II

(Non-legislative acts)

DIRECTIVES

COMMISSION DELEGATED DIRECTIVE (EU) 2021/802

of 12 March 2021

amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of the new psychoactive substances methyl 3,3-dimethyl-2-{[1-(pent-4-en-1-yl)-1*H*-indazole-3-carbonyl] amino}butanoate (MDMB-4en-PINACA) and methyl 2-{[1-(4-fluorobutyl)-1*H*-indole-3-carbonyl] amino}-3,3-dimethylbutanoate (4F-MDMB-BICA) in the definition of 'drug'

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking ([1]), and in particular Articles 1a(1) thereof,

Whereas:

(1) Risk assessment reports on the new psychoactive substances methyl 3,3-dimethyl-2-{[1-(pent-4-en-1-yl)-1*H*-indazole-3-carbonyl]amino}butanoate (MDMB-4en-PINACA) and methyl 2-{[1-(4-fluorobutyl)-1*H*-indole-3-carbonyl]amino}-3,3-dimethylbutanoate (4F-MDMB-BICA) were drawn up in compliance with Article 5c of Regulation (EC) No 1920/2006 of the European Parliament and of the Council ([2]) by the Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction extended following the procedure laid down in Article 5c(4) of the same Regulation. The Centre submitted the risk assessment reports to the Commission and to the Member States on 9 December 2020.

(2) MDMB-4en-PINACA and 4F-MDMB-BICA are synthetic cannabinoid receptor agonists (synthetic cannabinoids). They show similar effects to tetrahydrocannabinol (THC), which is responsible for the major psychoactive effects of cannabis, but with additional life-threatening toxicity. The high potency of the two substances constitutes a high risk of poisoning.

(3) MDMB-4en-PINACA has been available in the Union since at least 2017 and has been detected in 20 Member States, with a large increase in the number of Member States identifying the substance for the first time in 2019. In 2020 there was a large increase in the quantity of MDMB-4en-PINACA seized by customs. 389 seizures in total were reported by 20 Member States ([3]). In addition, six Member States reported 15 collected samples and one Member State reported 28 biological samples. MDMB-4en-PINACA in general is likely to be under-detected since the substance is not routinely screened for in some laboratories. In most cases, the substance was seized as powder and in smoking mixtures, but it was also identified as impregnated paper, including blotters, in liquid form and in other non-specified forms.

(4) Twelve deaths were reported by two Member States that are associated with MDMB-4en-PINACA. Both intoxications and deaths are likely to be under-detected and under-reported as they are not routinely screened for in some laboratories.

([1]) OJ L 335, 11.11.2004, p. 8.

([2]) Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction (OJ L 376, 27.12.2006, p. 1).

([3]) In addition, the United Kingdom reported 380 seizures, Norway 1 seizure and Turkey 663 seizures.

(5) 4F-MDMB-BICA has been available in the Union since at least March 2020 and has been detected in eleven Member States. 94 seizures in total were reported by eleven Member States ([4]). In addition, one Member State reported a collected sample and one Member State 126 biological samples. 4F-MDMB-BICA in general is likely to be under-detected since the substance is not routinely screened for due to its novelty on the market. In most cases, the substance was seized as powder, in smoking mixtures and as blotters, but it was also identified in liquid form and in other non-specified forms.

(6) Twenty-one deaths were reported in one Member State between May and August 2020 that are associated with 4F-MDMB-BICA. Both intoxications and deaths are likely to be under-detected and under-reported as they are not routinely screened for and as the substance appeared very recently on the Union market.

(7) MDMB-4en-PINACA and 4F-MDMB-BICA appear to be sold online in small and wholesale amounts as a 'legal' replacement for cannabis and controlled synthetic cannabinoids, mainly as a finished consumer product, such as in smoking mixtures, e-liquids or impregnated on paper.

(8) There is no direct evidence showing the involvement of organised crime in the manufacture, distribution (trafficking) and supply of MDMB-4en-PINACA and 4F-MDMB-BICA within the Union.

(9) MDMB-4en-PINACA and 4F-MDMB-BICA have no recognised human or veterinary medical use in the Union nor, it appears, elsewhere. There are no indications that the substances may be used for any other purpose aside from as an analytical reference standard and in scientific research.

