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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: Draft COUNCIL IMPLEMENTING DECISION on subjecting the new psychoactive substance
N-(4-fluorophenyl)-2-methyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]propanamide
(4-fluoroisobutyrylfentanyl) to control measures

DRAFT

COUNCIL IMPLEMENTING DECISION (EU) 2018/...

of ...

**on subjecting the new psychoactive substance
N-(4-fluorophenyl)-2-methyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]propanamide
(4-fluoroisobutyrylfentanyl) 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 OJ C , , p. .

Whereas:

- (1) In accordance with Article 6 of Decision 2005/387/JHA, a risk assessment report on the new psychoactive substance
N-(4-fluorophenyl)-2-methyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]propanamide ('4-fluoroisobutyrylfentanyl') was drawn up by a special session of the extended Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction and was submitted to the Commission and to the Council on 14 November 2017.
- (2) 4-fluoroisobutyrylfentanyl is a synthetic opioid structurally related to fentanyl, which is a controlled substance widely used in medicine as an adjunct to general anaesthesia during surgery and for pain management. It is also structurally related to acetylfentanyl, acryloylfentanyl¹ and furanylfentanyl².

¹ Council Implementing Decision (EU) 2017/1774 of 25 September 2017 on subjecting *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacrylamide (acryloylfentanyl) to control measures (OJ L 251, 29.9.2017, p. 21).

² Council Implementing Decision (EU) 2017/2170 of 15 November 2017 on subjecting *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (furanylfentanyl) to control measures (OJ L 306, 22.11.2017, p. 19).

- (3) 4-fluoroisobutyrylfentanyl has been available in the Union since at least August 2016 and has been seized in four Member States, which reported 24 seizures in total. In general, cases of detection are likely to be underreported since 4-fluoroisobutyrylfentanyl is not routinely screened for. In most cases, 4-fluoroisobutyrylfentanyl was seized as powder, but it has also been seized, to a smaller extent, in liquid form and as tablets. The quantities detected are relatively small. However, they should be seen within the context of the high potency that is typical of the fentanils.
- (4) One Member State has reported 16 deaths where exposure to 4-fluoroisobutyrylfentanyl was confirmed. In many of the cases, other drugs were detected in addition to 4-fluoroisobutyrylfentanyl. In the case of at least 13 deaths 4-fluoroisobutyrylfentanyl was either the cause of death or was likely to have contributed to the death. No acute intoxications with confirmed exposure to 4-fluoroisobutyrylfentanyl were reported. Both non-fatal intoxications and deaths caused by 4-fluoroisobutyrylfentanyl are likely to be underdetected and underreported as 4-fluoroisobutyrylfentanyl is not routinely screened for. Accidental exposure to 4-fluoroisobutyrylfentanyl may pose a risk to law enforcement personnel, emergency personnel, medical and forensic laboratory personnel, postal services personnel as well as to those working in custodial settings.

- (5) There is no information on the involvement of organised crime in the manufacture, distribution, trafficking and supply of 4-fluoroisobutyrylfentanyl within the Union. However, given the fact that it has been detected in heroin samples, the involvement of organised crime cannot be excluded. The available information suggests that 4-fluoroisobutyrylfentanyl is produced by chemical companies in China, but it is possible that the capability to manufacture fentanils also exists within the Union.
- (6) 4-fluoroisobutyrylfentanyl appears to be sold online in small and wholesale amounts, as a so-called research chemical or as a so-called legal replacement to illicit opioids, in powder form, in liquid form for example in ready-to-use nasal sprays, and in blotter form. Information from seizures suggests that 4-fluoroisobutyrylfentanyl has also been sold as heroin on the illicit opioid market, or has been found in mixtures with other opioids such as heroin and furanylfentanyl, or has been used to make counterfeits of highly sought-after analgesics and benzodiazepine. Due to this, users may not be aware that they are using a fentanyl.
- (7) 4-fluoroisobutyrylfentanyl has no recognised human or veterinary medical use in the Union nor, it appears, elsewhere. There are no indications that 4-fluoroisobutyrylfentanyl can be used for any other purpose aside from as an analytical reference standard and in scientific research.

- (8) The risk assessment report reveals that many of the questions related to 4-fluoroisobutyrylfentanyl that are posed by the lack of data on the risks to individual health, risks to public health, and social risks, could be answered through further research. However, the available evidence and information on the health and social risks that the substance poses, given also its similarities with fentanyl, acryloylfentanyl and furanylfentanyl, provides sufficient grounds for subjecting 4-fluoroisobutyrylfentanyl to control measures across the Union.
- (9) 4-fluoroisobutyrylfentanyl 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. 4-fluoroisobutyrylfentanyl is currently under assessment by the United Nations system and has been reviewed at the 39th meeting of the WHO Expert Committee on Drug Dependence held from 6 to 10 November 2017 in Geneva. That does not preclude the Union from taking a decision to subject 4-fluoroisobutyrylfentanyl to control measures.
- (10) Given that seven Member States control 4-fluoroisobutyrylfentanyl under national drug control legislation and five Member States control 4-fluoroisobutyrylfentanyl under other legislation, subjecting 4-fluoroisobutyrylfentanyl to control measures across the Union would help to 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 poses.

- (11) Decision 2005/387/JHA confers implementing powers upon the Council 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 4-fluoroisobutyrylfentanyl 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 and application of this Decision and is not bound by it or subject to its application,

HAS ADOPTED THIS DECISION:

Article 1

The new psychoactive substance

N-(4-fluorophenyl)-2-methyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]propanamide ('4-fluoroisobutyrylfentanyl') 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 4-fluoroisobutyrylfentanyl to control measures and criminal penalties, as provided for under their legislation, in compliance with their obligations under the 1961 United Nations Single Convention on Narcotic Drugs as amended by the 1972 Protocol.

Article 3

This Decision shall enter into force on the date following that of its publication in the *Official Journal of the European Union*.

This Decision shall apply in accordance with the Treaties.

Done at Brussels,

For the Council
The President
