Council of the European Union

Brussels, 6 April 2017
(OR. en)

8102/17

Interinstitutional File:
2017/0073 (NLE)

CORDROGUE 45
SAN 144
ENFOPOL 175

PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	6 April 2017
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2017) 161 final
Subject:	Proposal for a COUNCIL IMPLEMENTING DECISION on subjecting the new psychoactive substance N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide (acryloylfentanyl) to control measures

Delegations will find attached document COM(2017) 161 final.

Encl.: COM(2017) 161 final

EUROPEAN
COMMISSION

Brussels, 6.4.2017
COM(2017) 161 final

2017/0073 (NLE)

Proposal for a

COUNCIL IMPLEMENTING DECISION

on subjecting the new psychoactive substance *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacrylamide (acryloylfentanyl) 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 17 November 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 23 January 2017, following the request made by the Commission and 11 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 acryloylfentanyl, the involvement of organised crime and the possible consequences of control measures introduced on this substance.

The risks of acryloylfentanyl 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 24 February 2017. The main results of the risk assessment are the following:

– Acryloylfentanyl is a synthetic opioid. It is structurally similar to fentanyl, a controlled substance. The substance has been available in the European Union since at least April 2016 and has been detected in 6 Member States.

– 47 deaths associated with acryloylfentanyl have been reported by 3 Member States In at least 40 deaths acryloylfentanyl was the cause of death or is likely to have contributed to death. In addition, more than 20 acute intoxications suspected to be due to acryloylfentanyl have been reported

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 judgment 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 acryloylfentanyl is such that it can cause severe harms to the health of individuals.

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

2. OBJECTIVE OF THE PROPOSAL

The objective of this proposal for a Council Implementing Decision is to call upon the Member States to subject acryloylfentanyl 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.

2017/0073 (NLE)

Proposal for a

COUNCIL IMPLEMENTING DECISION

on subjecting the new psychoactive substance *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacrylamide (acryloylfentanyl) to control measures

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Having regard to Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances[2], and in particular Article 8(3) thereof,

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

Having regard to the proposal from the European Commission,

Whereas:

(1) A risk assessment report on the new psychoactive substance *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacrylamide (acryloylfentanyl) was drawn up in accordance 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 was subsequently submitted to the Commission and to the Council on 24 February 2017.

(2) Acryloylfentanyl is a synthetic opioid. It is structurally similar to fentanyl, a controlled substance widely used in medicine as an adjunct to general anaesthesia during surgery and for pain management. The available data suggest that acryloylfentanyl is a potent and long-lasting antinociceptive agent acting on the opioid system.

(3) Acryloylfentanyl has been available in the European Union since at least April 2016 and has been detected in 6 Member States. In most cases it has been seized as a liquid, but other forms such as tablets, powders and a capsule have also been detected. The detected quantities are relatively small. However, they should be considered in the context of the high potency of the substance.

(4) 47 deaths associated with acryloylfentanyl have been reported by 3 Member States. In at least 40 deaths acryloylfentanyl was the cause of death or is likely to have contributed to death. In addition, more than 20 acute intoxications suspected to be due to acryloylfentanyl have been reported.

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

(5) There is no information to suggest the involvement of organised crime in the manufacture, distribution, trafficking and supply of acryloylfentanyl within the Union. The available data suggest that most of the acryloylfentanyl on the market in Europe has been produced by chemical companies based in China.

(6) Acryloylfentanyl is sold as "research chemical", typically as powder and as ready-to-use nasal sprays, in small and wholesale amounts. Limited information from seizures suggests that acryloylfentanyl may have also been sold on the illicit opioid market.

(7) Acryloylfentanyl 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. The substance is not currently under assessment by the United Nations system.

(8) Acryloylfentanyl 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.

(9) The risk assessment report reveals that there is limited scientific evidence available on acryloylfentanyl 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 acryloylfentanyl to control measures across the Union.

(10) Given that only 9 Member States control acryloylfentanyl under national drug control legislation and 2 Member State 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) 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 subject acryloylfentanyl to control measures across the Union.

(12) 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.

(13) 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.

(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 *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacrylamide (acryloylfentanyl) shall be subjected to control measures across the Union.

Article 2

By *[one year from the date this Decision is published]* at the latest 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.

This Decision shall apply in accordance with the Treaties.

Done at Brussels,

For the Council
The President