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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2020) 5897 final
Subject:	COMMISSION DELEGATED DIRECTIVE (EU) .../… of 2.9.2020 amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of the new psychoactive substance *N*,*N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine (isotonitazene) in the definition of 'drug'

Delegations will find attached document C(2020) 5897 final.

Encl.: C(2020) 5897 final

EUROPEAN
COMMISSION

Brussels, 2.9.2020
C(2020) 5897 final

COMMISSION DELEGATED DIRECTIVE (EU) .../…

of 2.9.2020

amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of the new psychoactive substance *N*,*N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine (isotonitazene) in the definition of 'drug'

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Council Framework Decision 2004/757/JHA laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking[1] and Regulation (EC) 1920/2006 on the European Monitoring Centre for Drugs and Drug Addiction[2] provide for a three-step procedure that may lead to the inclusion of a new psychoactive substance in the definition of 'drug' and thereby covering it by the Union criminal law provisions on illicit drug trafficking.

On 3 April 2020, an initial report of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) drawn up in accordance with Article 5b of Regulation (EC) 1920/2006 was issued. On 17 April 2020, the European Commission requested in accordance with Article 5c (1) of Regulation (EC) 1920/2006 an assessment of the risks posed by the new psychoactive substance *N*,*N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine (isotonitazene).

The risks of isotonitazene were assessed by the Extended Scientific Committee of the EMCDDA, acting in compliance with the provisions of Article 5c of Regulation (EC) 1920/2006. The risk assessment report was submitted to the Commission and to the Member States on 29 May 2020 in line with the deadline set out in Article 5c(6) of Regulation (EC) 1920/2006.

The main results of the risk assessment are the following:

- Isotonitazene is a synthetic opioid analgesic[3] and is closely related to etonitazene and clonitazene, both of which are under international control under the 1961 UN Single Convention on narcotic drugs.

- Isotonitazene has been available in the European Union since at least April 2019 and has been detected in five Member States as well as in the United Kingdom[4]. Two deaths have been reported that are associated with isotonitazene.[5] No acute poisonings due to isotonitazene have been reported to the EMCDDA yet.

Pursuant to Article 1a of Council Framework Decision 2004/757/JHA, the Commission shall, without undue delay and in accordance with the criteria set out in paragraph 2 of this Article, adopt a delegated act in accordance with Article 8a amending the Annex to the Framework Decision in order to add the new psychoactive substance to it and thereby including it in the definiton of 'drug'. If within six weeks from the submission of risk assessment report, the Commission considers that it is not necessary to adopt a delegated act to include the new psychoactive substance in the definition of 'drug', it shall report to the European Parliament and the Council explaining the reasons for not doing so.

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1 OJ L 335, 11.11.2004, p. 8.
2 OJ L 376, 27.12.2006, p. 1.
3 Isotonitazene belongs to the 2-benzylbenzimidazole group of opioid analgesics.
4 The UK is still covered by the risk assessment report as the UK continues to be part of the early warning system of the EMCDDA during the transition period pursuant to the EU-UK Withdrawal Agreement.
5 Deaths have also been reported in Canada (3 cases) and the United States (18 cases).

Based on the findings of the risk assessment report, the Commission considers that there are grounds for including isotonitazene in the definition of 'drug'. According to the risk assessment report, it can be concluded that isotonitazene poses severe public health risks at Union level.

The objective of this draft delegated act is therefore to adopt a Delegated Directive in order to add isotonitazene to the Annex of Council Framework Decision 2004/757/JHA, thereby covering it by provisions on the criminal offences and sanctions as defined in the Framework Decision.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In line with paragraph 4 of the Common Understanding on Delegated Acts between the European Parliament, the Council and the European Commission, annexed to the Interinstitutional Agreement on better law-making of 19 April 2016[6], appropriate and transparent consultations, including at expert level, have been carried out in the preparation of this delegated act.

The Group of Experts on New Psychoactive Substances was consulted in written form between 2 and 23 June 2020.

As the decision about including isotonitazene in the definition of 'drug' is based on the risk assessment report of the Scientific Committee of the EMCDDA, the insertion of the substance in the Annex of the Directive is a technical act and the Commission therefore has limited discretion, the draft delegated act was not published for feedback from the public.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Article 1a of Council Framework Decision 2004/757/JHA provides for a delegated act to add substances to the Annex to Framework Decision 2004/757/JHA. The exercise of the delegation is governed by Article 8a of Council Framework Decision 2004/757/JHA.

