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Proposal for a

COUNCIL DECISION

on subjecting the new psychoactive substance 1-phenyl-2-(1-pyrrolidin-1-yl) pentan-1-one (α -pyrrolidinovalerophenone, α -PVP) 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 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 3 August 2015, 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 2015, following the request made by the Commission and seventeen 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 α -PVP, the involvement of organised crime and the possible consequences of control measures introduced on this substance.

The risks of α -PVP 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 27 November 2015. The main results of the risk assessment are the following:

α -PVP is a potent psychostimulant. The substance detected in all 28 Member States as well as in Turkey and Norway, is mainly imported into the EU drug market from China and then distributed across Europe.

There have been a total of 115 deaths and 191 acute intoxications registered in eight Member States reported where α -PVP was detected.

There are no available information or published studies assessing in a comprehensive way the health risks associated with α -PVP, namely chronic and acute toxicity, but observations in animals suggest similar effects with those observed with other stimulants.

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 α -PVP 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 Decision is to call upon the Member States to subject α -PVP 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.

¹ OJ L 127, 20.5.2005, p. 32.

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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 substances², and in particular Article 8(3) thereof,

Having regard to the initiative of the European Commission,

Having regard to the opinion of the European Parliament³,

Acting in accordance with a special legislative procedure,

Whereas:

- (1) A risk assessment report on the new psychoactive substance α -PVP 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 27 November 2015.
- (2) α -PVP is a potent psychostimulant, structurally related to cathinone, pyrovalerone and Methylenedioxypropylvaleron (MDPV) which are controlled under the 1971 United Nations Convention on Psychotropic Substances. The substance has been detected in all 28 Member States, as well as Turkey and Norway and the information from seizures and collected samples indicate that it is mainly present under powder and tablet form. The available information suggests that multi-kilogram quantities of α -PVP are imported into the Union drug market from China and then distributed across the Union. The capacity to manufacture α -PVP is also within the Union, as two illicit production sites have been seized within one Member State.
- (3) There have been a total of 115 deaths and 191 acute intoxications registered in eight Member States reported where α -PVP was detected. In most cases, the use of α -PVP was combined with other pharmacologically active substances, either intentionally or unintentionally. If α -PVP were to become more widely available and used, the implications for individual and public health could be significant.
- (4) The available data suggests that α -PVP is used by stimulant users in recreational settings as well as by high risk drug users, including those injecting stimulants and opioids, and that polydrug use may be common among them. There is limited data on

² OJ L 127, 20.5.2005, p. 32.

³ OJ C , , p. .

prevalence of drug use, the long-term consequences and on the social risks associated with the substance.

- (5) There are no available information or published studies assessing in a comprehensive way the health risks associated with α -PVP, namely chronic and acute toxicity, but observations in animals suggest similar effects with those observed with other stimulants. Adverse symptoms observed in humans have been described as tachycardia, hyperthermia, diaphoresis, agitation, convulsions or seizures, confusion, aggression. Data from non-clinical studies suggest that α -PVP may have an abuse liability and possibly a dependence potential in humans.
- (6) α -PVP has no established or acknowledged medical use (human or veterinary). 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.
- (7) α -PVP has not been under assessment and is currently not under assessment at the United Nations' level, and no such assessment is planned.
- (8) Despite the limited scientific evidence available on α -PVP, the evidence and information on the health risks that the substance poses, as documented in its detection in fatalities and acute intoxications, provides sufficient ground for subjecting α -PVP to control measures across the Union.
- (9) Since sixteen Member States control α -PVP under national legislation complying with the obligations of the 1971 United Nations Convention on Psychotropic Substances and 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,
- (10)

HAS ADOPTED THIS DECISION:

Article 1

The new psychoactive substance 1-phenyl-2-(1-pyrrolidin-1-yl)pentan-1-one (α -pyrrolidinovalerophenone, α -PVP) shall be 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 α -PVP 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*.

Done at Brussels,

*For the Council
The President*