



**COUNCIL OF
THE EUROPEAN UNION**

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CORDROGUE 48

PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	16 June 2014
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2014) 362 final
Subject:	Proposal for a COUNCIL DECISION on subjecting 4-iodo-2,5-dimethoxy- N-(2-methoxybenzyl)phenethylamine (25I-NBOMe), 3,4-dichloro-N-[[1- (dimethylamino)cyclohexyl]methyl]benzamide (AH-7921), 3,4- methylenedioxypropylvalerone (MDPV) and 2-(3-methoxyphenyl)-2- (ethylamino)cyclohexanone (methoxetamine) to control measures

Delegations will find attached document COM(2014) 362 final.

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Brussels, 16.6.2014
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Proposal for a

COUNCIL DECISION

on subjecting 4-iodo-2,5-dimethoxy-N-(2-methoxybenzyl)phenethylamine (25I-NBOMe), 3,4-dichloro-N-[[1-(dimethylamino)cyclohexyl]methyl]benzamide (AH-7921), 3,4-methylenedioxypropylvalerone (MDPV) and 2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone (methoxetamine) 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 28 January 2014, 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 substances 25I-NBOMe, AH-7921, MDPV and methoxetamine, the involvement of organised crime and the possible consequences of control measures introduced on these substances.

The risks of 25I-NBOMe, AH-7921, MDPV and methoxetamine 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 23 April 2014.

The main results of the risk assessment are the following:

- 25I-NBOMe is a derivative of 2C-I, a known synthetic derivative of phenethylamine with stimulant and hallucinogenic properties, subjected to risk assessment and control measures in 2003. It has been available on the EU drug market since at least May 2012 and has been detected in 23 Member States and Norway. There have been four deaths associated with 25I-NBOMe registered in three Member States. Severe toxicity associated with its use has been reported in four Member States, which notified 32 non-fatal intoxications. Information from seizures and collected samples suggest that 25I-NBOMe is being sold on the illicit market as LSD.
- AH-7921 is a structurally atypical synthetic opioid analgesic, which has been available in the EU since at least July 2012 and has been detected in eight Member States and Norway. There have been 15 deaths associated with AH-7921, all occurred in three Member States within a limited period, between December 2012 and September 2013. Severe toxicity was reported by one Member State, where six non-fatal intoxications occurred. AH-7921 appears to be sold by Internet retailers since 2011, advertised as 'research chemical' or 'legal opioid'.
- MDPV is a ring substituted synthetic derivative of cathinone, chemically related to pyrovalerone, which are both subject to control under the 1971 United Nations Convention on Psychotropic Substances. There have been 108 fatalities registered in eight Member States and Norway between September 2009 and August 2013, where MDPV has been detected in post-mortem biological samples or implicated in the cause of death. Eight Member States reported 525 non-fatal intoxications associated with MDPV. MDPV has been present in the EU drug market since November 2008. Multi-kilogram seizures of MDPV were reported in 27 Member States, Norway and

¹ OJ L 127, 20.5.2005, p. 32.

Turkey. It is mainly sold as a substance of its own right and it is widely available from Internet suppliers and retailers, head shops and street level dealers.

- Methoxetamine is an arylcyclohexylamine substance, chemically similar to ketamine and phencyclidine (PCP). Like ketamine and PCP, methoxetamine has dissociative properties. Some 20 deaths associated with methoxetamine were reported by six Member States that detected the substance in post-mortem samples. Used alone or in combination with other substances, methoxetamine was also detected in 20 non-fatal intoxications reported by five Member States. Twenty three Member States, as well as Turkey and Norway reported detections of methoxetamine, since November 2010. Information suggests that methoxetamine is sold and used as a substance in its own right, but also as a 'legal' replacement for ketamine by Internet retailers, head shops and street-level drug dealers.

Pursuant to Article 8(1) of Council Decision 2005/387/JHA, 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 substances to control measures across the Union, or a report explaining its views on why such an initiative is not deemed necessary.

Although the scientific evidence concerning the overall risks of 25I-NBOMe, AH-7921, MDPV and methoxetamine is limited at this stage, the Commission considers that there are grounds for subjecting these substances to control measures across the Union. The main reason is that, according to the information available from the risk assessment reports, the acute toxicity of 25I-NBOMe, AH-7921, MDPV and methoxetamine is such that it can cause severe harms to the health of individuals. Moreover, the risks are heightened by the fact that these substances have been reported, in some cases, to be consumed unknowingly by certain users together with or instead of other stimulant substances.

