EUROPEAN
COMMISSION

Brussels, XXX
[…](2022) XXX draft

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

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 certain drug precursors in the list of scheduled substances

(Text with EEA relevance)

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This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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.

Since December 2013 the Commission is empowered to adopt delegated acts to add new substances to the list of scheduled substances in order to adapt 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 in the Annex to the United Nations Convention.

The Commission on Narcotic Drugs of the United Nations decided at its 65th session from 14 to 18 March 2022, that three substances, 4-AP, 1-boc-4-AP and norfentanyl 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 65/4, 65/5 and 65/6 shall become fully effective with respect to each Party 180 days after the date of communication of the decisions, which is 23 November 2022. Consequently, by this date each Party to the Convention should be in the process of scheduling 4-AP, 1-boc-4-AP and norfentanyl in its drug precursor legislation.

4-AP is a substitute chemical for N-phenethyl-4-piperidone (NPP) to synthesize 4-anilino-N phenethylpiperidine (ANPP), which itself is an immediate precursor for the manufacture of fentanyl and some of its analogues.

1-boc-4-AP is a chemically protected derivative of 4-AP, which could be converted to 4-AP, norfentanyl or a number of norfentanyl analogues.

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

NPP and ANPP are already scheduled substances in the Regulations. Fentanyl and fentanyl analogues are very potent narcotic drugs, typically 10 to 100 times stronger than heroin. Their high potency continues to result in overdose deaths in users.

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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 Community and third countries in drug precursors, OJ L 22, 26.1.2005, p. 1.

3 OJ L 326, 24.11.1990, p. 57.

National competent authorities have indicated the seizure of diethyl (phenylacetyl) propanedioate (DEPAPD) and PMK ethyl glycidate.

DEPAPD is used to produce 1-Phenyl-2-propanone (P-2-P), also known as benzyl methyl ketone (BMK). BMK is a precursor of amphetamine and methamphetamine, two of the most common drugs illicitly produced in the EU. Both have severe consequences for the human health.

PMK ethyl glycidate is a precursor of PMK, which, in its turn, is used to produce 3,4-methylenedioxymethamphetamine (MDMA), commonly known as 'ecstasy'.

BMK, as well as some of its other pre-precursors which are very similar to DEPAPD (such as methyl alpha-phenylacetoacetate (MAPA) or alpha-phenylacetoacetamide (APAA)), as well as PMK are already scheduled substances in the Regulations.

Following the strict control of the scheduled substances mentioned above, 4-AP, 1-boc-4-AP, norfentanyl, DEPAPD and PMK ethyl glycidate have been designed by criminal organisations to avoid these controls. Therefore, 4-AP, 1-boc-4-AP, norfentanyl, DEPAPD and PMK ethyl glycidate should also be scheduled at EU level to reinforce their control and monitoring. 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-AP, 1-boc-4-AP, norfentanyl, DEPAPD and PMK ethyl glycidate 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-AP, 1-boc-4-AP, norfentanyl, DEPAPD and PMK ethyl glycidate should be scheduled as a Category 1 substances because they can be easily transformed to support the production of fentanyl and its analogues (4-AP, 1-boc-4-AP, norfentanyl) or support the production of methanphetamine, amphetamine and MDMA (DEPAPD and PMK ethyl glycidate) and the subsequent social and public health problems related to the consumption of these narcotic drugs are important.

Based on the information available, 4-AP, 1-boc-4-AP, norfentanyl, DEPAPD and PMK ethyl glycidate have no known licit uses, except research. Therefore, their scheduling in Category 1 will not create significant administrative burden for economic operators and competent authorities.

The Commission Implementing Regulation (EU) 2021/1832[4] of 12 October 2021 reclassified ANPP and NPP. The corrigendum will correcct the CN Code, the name of the substance as

[4] Commission Implementing Regulation (EU) 2021/1832 of 12 October 2021 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff, OJ L 385, 29.10.2021, p. 1.

determined in the European Customs Inventory of Chemical Substances[5] and the CN designation.

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 discussed the proposal in detail during its meeting from 12 to 13 May 2022 and Member States did not oppose to schedule the additional subtstances..

The draft has been published for feedback on 'Have-your-say' portal. [add details on the contributions received, if any].

The draft has been notified based on Article 2(9)(2) of the Agreement on Technical Barriers to Trade. No comments have been received [to be changed if needed].

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.

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.

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[5] ECICS - European Customs Inventory of Chemical Substances: https://taxation-customs.ec.europa.eu/online-services/online-services-and-databases-customs/ecics-european-customs-inventory-chemical-substances_en

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(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 a number of harmonised control and monitoring measures provided for by those Regulations.

