Council of the European Union

Brussels, 27 September 2016
(OR. en)

12356/16

Interinstitutional Files:
2015/0309 (CNS)
2016/0262 (NLE)

CORDROGUE 47
SAN 327

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject:	Draft COUNCIL IMPLEMENTING DECISION on subjecting methyl 2-[[1-(cyclohexylmethyl)-1*H*-indole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-CHMICA) to control measures

DRAFT

COUNCIL IMPLEMENTING DECISION (EU) 2016/…

of …

on subjecting
methyl 2-[[1-(cyclohexylmethyl)-1*H*-indole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-CHMICA) 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 substances[1], 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[2],

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

Whereas:

(1) A risk-assessment report on the new psychoactive substance methyl 2-[[1-(cyclohexylmethyl)-1*H*-indole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-CHMICA) was drawn up in accordance with 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 submitted to the Commission and to the Council on 28 July 2016.

(2) MDMB-CHMICA is classed as a synthetic cannabinoid receptor agonist. Synthetic cannabinoid receptor agonists, also referred to as synthetic cannabinoids, are a chemically diverse group of substances functionally similar to Δ^9-tetrahydrocannabinol (Δ^9-THC), the major psychoactive principle of cannabis. Δ^9-THC and the 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) are cannabinoid receptor agonists controlled under the 1971 United Nations Convention on Psychotropic Substances.

(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 drug 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 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, self-prepared. In commercial products it is usually not stated whether 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, such consumers might be unaware of the dose that 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 "hot pockets" 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 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-CHMICA 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 where MDMB-CHMICA was detected. 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 which makes recommendations to the United Nations Commission on 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 provide sufficient grounds for subjecting MDMB-CHMICA to control measures across the Union.

(13) Given that 10 Member States control MDMB-CHMICA under national legislation in compliance with their obligations under 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 could pose.

(14) Decision 2005/387/JHA confers upon the Council implementing powers 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 put MDMB-CHMICA under control across the Union.

(15) 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.

(16) 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.

(17) 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 of publication of this Decision]* 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 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 …,

For the Council
The President