that may lead to the submission of a new psychoactive substance to control measures across the Union.

On 15 April 2016, a joint report of the European Monitoring Centre for Drugs and Drug Addition (EMCDDA) and Europol drawn up in accordance with Article 5 of Council Decision 2005/387/JHA was issued. On 26 May 2016, following the request made by the Commission and 13 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 MDMB-CHMICA, the involvement of organised crime and the possible consequences of control measures introduced on this substance.

The risks of MDMB-CHMICA 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 Chair of the Scientific Committee submitted the risk assessment report to the Commission and to the Council on 28 July 2016. The main results of the risk assessment are the following:

- MDMB-CHMICA is classed as a synthetic cannabinoid receptor agonist, a chemically diverse group of substances also referred to as synthetic cannabinoids. The substance has been available on the drug market in the European Union since at least August 2014 and has been detected in 23 Member States.
- The high potency of MDMB-CHMICA and the highly variable amounts of the compound in "legal high" products constitute a high risk of acute toxicity. Eight Member States have reported a total of 28 deaths and 25 acute intoxications associated with MDMB-CHMICA.

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 judgement 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 MDMB-CHMICA is such that it can cause severe harms to the health of individuals. Multiple reports have also indicated a possibility for violence and aggression as a consequence of its use.

2. OBJECTIVE OF THE PROPOSAL

The objective of this proposal for a Council Decision is to call upon the Member States to subject MDMB-CHMICA to control measures and criminal penalties as provided under their

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

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

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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[2], and in particular Article 8(3) thereof,

Having regard to the proposal of the European Commission,

Having regard to the opinion of the European Parliament[3],

Acting in accordance with a special legislative procedure,

Whereas:

(1) A risk assessment report on the new psychoactive substance MDMB-CHMICA was drawn up in compliance with Article 6 of Council 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 28 July 2016.

(2) MDMB-CHMICA is classed as a synthetic cannabinoid receptor agonist, a chemically diverse group of substances also referred to as synthetic cannabinoids. Synthetic cannabinoid receptor agonists are functionally similar to Δ^9-tetrahydrocannabinol (THC), the major psychoactive principle of cannabis. Cannabinoid receptor agonists controlled under the 1971 United Nations Convention on Psychotropic Substances are: the major active principle of cannabis, delta-9-tetrahydocannabinol (Δ^9-THC) and two synthetic cannabinoids, naphtalen-1-yl(1-pentyl-1*H*-indol-3-yl)methanone (JWH-018) and 1-(5-fluoropentyl)-1*H*-indol-3-yl]-(naphthalen-1-yl)-methanone (AM-2201).

(3) The high potency of MDMB-CHMICA and the highly variable amounts of the compound in "legal high" products constitute a high risk of acute toxicity.

(4) MDMB-CHMICA has been available on the drugs market in the Union since at least August 2014 and has been detected in 23 Member States. It is sold typically as commercial branded "legal high" products in head shops, as well as on the Internet as a "legal" replacement for cannabis. The available information suggests that bulk powders of MDMB-CHMICA are produced by chemical companies based in China. They are imported into the Union where they are either processed and packaged into

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

[3] OJ C , , p. .

commercial smoking mixtures or sold as powder. There is no information indicating production of MDMB-CHMICA within the Union.

(5) MDMB-CHMICA is typically administered by smoking a herbal mixture that is either from a ready-to-use commercial "legal high" product, or, less commonly, that is self-prepared. In commercial products it is usually not stated if the product contains MDMB-CHMICA or any other synthetic cannabinoid receptor agonist. Therefore, many individuals exposed to MDMB-CHMICA might be unaware that they are using the substance. In addition, these consumers might be unaware of the dose they are consuming. The manufacturing process can also lead to an uneven distribution of the substance within the plant material with the result that some products contain regions where cannabinoid is highly concentrated, increasing the risk of acute toxicity and outbreak of mass poisonings.

(6) The available data suggests that MDMB-CHMICA is used by cannabis users, "psychonauts" and by those who are regularly subjected to drug testing procedures, including those in prison.

(7) While there is no specific information on the possible effects of MDMB-CHIMICA on the direct social environment or on society as a whole, multiple reports have indicated a possibility for violence and aggression as a consequence of its use. In addition, the detection of MDMB-CHMICA in cases of suspected driving under influence indicated a potential for wider risk to public safety.

(8) Eight Member States have reported a total of 28 deaths and 25 acute intoxications associated with MDMB-CHMICA. If MDMB-CHMICA were to become more widely available and used, the implications for individual and public health could be significant.

(9) There is limited information to suggest the potential involvement of organised crime in the manufacture, distribution, trafficking and supply of MDMB-CHMICA within the Union.

(10) MDMB-CHMICA 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. However, it is listed among the substances considered for review at the 38th WHO Expert Committee on Drug Dependence (ECDD) which makes recommendations to the United Nations Commission of Narcotic Drugs on the control measures that it considers appropriate.

(11) MDMB-CHMICA has no established or acknowledged human or veterinary medical use. Apart from its use in analytical reference materials and in scientific research investigating its chemistry, pharmacology and toxicology as a result of its emergence on the drug market, there is no indication that it is being used for other purposes.

(12) The risk assessment report reveals that there is limited scientific evidence available on MDMB-CHMICA and points out that further research would be needed. However, the available evidence and information on the health and social risks that the substance poses provides sufficient ground for subjecting MDMB-CHMICA to control measures across the Union.

(13) Given that ten Member States control MDMB-CHMICA under national legislation complying with the obligations of the 1971 United Nations Convention on Psychotropic Substances and that five Member States use other legislative measures to control it, 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.

(14) 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

HAS ADOPTED THIS DECISION:

Article 1

The new psychoactive substance methyl 2-[[1-(cyclohexylmethyl)-1*H*-indole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-CHMICA) shall be subjected to control measures across the Union.

Article 2

As soon as possible, but no later than by *[one year from the date this Decision is published]* 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, 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*.

This Decision shall apply in accordance with the Treaties.

Done at Brussels,

For the Council
The President