(2) By means of Decisions 65/4, 65/5 and 65/6 of the Commission on Narcotic Drugs of the United Nations, taken at its sixty-fifth session from 14 to 18 March 2022, the substances N-phenylpiperidin-4-amine (4-AP), tert-butyl 4-anilinopiperidine-1-carboxylate (1-boc-4-AP) and N-phenyl-N-(piperidin-4-yl)propanamide (norfentanyl) have been added to Table I of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances done at Vienna on 19 December 1988 and approved by Council Decision 90/611/EEC[3] ('the 1988 UN Convention').

(3) 4-AP is a substitute chemical for *N*-phenethyl-4-piperidone (NPP) to synthesize 4-anilino-*N*-phenethylpiperidine (ANPP), which itself is an immediate precursor for the manufacture of fentanyl and some of its analogues.

(4) 1-boc-4-AP is a chemically protected derivative of 4-AP, which could be converted to 4-AP, norfentanyl or a number of norfentanyl analogues.

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1 OJ L 47, 18.2.2004, p. 1.

2 OJ L 22, 26.1.2005, p. 1.

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).

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

(6) NPP and ANPP are already scheduled substances in Regulations (EC) No 273/2004 and (EC) No 111/2005. Fentanyl and fentanyl analogues are very potent narcotic drugs, typically 10 to 100 times stronger than heroin. Their high potency continues to result in overdose deaths in users.

(7) National competent authorities have indicated the seizure of diethyl (phenylacetyl) propanedioate (DEPAPD) and ethyl 3-(2H-1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (PMK ethyl glycidate).

(8) DEPAPD is used to produce 1-Phenyl-2-propanone (P-2-P), also known as benzyl methyl ketone (BMK). BMK is a precursor of amphetamine and methamphetamine, two of the most common drugs illicitly produced in the Union. Both have severe consequences for human health.

(9) PMK ethyl glycidate is a precursor of 3,4-Methylenedioxyphenylpropan-2-one (PMK), which, in turn, is used to produce 3,4-methylenedioxymethamphetamine (MDMA), commonly known as 'ecstasy'.

(10) BMK, as well as some of its other pre-precursors which are very similar to DEPAPD (such as methyl *alpha*-phenylacetoacetate (MAPA) or *alpha*-phenylacetoacetamide (APAA)), and PMK are already scheduled substances in Regulations (EC) No 273/2004 and (EC) No 111/2005.

(11) Amphetamine, methamphetamine and MDMA are some of the most common drugs illicitly produced in the Union. They have severe consequences for human health and are causing serious social and public health problems in some regions of the Union.

(12) 4-AP, 1-boc-4-AP, norfentanyl, DEPAPD and PMK ethyl glycidate have been designed by criminal organisations to avoid the strict controls of scheduled substances provided for by Regulations (EC) No 273/2004 and (EC) No 111/2005. Therefore, 4-AP, 1-boc-4-AP, norfentanyl, DEPAPD and PMK ethyl glycidate should also be scheduled at Union level to reinforce the control and monitoring of those substances.

(13) 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.

(14) 4-AP, 1-boc-4-AP and norfentanyl, should be scheduled as Category 1 substances because they can be easily transformed to support the production of fentanyl and its analogues and pose a significant threat to social and public health in the Union.

(15) DEPAPD and PMK ethyl glycidate should be scheduled as Category 1 substances because they can be easily transformed to support the production of methamphetamine, amphetamine and MDMA and pose a significant threat to social and public health in the Union.

(16) 4-AP, 1-boc-4-AP, norfentanyl, DEPAPD and PMK ethyl glycidate have no known licit production, trade or use, except for research purposes. Therefore, including those substances under Category 1 in Annex I to Regulation (EC) No 273/2004 and under Category 1 in the Annex to Regulation (EC) No 111/2005 would be an adequate response to avoid their use in the illicit manufacture of narcotic drugs and, at the same time, would not entail any significant extra administrative burden for economic operators and competent authorities in the Union.

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

(18) The Commission Implementing Regulation (EU) 2021/1832 of 12 October 2021 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff[4] reclassified ANPP and NPP. Regulations (EC) No 273/2004 and (EC) No 111/2005 should therefore be amended and corrected accordingly.

(19)

(20) Regulations (EC) No 273/2004 and (EC) No 111/2005 jointly implement the drug precursors related 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,

For the Commission
The President
Ursula VON DER LEYEN

[4] OJ L 385, 29.10.2021, p. 1.

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