Basic information

2017/0339(NLE) NLE - Non-legislative enactments	Procedure lapsed or withdrawn
Subjecting the new psychoactive substance N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl)propanamide (4-fluoroisobutyrylfentanyl) to control measures **Subject** 7.30.30.04 Action to combat drugs and drug-trafficking	

Key players

Council of the European Union	
European Commission	**Commission DG** / **Commissioner** Migration and Home Affairs / AVRAMOPOULOS Dimitris

Key events

Date	Event	Reference	Summary
18/12/2017	Preparatory document	COM(2017)0756	Summary
02/02/2018	Legislative proposal published	05386/2018	Summary
28/02/2018	Committee referral announced in Parliament		

Technical information

Procedure reference	2017/0339(NLE)
Procedure type	NLE - Non-legislative enactments
Procedure subtype	Consent by Parliament
Stage reached in procedure	Procedure lapsed or withdrawn
Committee dossier	LIBE/8/11877

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE618.022	06/02/2018	

Council of the EU

Document type	Reference	Date	Summary
Legislative proposal	05386/2018	02/02/2018	Summary

European Commission

Document type	Reference	Date	Summary
Preparatory document	COM(2017)0756	18/12/2017	Summary

Subjecting the new psychoactive substance N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl)propanamide (4-fluoroisobutyrylfentanyl) to control measures

2017/0339(NLE) - 18/12/2017

PURPOSE: to subject the new psychoactive substance N-(4-fluorophenyl)-2-methyl-N-[1-(2phenylethyl)piperidin-4-yl)propanamide (4-fluoroisobutyrylfentanyl) to control measures.

PROPOSED ACT: Council Implementing Decision.

ROLE OF THE EUROPEAN PARLIAMENT: the Council adopts the act after consulting the European Parliament but without being obliged to follow the opinion of the European Parliament.

BACKGROUND: on 15 September 2017, following the request made by the Commission and seven Member States and pursuant to Council Decision 2005/387/JHA on the information exchange, risk-assessment and control of new psychoactive substances, the Council requested an assessment of the risks caused by the use, manufacture and trafficking of the new psychoactive substance N-(4-fluorophenyl)-2methyl-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.

A **risk assessment report** on the new psychoactive substance was drawn up by the Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), and was subsequently submitted to the Commission on 14 November 2017.

The main conclusions of the report are as follows:

- 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 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;
- 4-fluoroisobutyrylfentanyl has been available in the 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 4fluoroisobutyrylfentanyl was confirmed. No acute intoxications with confirmed exposure to 4-fluoroisobutyrylfentanyl were reported. 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.

This substance has been detected in heroin samples, the involvement of organised crime cannot be excluded. 4-fluoroisobutyrylfentanyl has no recognised human or veterinary medical use in the Union.

The risk assessment report reveals that many of the questions related to 4fluoroisobutyrylfentanyl could be answered through further research. However, the available evidence and information on the **health and social risks** that the substance poses provides sufficient ground for subjecting 4fluoroisobutyrylfentanyl to control measures across the Union.

CONTENT: the purpose 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 1971 United Nations Single Convention on Narcotic Drugs.

Currently 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.

The United Kingdom shall not take part in the adoption of this Decision.

Subjecting the new psychoactive substance N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl)propanamide (4-fluoroisobutyrylfentanyl) to control measures

2017/0339(NLE) - 18/12/2017 - Preparatory document

PURPOSE: to subject the new psychoactive substance N-(4-fluorophenyl)-2-methyl-N-[1-(2phenylethyl)piperidin-4-yl)propanamide (4-fluoroisobutyrylfentanyl) to control measures.

PROPOSED ACT: Council Implementing Decision.

ROLE OF THE EUROPEAN PARLIAMENT: the Council adopts the act after consulting the European Parliament but without being obliged to follow the opinion of the European Parliament.

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A **risk assessment report** on the new psychoactive substance was drawn up by the Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), and was subsequently submitted to the Commission on 14 November 2017.

The main conclusions of the report are as follows:

- 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 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;
- 4-fluoroisobutyrylfentanyl has been available in the 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 4fluoroisobutyrylfentanyl was confirmed. No acute intoxications with confirmed exposure to 4-fluoroisobutyrylfentanyl were reported. 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.

This substance has been detected in heroin samples, the involvement of organised crime cannot be excluded. 4-fluoroisobutyrylfentanyl has no recognised human or veterinary medical use in the Union.

The risk assessment report reveals that many of the questions related to 4fluoroisobutyrylfentanyl could be answered through further research. However, the available evidence and information on the **health and social risks** that the substance poses provides sufficient ground for subjecting 4fluoroisobutyrylfentanyl to control measures across the Union.

CONTENT: the purpose 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 1971 United Nations Single Convention on Narcotic Drugs.

Currently 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.

The United Kingdom shall not take part in the adoption of this Decision.

Subjecting the new psychoactive substance N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl)propanamide (4-fluoroisobutyrylfentanyl) to control measures

2017/0339(NLE) - 02/02/2018 - Legislative proposal

PURPOSE: to subject the new psychoactive substance N-(4-fluorophenyl)-2-methyl-N-[1-(2phenylethyl)piperidin-4-yl)propanamide (4-fluoroisobutyrylfentanyl) to control measures.

PROPOSED ACT: Council Implementing Decision.

ROLE OF THE EUROPEAN PARLIAMENT: the Council adopts the act after consulting the European Parliament but without being obliged to follow its opinion.

BACKGROUND : the risk assessment report on **4-fluoroisobutyrylfentanyl** prepared by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and sent to the Commission and the Council on 14 November 2017 concludes that this substance - available in the Union since at least August 2014 and detected in 4 Member States - 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.

The substance appears to be sold online in small and wholesale amounts, as a so-called research chemical or as a legal replacement to illicit opioids, in powder form, in liquid form for example in ready-to-use nasal sprays, and in blotter form. It has no recognised human or veterinary medical use in the Union.

One Member State has reported **16 deaths** where exposure to 4-fluoroisobutyrylfentanyl was confirmed. No acute intoxications with confirmed exposure to the substance were reported.

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.

CONTENT: the draft Council decision aims to **subject the new psychoactive substance 4-fluoroisobutyrylfentanyl to the control measures** and criminal penalties provided for by Member States legislation, in accordance with their obligations under the United Nations Single Convention on Narcotic Drugs of 1971.

For more details, see the summary of the Commission's initial legislative proposal dated 18.12.2017.