2. OBJECTIVE OF THE PROPOSAL

The objective of this proposal for a Council Decision is to call upon the Member States to subject 25I-NBOMe, AH-7921, MDPV and methoxetamine 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

COUNCIL DECISION

on subjecting 4-iodo-2,5-dimethoxy-N-(2-methoxybenzyl)phenethylamine (25I-NBOMe), 3,4-dichloro-N-[[1-(dimethylamino)cyclohexyl]methyl]benzamide (AH-7921), 3,4-methylenedioxypropylamphetamine (MDPV) and 2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone (methoxetamine) 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 substances², and in particular Article 8(3) thereof,

Having regard to the initiative of the European Commission,

Whereas:

- (1) Risk assessment reports on the new psychoactive substances 25I-NBOMe, AH-7921, MDPV and methoxetamine were 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 (EMCDDA), and were subsequently submitted to the Commission and to the Council on 23 April 2014.
- (2) 25I-NBOMe, AH-7921, MDPV and methoxetamine have not been under assessment at the United Nations' level, but they will be subject to evaluation in June 2014 by the Expert Committee on Drug Dependence of the World Health Organization.
- (3) 25I-NBOMe, AH-7921, MDPV and methoxetamine have no established or acknowledged medical use (human or veterinary). Apart from their use in analytical reference materials, and in scientific research investigating their chemistry, pharmacology and toxicology as a result of their emergence on the drug market - and, in the case of 25I-NBOMe, also in the field of neurochemistry - there is no indication that they are being used for other purposes.
- (4) 25I-NBOMe is a potent synthetic derivative of the 2C-I, a classical serotonergic hallucinogen, which was subject to risk assessment and to control measures and criminal penalties at Union level in 2003.
- (5) The specific physical effects of 25I-NBOMe are difficult to determine because there are no published studies assessing its acute and chronic toxicity, its psychological

² OJ L 127, 20.5.2005, p. 32.

and behavioural effects, and dependence potential, and because of the limited information and data available. Clinical observations of individuals who have used this substance suggest that it has hallucinogenic effects and has the potential for inducing severe agitation, confusion, intense auditory and visual hallucinations, aggression, violent accidents and self-induced trauma.

- (6) There have been four deaths associated with 25I-NBOMe registered in three Member States. Severe toxicity associated with its use has been reported in four Member States, which notified 32 non-fatal intoxications. If this new psychoactive substance were to become more widely available and used, the implications for individual and public health could be significant. There is no available information on the social risks associated with 25I-NBOMe.
- (7) Twenty two Member States and Norway have reported to the EMCDDA and Europol that they detected 25I-NBOMe. No prevalence data is available on the use of 25I-NBOMe, but the limited information that exists suggests that it may be consumed in a wide range of settings, such as home, bars, nightclubs and music festivals.
- (8) 25I-NBOMe is openly marketed and sold on the Internet as a 'research chemical' and information from seizures, collected samples, user websites and Internet retailers suggests that it is being sold as a drug in its own right and also marketed as a 'legal' replacement for LSD. EMCDDA identified more than 15 Internet retailers selling this substance, which may be based within the Union and China.
- (9) The risk assessment report reveals that there is limited scientific evidence available on 25I-NBOMe 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 25I-NBOMe 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 of the substance, 25I-NBOMe should be subjected to control measures across the Union.
- (10) Since six Member States control 25I-NBOMe under national legislation complying with the obligations of the 1971 United Nations Convention on Psychotropic Substances and seven 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.
- (11) AH-7921 is a structurally atypical synthetic opioid analgesic commonly known by Internet suppliers, user websites and media as 'doxylam'. It can be easily confused with 'doxylamine', an antihistaminic medicine with sedative-hypnotic properties, which could lead to unintentional overdoses.
- (12) The specific physical effects of AH-7921 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. Based on user reports, the effects of AH-7921 appear to resemble those of classical opioids with the feeling of mild euphoria, itchiness and relaxation; nausea appears to be a typical adverse effect. In addition to self-

experimentation with AH-7921, as well as 'recreational use', some of the users report self-medicating with this new drug to relieve pain, others to alleviate withdrawal symptoms due to cessation of the use of other opioids. This may indicate a potential of AH-7921 to spread among the injecting opioid population.

- (13) There is no prevalence data on the use of AH-7921, but the information available suggests that it is not widely used and that it is used in the home environment.
- (14) There have been 15 fatalities registered in three Member States between December 2012 and September 2013 where AH-7921, alone or in combination with other substances, was detected in post-mortem samples. While it is not possible to determine with certainty the role of AH-7921 in all of fatalities, in some cases it has been specifically noted in the cause of death. One Member State reported six non-fatal intoxications associated with AH-7921. If this new psychoactive substance were to become more widely available and used, the implications for individual and public health could be significant. There is no available information on the social risks associated with AH-7921.
- (15) The risk assessment report reveals that there is limited scientific evidence available on AH-7921 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 AH-7921 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 of the substance, AH-7921 should be subjected to control measures across the Union.
- (16) Since one Member State controls AH-7921 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.
- (17) MDPV is a ring substituted synthetic derivative of cathinone chemically related to pyrovalerone, which are both subject to control under the 1971 United Nations Convention on Psychotropic Substances.
- (18) Information on the chronic and acute toxicity associated with MDPV, as well as on psychological and behavioural effects, and on dependence potential, is not collected uniformly across the Union. Information from published studies, confirmed by clinical cases, suggests that the psychopharmacological profile observed for MDPV is similar to that for cocaine and methamphetamine, albeit more potent and longer lasting. Furthermore, MDPV was found to be ten-time more potent in its ability to induce locomotor activation, tachycardia and hypertension.
- (19) Users' websites indicate that its acute toxicity can provoke adverse effects on humans, similar to those associated with other stimulants. These include paranoid psychosis, tachycardia, hypertension, diaphoresis, breathing problems, severe agitation, auditory and visual hallucinations, profound anxiety, hyperthermia, violent outbursts and multiple organ dysfunctions.

