



Brussels, 30 May 2017
(OR. en)

8858/17

Interinstitutional File:
2017/0073 (NLE)

CORDROGUE 56
SAN 181
ENFOPOL 212

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: Draft COUNCIL IMPLEMENTING DECISION on subjecting
N-(1-phenethylpiperidin-4-yl)-*N*-phenylacrylamide (acryloylfentanyl) to
control measures

DRAFT

COUNCIL IMPLEMENTING DECISION (EU) 2017/...

of ...

**on subjecting *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 Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances¹, and in particular Article 8(3) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament²,

¹ OJ L 127, 20.5.2005, p. 32.

² Opinion of ... (not yet published in the Official Journal).

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 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 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 Union since at least April 2016 and has been detected in six Member States. In most cases where it has been seized, the substance was in liquid form, but other forms such as tablets, powders and a capsule have also been detected. The detected quantities are relatively small, but should be considered in the context of the high potency of the substance.
- (4) Three Member States have collectively reported 47 deaths associated with acryloylfentanyl. In at least 40 deaths, acryloylfentanyl was the cause of death or is likely to have been a contributing cause of death. In addition, more than 20 acute intoxications suspected to be due to acryloylfentanyl have been reported.

- (5) There is no information to suggest the involvement of organised crime in the manufacture, distribution, trafficking or 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 a powder or as ready-to-use nasal sprays. It is sold 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 into its chemistry, pharmacology and toxicology in response to its emergence on the drug market, there is no indication that it is being used for other legitimate purposes.
- (9) The risk assessment report reveals that there is limited scientific evidence available on acryloylfentanyl, and observes 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 acryloylfentanyl to control measures across the Union.

- (10) Only nine Member States control acryloylfentanyl under national drug control legislation, while two other Member States use other legislative measures to control it. Therefore, 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.
- (11) Decision 2005/387/JHA confers upon the Council implementing powers to submit new psychoactive substances to control measures across the Union in order to ensure a quick and expertise-based response at Union level to the emergence of such substances that have been detected and reported by the Member States. 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 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 day 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