(10) The risk assessment reports reveal that many of the questions related to MDMB-4en-PINACA and 4F-MDMB-BICA 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. The available information would suggest that the consumption of MDMB-4en-PINACA and 4F-MDMB-BICA causes harm to health associated with their acute toxicity and abuse liability or dependence producing potential. This harm to health is considered life-threatening. There is no specific information on the social risks posed by MDMB-4-en-PINACA and 4F-MDMB-BICA. Therefore, there is sufficient ground for including MDMB-4en-PINACA and 4F-MDMB-BICA in the definition of 'drug'.

(11) MDMB-4en-PINACA and 4F-MDMB-BICA are not listed for control under the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or under the 1971 United Nations Convention on Psychotropic Substances. 4F-MDMB-BICA is not currently under assessment by the United Nations system, whereas MDMB-4en-PINACA has been recommended for scheduling under the United Nations system as well. However, there is sufficient evidence for the urgency to add this substance in the definition of 'drug' also under EU law.

(12) Nine Member States control MDMB-4en-PINACA under national drug control legislation, four Member States control it under new psychoactive substances legislation and one Member State controls it under other legislation. Seven Member States control 4F-MDMB-BICA under national drug control legislation and four Member States control it under new psychoactive substances legislation and one Member State controls it under other legislation. Given that these national control measures are already in place, including MDMB-4en-PINACA and 4F-MDMB-BICA in the definition of 'drug' and thereby covering them by provisions on the criminal offences and sanctions as defined in Framework Decision 2004/757/JHA would help avoiding the emergence of obstacles in cross-border law enforcement and judicial cooperation, and would help protecting from the risks that their availability and use can pose.

(13) As the conditions and procedure for triggering the exercise of the powers to adopt a delegated act have been met, a delegated directive should be adopted in order to include MDMB-4en-PINACA and 4F-MDMB-BICA in the Annex to Framework Decision 2004/757/JHA and, as a consequence thereof, subject those substances to the Union criminal law provisions on illicit drug trafficking.

(14) Ireland is bound by Framework Decision 2004/757/JHA, as amended by Directive (EU) 2017/2103 of the European Parliament and of the Council ([5]), and is therefore taking part in the adoption and application of this Decision.

(15) Denmark is bound by Framework Decision 2004/757/JHA as applicable until 21 November 2018, but is not bound by Directive (EU) 2017/2103. It is therefore not taking part in the adoption and application of this Directive and is not bound by it or subject to its application.

([4]) In addition, the United Kingdom reported 17 seizures.

([5]) Directive (EU) 2017/2103 of the European Parliament and of the Council of 15 November 2017 amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of 'drug' and repealing Council Decision 2005/387/JHA (OJ L 305, 21.11.2017, p. 12).

(16) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents ([6]), Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.

(17) Framework Decision 2004/757/JHA should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Amendment to Framework Decision 2004/757/JHA

In the Annex to Framework Decision 2004/757/JHA, new points 18 and 19 are added as follows:

'18. Methyl 3,3-dimethyl-2-{[1-(pent-4-en-1-yl)-1*H*-indazole-3-carbonyl]amino}butanoate (MDMB-4en-PINACA) *.

19. Methyl 2-{[1-(4-fluorobutyl)-1*H*-indole-3-carbonyl]amino}-3,3-dimethylbutanoate (4F-MDMB-BICA) *.

* Commission Delegated Directive (EU) 2021/802 of 12 March 2021 amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of the new psychoactive substances methyl 3,3-dimethyl-2-{[1-(pent-4-en-1-yl)-1*H*-indazole-3-carbonyl]amino}butanoate (MDMB-4en-PINACA) and methyl 2-{[1-(4-fluorobutyl)-1*H*-indole-3-carbonyl]amino}-3,3-dimethylbutanoate (4F-MDMB-BICA) in the definition of 'drug' (OJ L 178, 20.05.2021, p. 1).'

Article 2

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 9 December 2021 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States in accordance with the Treaties.

Done at Brussels, 12 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

([6]) OJ C 369, 17.12.2011, p. 14.