- (20) There have been 108 fatalities registered in eight Member States and Norway between September 2009 and August 2013, where MDPV has been detected in post-mortem biological samples or implicated in the cause of death. A total of 525 non-fatal intoxications associated with MDPV have been reported by eight Member States. If this new psychoactive substance were to become more widely available and used, the implications for individual and public health could be significant.
- (21) The detection of MDPV has also been reported in biological samples related to fatal and non-fatal road traffic accidents, or driving under the influence of drugs, in four Member States since 2009.
- (22) MDPV has been present in the Union drug market since November 2008 and 27 Member States, Norway and Turkey reported multi-kilogram seizures of the substance. MDPV is being sold as a substance of its own right but it has also been detected in combination with other substances. It is widely available from Internet suppliers and retailers, head shops and street-level dealers. There are some indications that suggest a degree of organisation in the tableting and distribution of this substance in the Union.
- (23) The risk assessment report reveals that further research would be needed to determine the health and social risks posed by MDPV. However, the available evidence and information provides sufficient ground for subjecting MDPV 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 of the substance, MDPV should be subjected to control measures across the Union.
- (24) Since 21 Member States control MDPV under national legislation complying with the obligations of the 1971 United Nations Convention on Psychotropic Substances and four 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 protect from the risks that its availability and use can pose.
- (25) Methoxetamine is an arylcyclohexylamine substance which is chemically similar to ketamine and the internationally control substance phencyclidine (PCP). Like ketamine and PCP, it has dissociative properties.
- (26) There are no studies assessing the chronic and acute toxicity associated with methoxetamine, as well as its psychological and behavioural effects, and dependence potential. Self-reported experiences from user websites suggest adverse effects similar to ketamine intoxication. These include nausea and severe vomiting, difficulty in breathing, seizures, disorientation, anxiety, catatonia, aggression, hallucination, paranoia and psychosis. In addition, acute methoxetamine intoxications may include stimulants effects (agitation, tachycardia and hypertension) and cerebral features, which are not expectable with acute ketamine intoxication.
- (27) Twenty deaths associated with methoxetamine were reported by six Member States that detected the substance in post-mortem samples. Used alone or in combination with other substances, methoxetamine was detected in 20 non-fatal intoxications reported by five Member States. If this new psychoactive substance were to become

more widely available and used, the implications for individual and public health could be significant.

- (28) Twenty three Member States, Turkey and Norway have reported that they detected methoxetamine, since November 2010. Information suggests that it is sold and used as a substance in its own right, but it is also sold as a 'legal' replacement for ketamine by Internet retailers, head shops and street-level drug dealers.
- (29) Multi-kilograms quantities in powder were seized within the Union, but there is no information on the possible involvement of organised crime. The manufacture of methoxetamine does not require sophisticated equipment.
- (30) Data prevalence is limited to non-representatives studies in two Member States. These suggest that the prevalence of the use of methoxetamine is lower than that of ketamine. The available information suggests that it may be consumed in a wide range of settings, including home, bars, nightclubs and music festivals.
- (31) The risk assessment report reveals that further research would be needed to determine the health and social risks posed by methoxetamine. However, the available evidence and information provides sufficient ground for subjecting methoxetamine 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, methoxetamine should be subjected to control measures across the Union.
- (32) Since nine Member States control methoxetamine under national legislation complying with the obligations of the 1971 United Nations Convention on Psychotropic Substances and nine 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 protect from the risks that its availability and use can pose,

HAS ADOPTED THIS DECISION:

Article 1

The following new psychoactive substances shall be subjected to control measures across the Union:

- (a) 4-iodo-2,5-dimethoxy-N-(2-methoxybenzyl) phenethylamine(25I-NBOMe);
- (b) 3,4-dichloro-N-[[1-dimethylamino) cyclohexyl]methyl] benzamide (AH-7921);
- (c) 3,4-methylenedioxypropylvalerone (MDPV);
- (d) 2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone (methoxetamine).

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 the new psychoactive

substances 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 twentieth day following that of its publication in the *Official Journal of the European Union*

Done at Brussels,

*For the Council
The President*