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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	21 May 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2025) 3079 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 21.5.2025 amending Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 as regards the inclusion of the drug precursors 4-piperidone and 1-boc-4-piperidone in the list of scheduled substances

Delegations will find attached document C(2025) 3079 final.

Encl.: C(2025) 3079 final

EUROPEAN
COMMISSION

Brussels, 21.5.2025
C(2025) 3079 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 21.5.2025

amending Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 as regards the inclusion of the drug precursors 4-piperidone and 1-boc-4-piperidone in the list of scheduled substances

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Drug precursors are chemicals which may be used for the illicit manufacture of narcotic drugs or psychotropic substances. Regulation (EC) No 273/2004 of the European Parliament and of the Council[1] lays down measures for monitoring trade in drug precursors within the EU, while Council Regulation (EC) No 111/2005[2] governs trade in drug precursors between the EU and third countries.

The two Regulations jointly implement the measures envisaged by Article 12 of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 19 December 1988[3] (the '1988 UN Convention').

Drug precursors may be scheduled substances (listed in the Annexes of the two Regulations, with various legal obligations attached depending on their category - license, registration, export/import authorisation etc.). Drug precursors may also be non-scheduled substances, meaning they are not listed in the Annexes. Each Member State may adopt the measures necessary to enable its competent authorities to control and monitor suspicious transactions involving non-scheduled substances.

The Commission is empowered to adopt delegated acts to add new substances to the list of substances scheduled as drug precursors in the annexes of these Regulations. This empowerment allows to adapt the EU legislation to new trends in diversion of drug precursors, in particular substances which can be easily transformed into scheduled substances, and to follow any amendment to the tables of drug precursors in the Annex to the 1988 UN Convention.

The Commission on Narcotic Drugs of the United Nations decided at its 67th session from 18 to 23 March 2024, that two substances namely 4-piperidone and 1-boc-4-piperidone are to be added to Table I of the 1988 UN Convention.

In accordance with Article 12, paragraph 6 of the 1988 UN Convention, decisions 67/6, 67/7 shall become fully effective with respect to each Party 180 days after the date of communication of the decisions. Consequently, each Party to the Convention should be in the process of scheduling 4-piperidone and 1-boc-4-piperidone in its drug precursor legislation.

Therefore, the Commission needs to adopt a Delegated Regulation amending Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 so as to add 4-piperidone and 1-boc-4-piperidone to the annexes of these regulations.

4-Piperidone [chemical name: piperidin-4-one] and 1-boc-4-piperidone [chemical name: tert-butyl 4-oxopiperidine-1-carboxylate] are very suitable precursors for the illicit manufacture of fentanyl and a number of fentanyl analogues, several of which are included in Schedule I of the 1961 Convention, some are also included in Schedule IV of that Convention .

4-Piperidone is an early-stage precursor involved in most synthetic routes to fentanyl and some fentanyl analogues. It can be used to make NPP, ANPP, 4-AP and norfentanyl (all four are listed in Table I of the 1988 Convention).

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1 Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors, OJ L 47, 18.2.2004, p. 1.

2 Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Union and third countries in drug precursors, OJ L 22, 26.1.2005, p. 1.

3 OJ L 326, 24.11.1990, p. 57.

1-Boc-4-piperidone is a chemically protected derivative of 4-piperidone and can be used to make 1-boc-4-AP and subsequently norfentanyl (both listed in Table I of the 1988 Convention). 1-Boc-4-piperidone may also be converted back into 4-piperidone.

Norfentanyl is an immediate precursor of fentanyl and a number of fentanyl analogues.

Fentanyl and fentanyl analogues are very potent narcotic drugs, typically 10-100 times stronger than heroin. Consequently, small amounts of 4-piperidone and 1-boc-4-piperidone (kg range) are sufficient to manufacture millions of doses of endproducts (fentanyls). The high potency of the end-products has resulted not only in overdose deaths in users, but also in inadvertent exposure of law enforcement personnel and other personnel along the distribution chain (e.g. employees of courier and postal services)

The scheduling will provide national authorities with the legal means to fight effectively against their use in the illicit production of narcotic drugs.

Therefore, the Commission needs to adopt a Delegated Regulation amending Regulation (EC) No 273/2004 and Council Regulation (EC) No 111/2005 as regards the inclusion of certain drug precursors in the list of scheduled substances so as to add 4-piperidone and 1-boc-4-piperidone to the annexes of these regulations.

The Commission has discretion as regards the category in which to schedule a drug precursor.

Substances scheduled in Category 1 pose the greatest risk when diverted and usually become incorporated in full or in part into the molecule of the narcotic drug or psychotropic substance. The Regulations set out the strictest control and monitoring measures for such substances: they need to be stored in secured premises (e.g. locks, video-camera surveillance, etc.); each operator dealing with these substances needs a licence; they also require an import and export authorisation.

4-piperidone and 1-boc-4-piperidone can be easily transformed to support the production of fentanyl and its analogues. Therefore, they should be scheduled as a Category 1 substances because of the subsequent social and public health problems related to the consumption of these narcotic drugs are important. These substances should be added to the list of scheduled substances in the Regulations, to reinforce their control and monitoring.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In accordance with the Interinstitutional Agreement on Better Law-Making of 13 April 2016[4], appropriate and transparent consultations, including at expert level, have been carried out in the preparation of this delegated act. The Group of Experts on Drug Precursors has been consulted and received the proposal positevely.