[6] OJ L 123, 12.5.2016, p. 1.

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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[7], and in particular Articles 1a and 8a thereof,

Whereas:

(1) A risk assessment report on the new psychoactive substance *N*,*N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine (isotonitazene) was drawn up in compliance with Article 5c of Regulation (EC) 1920/2006 of the European Parliament and of the Council[8] by the Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA; the Centre), extended following the procedure laid down in Article 5c(4) of the same Regulation, on 26 May 2020. The Centre submitted the risk assessment report to the Commission and to the Member States on 29 May 2020.

(2) Isotonitazene is a synthetic opioid analgesic and is closely related to etonitazene and clonitazene, both of which are under international control under the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol.

(3) Isotonitazene has been available in the Union since at least April 2019 and has been detected in five Member States as well as in the United Kingdom. 24 seizures in total were reported by four Member States; in addition, one Member State reported a collected sample and the United Kingdom reported post-mortem biological samples. Isotonitazene 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, but it was also identified in liquid form. The detected quantities are relatively small. However, they should be seen within the context of the high potency of isotonitazene.

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7 OJ L 335, 11.11.2004, p. 8.

8 Regulation (EC) 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).

(4) Two deaths have been reported so far by Germany and the United Kingdom where isotonitazene was involved. The deaths occurred in 2019. No detailed information is available for the death case in Germany. In the case reported by the United Kingdom, several other substances were identified in the postmortem biological samples[9]. No acute intoxications with confirmed exposure to isotonitazene were reported so far. It is likely that naloxone works as an antidote to poisoning caused by isotonitazene as for other synthetic opioids. 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.

(5) There is no direct evidence showing the involvement of organised crime in the manufacture, distribution (trafficking) and supply of isotonitazene within the Union. The available information suggests that isotonitazene is produced by chemical companies based outside the Union.

(6) Isotonitazene appears to be sold online in small and wholesale amounts, mainly as a powder; it is also sold as ready to-use nasal sprays. Information from seizures suggests that isotonitazene may have also been sold on the illicit opioid market. Due to this, users may not be aware that they are using isotonitazene.

(7) Isotonitazene has no recognised human or veterinary medical use in the Union nor, it appears, elsewhere. There are no indications that the substance 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 isotonitazene 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. There is no specific information on the social risks posed by isotonitazene. However, the available evidence and information on the health risks that the substance poses, given also that the substance is relatively unknown, provides sufficient ground for including isotonitazene in the definition of 'drug'.

(9) Isotonitazene is 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. Isotonitazene is not currently under assessment by the United Nations system.

(10) Given that four Member States control isotonitazene under national drug control legislation and one Member State as well as the United Kingdom and Norway control isotonitazene under other legislation, including this substance in the definition of 'drug' and thereby covering it by provisions on the criminal offences and sanctions as defined in Framework Decision 2004/757 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) Article 1a of Framework Decision 2004/757/JHA confers the power to adopt delegated acts upon the Commission 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 amending the Annex to that Framework Decision to include those substances in the definition of 'drug'.

[9] Deaths have also been reported by Canada (three cases) and the United States (18 cases).

(12) The available information would suggest that the consumption of isotonitazene causes harm to health associated with its acute toxicity and abuse liability or dependence producing potential. This harm to health is considered life-threatening. In addition, there is a potential for severe physical and mental impairment and a significant spread of diseases, including the transmission of blood-borne viruses. These effects, including dependence, are comparable to other opioid analgesics that are under international control.

(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 isotonitazene in the Annex to Framework Decision 2004/757/JHA and, as a consequence thereof, subject that substance 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[10], 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.

(16) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents[11], 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, the following point 17 is added:

‘17. *N*,*N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine (isotonitazene).*

* Commission Delegated Directive (EU) .../… of XXX amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of the new psychoactive

[10] 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).

[11] OJ C 369, 17.12.2011, p. 14.

substance *N*,*N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine (isotonitazene) in the definition of 'drug', OJ L xxx, xx.xx.2020, p. xx.'

Article 2

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [6 months after the entry into force] 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, 2.9.2020

For the Commission
The President
Ursula VON DER LEYEN