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Proposal for a

COUNCIL DECISION

on subjecting 5-(2-aminopropyl)indole to control measures

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

The Council Decision 2005/387/JHA on the information exchange, risk-assessment and control of new psychoactive substances¹ provides for a three-step procedure that may lead to the submission of a new psychoactive substance to control measures across the Union.

On 22 January 2013, pursuant to Article 6(1) of the above-mentioned Council Decision, the Council requested² an assessment of the risks caused by the use, manufacture and trafficking of the new psychoactive substance 5-(2-aminopropyl)indole, the involvement of organised crime and the possible consequences of control measures introduced on this substance.

The risks of 5-(2-aminopropyl)indole were assessed by the Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction (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 16 April 2013.

The main results of the risk assessment are the following:

- (1) 5-(2-aminopropyl)indole is a synthetic derivative of indole substituted at the phenyl side of the indole ring system. It appears to be a stimulant substance that may also have hallucinogenic effects. Despite the structural similarities with better known compounds such as α -Methyltryptamine (AMT), 5-(2-aminopropyl)benzofuran (5-APB) and the internationally controlled drug 3,4-methylenedioxymphetamine (MDA), the effects of 5-(2-aminopropyl)indole cannot be compared with the ones of these substances due to potential differences in mechanisms of action.
- (2) The acute toxicity of 5-(2-aminopropyl)indole appears to provoke adverse effects in humans such as tachycardia and hyperthermia, and may also cause mydriasis, agitation and tremor. In addition, 5-(2-aminopropyl)indole may interact with other substances, including medical products and stimulants that act on the monoaminergic system.
- (3) Since 2012, seven Member States, as well as Croatia and Norway, have detected 5-(2-aminopropyl)indole and reported information about it to the EMCDDA and Europol. Between April and August 2012, four Member States reported 24 fatalities where 5-(2-aminopropyl)indole alone or in combination with other substances has been detected post-mortem, and three Member States have reported 21 non-fatal intoxications associated with this new psychoactive substance. If this new psychoactive substance were to become more widely available and used, the implications for individual and public health could be significant.
- (4) 5-(2-aminopropyl)indole has no known, established or acknowledged medical value or use and, apart from its use as an analytical reference standard and in scientific research, there is no indication that it is being used for other purposes.

Pursuant to Article 8 (1) of the Council Decision, within six week 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 substance to control measures across the Union, or a report explaining its views on why such an initiative is not deemed necessary.

¹ OJ L 127, 20.5.2005, p. 32.

² Council Document 5284/13.

Although the scientific evidence concerning the overall risks of 5-(2-aminopropyl)indole is limited at this stage, the Commission considers that there are grounds for subjecting the substance to control measures across the Union. The main reason is that, according to the information available from the risk assessment report, the acute toxicity of 5-(2-aminopropyl)indole is such that it can cause severe harms to the health of individuals. Moreover, the risks are heightened by the fact that 5-(2-aminopropyl)indole has been reported to be consumed unknowingly by some users together with or instead of other stimulant substances.

The objective of this proposal for a Council Decision is to call upon the Member States to subject 5-(2-aminopropyl)indole to control measures and criminal penalties as provided under their legislation by virtue of their obligations under the 1971 United Nations Convention on Psychotropic Substances.

Proposal for a

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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 the information exchange, risk-assessment and control of new psychoactive substances³, and in particular Article 8(3) thereof,

Having regard to the initiative of the European Commission,

Whereas:

- (1) A risk assessment report on the new psychoactive substance 5-(2-aminopropyl)indole 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, and was subsequently submitted to the Commission and to the Council on 16 April 2013.
- (2) 5-(2-aminopropyl)indole is a synthetic derivative of indole substituted at the phenyl side of the indole ring system. It appears to be a stimulant substance that may also have hallucinogenic effects. 5-(2-aminopropyl)indole has been found mostly as a powder but also in tablets and capsules, and is commercially available on the internet and from 'head shops', marketed as 'research chemical'. It has also been detected in samples of a product sold as a 'legal high', called 'Benzo Fury', and in tablets resembling ecstasy.
- (3) The existing information and data suggests that the acute toxicity of 5-(2-aminopropyl)indole can provoke adverse effects in humans, such as tachycardia and hyperthermia, and may also cause mydriasis, agitation and tremor. 5-(2-aminopropyl)indole may interact with other substances, including medical products and stimulants that act on the monoaminergic system. The specific physical effects of 5-(2-aminopropyl)indole in humans are difficult to determine because there are no published studies assessing its acute and chronic toxicity, its psychological and behavioural effects, and dependence potential, and because of the limited information and data available.
- (4) There have been a total of 24 fatalities registered in four Member States between April and August 2012, where 5-(2-aminopropyl)indole alone, or in combination with other substances, has been detected in post-mortem samples. While it is not possible to determine with certainty the role of 5-(2-aminopropyl)indole in all of the fatalities, in some cases it has been specifically noted in the cause of death. If this new psychoactive substance were to become more widely available and used, the

³ OJ L 127, 20.5.2005, p. 32.

implications for individual and public health could be significant. There is no information available on the social risks posed by 5-(2-aminopropyl)indole.

- (5) Nine European countries have reported to the European Monitoring Centre for Drugs and Drug Addiction and Europol that they detected 5-(2-aminopropyl)indole. No prevalence data is available on the use of 5-(2-aminopropyl)indole, but the limited information that exists suggests that it may be consumed in similar environments as other stimulants, such as home, bars, nightclubs, music festivals.
- (6) There is no information that suggests that 5-(2-aminopropyl)indole is manufactured in the Union, and there is no evidence suggesting the involvement of organised crime in the manufacture, distribution or supply of this new psychoactive substance.
- (7) 5-(2-aminopropyl)indole has no known, established or acknowledged medical value or use, and there is no marketing authorisation covering this new psychoactive substance in the Union. Apart from its use as an analytical reference standard and in scientific research, there is no indication that it is being used for other purposes.
- (8) 5-(2-aminopropyl)indole has not been under assessment and is currently not under assessment by the United Nations system. Two Member States control this new psychoactive substance under national legislation complying with the obligations of the 1971 United Nations Convention on Psychotropic Substances. Five European countries apply legislation on new psychoactive substances, dangerous goods or medicines to control 5-(2-aminopropyl)indole.
- (9) The risk assessment report reveals that there is limited scientific evidence available on 5-(2-aminopropyl)indole and points out that further research would be needed to determine the health and social risks that it poses. However, the available evidence and information provides sufficient ground for subjecting 5-(2-aminopropyl)indole to control measures across the Union. As a result of the health risks that it poses, as documented by its detection in several reported fatalities, of the fact that users may unknowingly consume it, and of the lack of medical value or use, 5-(2-aminopropyl)indole should be subjected to control measures across the Union.
- (10) Since six Member States already control 5-(2-aminopropyl)indole via legislative provisions of different nature, 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 protect users from the risks that its consumption can pose,

HAS ADOPTED THIS DECISION:

Article 1

The new psychoactive substance, 5-(2-aminopropyl)indole, is hereby subjected to control measures across the Union.

Article 2

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 5-(2-aminopropyl)indole 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 twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels,

For the Council
The President