

## II

*(Non-legislative acts)*

## REGULATIONS

## COMMISSION DELEGATED REGULATION (EU) 2023/196

of 25 November 2022

**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)**

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 <sup>(1)</sup>, 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 <sup>(2)</sup>, 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 <sup>(3)</sup> ('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.
- (5) Norfentanyl is an immediate precursor of fentanyl and a number of fentanyl analogues.

<sup>(1)</sup> OJ L 47, 18.2.2004, p. 1.<sup>(2)</sup> OJ L 22, 26.1.2005, p. 1.<sup>(3)</sup> 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).

- (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*-phenylacetate (MAPA) or *alpha*-phenylacetamide (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.
- (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 (\*) reclassified ANPP and NPP. Regulations (EC) No 273/2004 and (EC) No 111/2005 should therefore be amended and corrected accordingly.

(\*) OJ L 385, 29.10.2021, p. 1.

- (19) 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, 25 November 2022.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX I

In Regulation (EC) No 273/2004, in Annex I, in the table for Category 1,

- (1) the following entries are inserted in the list of substances in the appropriate place sequentially according to the CN Code:

| Substance                                                                              | CN designation (if different) | CN Code    | CAS No       |
|----------------------------------------------------------------------------------------|-------------------------------|------------|--------------|
| 'diethyl (phenylacetyl) propanedioate (DEPADP)                                         |                               | 2918 30 00 | 20320-59-6'  |
| 'ethyl 3-(2H-1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (PMK ethyl glycidate) |                               | 2932 99 00 | 28578-16-7'  |
| 'N-phenylpiperidin-4-amine (4-AP)                                                      |                               | 2933 39 99 | 23056-29-3'  |
| 'tert-butyl 4-anilinopiperidine-1-carboxylate (1-boc-4-AP)                             |                               | 2933 39 99 | 125541-22-2' |
| 'N-phenyl-N-(piperidin-4-yl) propanamide (norfentanyl)                                 |                               | 2933 39 99 | 1609-66-1'   |

- (2) for:

| Substance                               | CN designation (if different) | CN Code    | CAS No      |
|-----------------------------------------|-------------------------------|------------|-------------|
| '4-anilino-N-phenethylpiperidine (ANPP) |                               | 2933 39 99 | 21409-26-7' |
| 'N-phenethyl-4-piperidone (NPP)         |                               | 2933 39 99 | 39742-60-4' |

read:

| Substance                                    | CN designation (if different)          | CN Code    | CAS No      |
|----------------------------------------------|----------------------------------------|------------|-------------|
| 'N-phenyl-1-(2-phenylethyl)piperidin-4-amine | 4-anilino-N-phenethylpiperidine (ANPP) | 2933 36 00 | 21409-26-7' |
| '1-(2-phenylethyl)piperidin-4-one            | N-phenethyl-4-piperidone (NPP)         | 2933 37 00 | 39742-60-4' |

## ANNEX II

In Regulation (EC) No 111/2005, in the Annex, in the table for Category 1,

- (1) the following entries are inserted in the list of substances in the appropriate place sequentially according to the CN Code:

| Substance                                                                              | CN designation (if different) | CN Code    | CAS No       |
|----------------------------------------------------------------------------------------|-------------------------------|------------|--------------|
| 'diethyl (phenylacetyl) propanedioate (DEPADP)                                         |                               | 2918 30 00 | 20320-59-6'  |
| 'ethyl 3-(2H-1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (PMK ethyl glycidate) |                               | 2932 99 00 | 28578-16-7'  |
| 'N-phenylpiperidin-4-amine (4-AP)                                                      |                               | 2933 39 99 | 23056-29-3'  |
| 'tert-butyl 4-anilinopiperidine-1-carboxylate (1-boc-4-AP)                             |                               | 2933 39 99 | 125541-22-2' |
| 'N-phenyl-N-(piperidin-4-yl) propanamide (norfentanyl)                                 |                               | 2933 39 99 | 1609-66-1'   |

- (2) for:

| Substance                               | CN designation (if different) | CN Code    | CAS No      |
|-----------------------------------------|-------------------------------|------------|-------------|
| '4-anilino-N-phenethylpiperidine (ANPP) |                               | 2933 39 99 | 21409-26-7' |
| 'N-phenethyl-4-piperidone (NPP)         |                               | 2933 39 99 | 39742-60-4' |

read:

| Substance                                    | CN designation (if different)          | CN Code    | CAS No      |
|----------------------------------------------|----------------------------------------|------------|-------------|
| 'N-phenyl-1-(2-phenylethyl)piperidin-4-amine | 4-anilino-N-phenethylpiperidine (ANPP) | 2933 36 00 | 21409-26-7' |
| '1-(2-phenylethyl)piperidin-4-one            | N-phenethyl-4-piperidone (NPP)         | 2933 37 00 | 39742-60-4' |