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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject:	Draft COUNCIL IMPLEMENTING DECISION on subjecting the new psychoactive substance methyl 1-(2-phenylethyl)-4-[phenyl(propanoyl)amino]piperidine-4-carboxylate (carfentanil) to control measures

DRAFT

COUNCIL IMPLEMENTING DECISION (EU) 2018/…

of …

on subjecting the new psychoactive substance methyl 1-(2-phenylethyl)-4-[phenyl(propanoyl)amino]piperidine-4-carboxylate (carfentanil) 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 substances[1], and in particular Article 8(3) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament[2],

[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 methyl 1-(2-phenylethyl)-4-[phenyl(propanoyl)amino]piperidine-4-carboxylate ('carfentanil') was drawn up by a special session of the extended Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and was submitted to the Commission and to the Council on 14 November 2017.

(2) Carfentanil is a synthetic opioid and is closely related to fentanyl, which is a controlled substance widely used in medicine as an adjunct to general anaesthesia during surgery and for pain management. Carfentanil is one of the most potent narcotic opioid analgesics.

(3) Carfentanil was formally notified to the EMCDDA in February 2013 based on a first detection in December 2012. In the past two years there has been an increase in the availability of the substance as well as in the seizures by law enforcement. In general, cases of detection are likely to be underreported since carfentanil is not routinely screened for. More than 800 seizures were reported by seven Member States, more than a fourth of it in the first half of 2017. Typically, carfentanil was seized as a powder. In some cases, it has also been seized in liquid form. 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) Seven Member States have reported 60 deaths which occurred between November 2016 and June 2017 and where exposure to carfentanil was confirmed. Many of those deaths involved high-risk drug users, including heroin injectors. Other drugs, including morphine and other fentanils, were also detected in many of the cases. In the case of at least six deaths, carfentanil was either the cause of death or was likely to have contributed to the death. In many of the remaining cases, the investigation into the cause of death is ongoing. In addition, two Member States have reported three cases of acute non-fatal intoxication associated with carfentanil. Both non-fatal intoxications and deaths caused by carfentanil are likely to be underdetected and underreported as carfentanil is not routinely screened for. Accidental exposure to carfentanil 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 limited information on the involvement of organised crime or established criminal groups in the manufacture, distribution, trafficking and supply of carfentanil. In this respect, one Member State reported that almost all trafficking and distribution of fentanils, including carfentanil, are linked with organised crime groups in that Member State. The available data suggest that carfentanil is produced by chemical companies in China and Hong Kong. Data also demonstrate that it is possible that the capability to manufacture fentanils also exists within the Union.

(6) Carfentanil is sold typically in powder form. It is sold online, both on the surface web and on the darknet, in small and wholesale amounts, as a drug in its own right, but also as a so-called research chemical, pharmaceutical intermediate or as a so-called legal replacement to illicit opioids. Information from reported seizures and deaths show that carfentanil is being mixed with heroin, fentanyl and other fentanils, is sold on the illicit opioid market and is injected by opioid users, including heroin injectors. It is highly unlikely that users are aware that they are using carfentanil.

(7) Carfentanil is authorised as a veterinary medicine in the United States for the immobilisation of large animals. It is possible that carfentanil may have limited use in veterinary medicine in the Union based on a medicinal product that is prepared extemporaneously in accordance with national legislation. A radiolabelled form of carfentanil is widely used in scientific research. Carfentanil is also used as an analytical reference standard and in scientific research.

(8) The risk assessment report reveals that many of the questions related to carfentanil 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, provides sufficient grounds for subjecting carfentanil to control measures across the Union.

(9) Carfentanil 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. Carfentanil 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 carfentanil to control measures.

(10) Given that 12 Member States control carfentanil under national drug control legislation and four Member States control carfentanil under other legislation, subjecting carfentanil 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 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 carfentanil 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
methyl 1-(2-phenylethyl)-4-[phenyl(propanoyl)amino]piperidine-4-carboxylate ('carfentanil') 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 carfentanil 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