The draft has been published for feedback on 'Have-your-say' portal. The draft has been notified based on Article 2(9)(2) of the Agreement on Technical Barriers to Trade. No comments have been received.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Based on Article 15 of Regulation (EC) No 273/2004 and Article 30a of Regulation (EC) No 111/2005, the Commission is empowered to adopt delegated acts in order to adapt the Annexes to new trends in diversion of drug precursors and to follow any amendment to the tables in the Annex to the United Nations Convention.

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4 OJ L 123, 12.5.2016, p. 10

Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 are closely linked. They jointly implement the measures envisaged by Article 12 of the 1988 UN Convention. Therefore, the bundling of two empowerments based on different basic legislative acts into one single delegated act is justified by the close material link between the empowerments in question.

COMMISSION DELEGATED REGULATION (EU) …/...

of 21.5.2025

amending Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 as regards the inclusion of the drug precursors 4-piperidone and 1-boc-4-piperidone in the list of scheduled substances

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors[1], and in particular Article 15 thereof,

Having regard to Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Union and third countries in drug precursors[2], and in particular Article 30a thereof,

Whereas:

(1) Regulation (EC) No 273/2004 lays down measures for monitoring trade in drug precursors within the Union, while Regulation (EC) No 111/2005 governs trade in drug precursors between the Union and third countries. Annex I to Regulation (EC) No 273/2004 and the Annex to Regulation (EC) No 111/2005 each contain a list of scheduled substances, which are subject to several harmonised control and monitoring measures provided for by those Regulations.

(2) By Decisions 67/6 and 67/7 of the Commission on Narcotic Drugs of the United Nations, taken at its sixty-seventh session from 18 to 23 March 2024, the substances 4-piperidone and 1-boc-4-piperidone have been added to Table I of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, adopted in Vienna on 19 December 1988 ('the 1988 UN Convention') and approved on behalf of the Union by Council Decision 90/611/EEC[3].

(3) The substances 4-piperidone and 1-boc-4-piperidone should consequently be included in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005.

(4) The substance 4-piperidone is an early-stage precursor involved in most synthetic routes to fentanyl and some fentanyl analogues. It can be used to make N-Phenethyl-4-piperidone (NPP), 4-Anilino-N-phenethylpiperidine (ANPP), N-Phenylpiperidin-4-amine (4-AP) and norfentanyl, which are all substances listed in Table I of the 1988 UN Convention.

[1] OJ L 47, 18.2.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/273/oj.

[2] OJ L 22, 26.1.2005, p. 1, ELI: http://data.europa.eu/eli/reg/2005/111/oj.

[3] Council Decision 90/611/EEC of 22 October 1990 concerning the conclusion, on behalf of the European Economic Community, of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (OJ L 326, 24.11.1990, p. 56, ELI: http://data.europa.eu/eli/dec/1990/611/oj).

(5) The substance 1-boc-4-piperidone is a chemically protected derivative of 4-piperidone and can be used to make tert-butyl 4-anilinopiperidine-1-carboxylate (1-boc-4-AP) and subsequently norfentanyl, which are both substances listed in Table I of the 1988 UN Convention. The substance 1-boc-4-piperidone may also be converted back into 4-piperidone.

(6) Both 4-piperidone and 1-boc-4-piperidone are very suitable precursors for the illicit manufacture of fentanyl and its analogues.

(7) Fentanyl and fentanyl analogues are very potent narcotic drugs, typically 10-100 times stronger than heroin. Consequently, small amounts of 4-piperidone and 1-boc-4-piperidone (kg range) are sufficient to manufacture millions of doses of end products (fentanyls).

(8) Therefore, 4-piperidone and 1-boc-4-piperidone should be included in the list of scheduled substances at Union level to reinforce their control and monitoring.

(9) The scheduled substances listed in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005 are divided into categories for which different measures apply, so as to achieve a proportionate balance between the level of threat posed by each specific substance and the burden on licit trade. The strictest control and monitoring measures apply to substances of Category 1.

(10) There is limited known legitimate manufacture of and trade in 4-piperidone and 1-boc-4-piperidone. The scheduling of those substances in Category 1 would consequently entail limited additional administrative burden for economic operators and for the competent authorities in the Union.

(11) Regulations (EC) No 273/2004 and (EC) No 111/2005 should therefore be amended accordingly.

(12) Regulations (EC) No 273/2004 and (EC) No 111/2005 jointly implement certain provisions of the 1988 UN Convention. In view of the close substantive link between the empowerments contained in those Regulations, it is appropriate to adopt the amendments by way of one single delegated act,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 273/2004

Annex I to Regulation (EC) No 273/2004 is amended in accordance with Annex I to this Regulation.

Article 2

Amendments to Regulation (EC) No 111/2005

The Annex to Regulation (EC) No 111/2005 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21.5.2025

For the Commission
The President
Ursula VON DER LEYEN