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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	Proposal for a COUNCIL IMPLEMENTING DECISION on subjecting the new psychoactive substance <i>N</i> -(4-fluorophenyl)-2-methyl- <i>N</i> -[1-(2- phenylethyl)piperidin-4-yl]propanamide (4-fluoroisobutyrylfentanyl) to control measures

Delegations will find attached document COM(2017) 756 final.

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Proposal for a

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

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 4 July 2017, 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 2017, following the request made by the Commission and seven 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 *N*-(4-fluorophenyl)-2-methyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]propanamide (4-fluoroisobutyrylfentanyl) the involvement of organised crime and the possible consequences of control measures introduced on this substance.

The risks of 4-fluoroisobutyrylfentanyl 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 risk assessment report was submitted to the Commission and to the Council on 14 November 2017. The main results of the risk assessment are the following:

- 4-fluoroisobutyrylfentanyl is a synthetic opioid and is structurally related to fentanyl, an internationally controlled substance. It is also structurally related to acetylfentanyl, acryloylfentanyl² and furanylfentanyl³.
- 4-fluoroisobutyrylfentanyl has been available in the European Union since at least August 2016 and has been seized in four Member States. 16 deaths have been reported by one Member State where exposure to 4-fluoroisobutyrylfentanyl was confirmed. In at least 13 deaths 4-fluoroisobutyrylfentanyl was the cause of death or is likely to have contributed to the death.

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 4-fluoroisobutyrylfentanyl is such that it can cause severe harms to the health of individuals.

¹ OJ L 127, 20.5.2005, p. 32.

² Acryloylfentanyl has been subjected to control measures by 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.

³ Furanylfentanyl has been subjected to control measures by 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.

2. OBJECTIVE OF THE PROPOSAL

The objective of this proposal for a Council Implementing Decision is to call upon the Member States to subject 4-fluoroisobutyrylfentanyl to control measures and criminal penalties as provided under their legislation by virtue of their obligations under the 1961 United Nations Single Convention on Narcotic Drugs as amended by the 1972 Protocol.

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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 substances⁴, and in particular Article 8(3) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament⁵,

Whereas:

- (1) 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 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 was subsequently submitted to the Commission and to the Council on 14 November 2017.
- (2) 4-fluoroisobutyrylfentanyl is a synthetic opioid and is structurally related to fentanyl, 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, acryloylfentanyl⁶ and furanylfentanyl⁷.
- (3) 4-fluoroisobutyrylfentanyl has been available in the Union since at least August 2016 and has been seized in four Member States who reported 24 seizures in total. Detections in general are likely to be under-reported since the substance is not routinely screened for. In most cases, the substance was seized as powder, but it was also seized, to a smaller extent, in liquid form and as tablets. The detected quantities are relatively small. However, they should be seen within the context of the high potency that is typical of the fentanils.
- (4) 16 deaths have been reported by one Member State where exposure to 4-fluoroisobutyrylfentanyl was confirmed. In many of the cases, other drugs were also

⁴ OJ L 127, 20.5.2005, p. 32.

⁵ OJ C , , p. .

⁶ 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.

⁷ 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.

detected with 4-fluoroisobutyrylfentanyl. In at least 13 deaths 4-fluoroisobutyrylfentanyl was the cause of death or is likely to have contributed to the death. No acute intoxications with confirmed exposure to 4-fluoroisobutyrylfentanyl were reported. It is likely that naloxone works as an antidote to poisoning caused by 4-fluoroisobutyrylfentanyl. Both non-fatal intoxications and deaths are likely to be under-detected and under-reported as they are not routinely screened for. Accidental exposure to 4-fluoroisobutyrylfentanyl may pose a risk to law enforcement, emergency personnel, medical and forensic laboratory personnel, as well as to those in custodial settings and postal services.

- (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 the capability to manufacture fentanils may also exist within the Union.
- (6) 4-fluoroisobutyrylfentanyl appears to be sold online in small and wholesale amounts, under the guise of a "research chemical" or as a "legal" replacement to illicit opioids, as powder, liquid (e.g. in ready-to-use nasal spray) and blotter. Information from seizures suggests that 4-fluoroisobutyrylfentanyl may have also been sold on the illicit opioid market, where it is sold as heroin or was found in mixtures with other opioids such as heroin and furanylfentanyl, or is 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 may 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 ground 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. The substance 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 (ECDD) held from 6 to 10 November 2017 in Geneva. This does not preclude the Union taking a decision to subject the substance 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 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 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.
- (13) Ireland is bound by Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision.
- (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 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, 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 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 Brussels,

For the Council
The President