EUROPEAN
COMMISSION

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COMMISSION DELEGATED REGULATION (EU) …/...

of 26.2.2018

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Introduction

Drug precursors are chemicals which may be used for the illicit manufacture of narcotic drugs or psychotropic substances. Regulation (EC) No 273/2004 lays down measures for monitoring trade in drug precursors within the EU, while Regulation (EC) No 111/2005 governs trade in drug precursors between the EU and third countries. Both Regulations jointly implement the obligations stemming from Article 12 of the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 (the 1988 UN Convention) in the EU.

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.

In October 2016, in the light of an epidemic of overdose deaths linked to opioids, including fentanyl-laced heroin and other forms of illicitly manufactured fentanyl and fentanyl analogues, the Government of the United States of America proposed to initiate a scheduling process for two fentanyl precursors, namely 4-anilino-*N*-phenethylpiperidine (ANPP) and *N*-phenethyl-4-piperidone (NPP), in order to add them to Table I of the 1988 UN Convention.

Subsequently, by its decisions 60/12 and 60/13, taken at its sixtieth session on 16 March 2017, the Commission on Narcotic Drugs of the United Nations decided to include, respectively, ANPP and NPP in Table I of the 1988 UN Convention. Decisions 60/12 and 60/13 shall become fully effective as of 18 October 2017. Consequently, by this date each Party to the Convention should be in the process of scheduling ANPP and NPP 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 ANPP and NPP to the annexes of these regulations.

Possibility to schedule in Category 1 or Category 2 of Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005

The Commission has discretion as to whether to add ANPP and NPP to Category 1 or Category 2 of the Regulations. Category 3 of the Regulations is not appropriate as this would mean that the obligations stemming from the UN 1988 Convention could not be met; Category 4, which only exists for Council Regulation (EC) No 111/2005, is excluded as well because this category can only include medicinal products and veterinary medicinal products containing scheduled substances.

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 (i.e. an immediate precursor). Therefore the control and monitoring measures applicable to these substances are the strictest in both Regulations. Substances in Category 2 either pose a lower risk or the amounts of these substances diverted to the illicit manufacture of drugs

represent such a small proportion of the total amounts legally traded and used in the EU that scheduling them under Category 1 would cause a disproportionate burden; hence, the corresponding control and monitoring measures are consequently somewhat less strict.

Category 1 substances need to be stored in secured premises (e.g. locks, video-camera surveillance, etc.) and each operator dealing with these substances needs a licence. For substances of Category 2 there is no obligation to store them into secured premises and the operators only need a registration. As to the control of external trade the main difference between the two categories is that substances in Category 1 require an import and export authorisation, while for Category 2 substances there is only an obligation for an export authorisation.

Legal use of ANPP and NPP in the EU

Based on information collected during the scheduling process in the 1988 UN Convention it can be concluded that there is legitimate trade and use of ANPP and NPP in the EU, but that the number of transactions and quantities involved is limited.

ANPP is produced in three Member States with an approximate average total yearly production of 187 kilograms. Only one EU Member State reported imports.

NPP is produced in two Member States with an approximate average total yearly production of 1 565 kilograms. A substantial part of this quantity is exported; intra-EU shipments to other Member States also occur. Other Member States which have no domestic production also reported imports and exports but always in very small quantities.

As for the legitimate uses of ANPP and NPP, one Member State reported an annual use of 600 to 700 kilograms of those substances for the production of fentanyl in the pharmaceutical industry; another Member State also reported the manufacture of fentanyl using NPP (in total 94 kilogrammes of fentanyl in 2015). Some other Member States reported limited amounts of legitimate use for medicinal products and research purposes. Finally another Member State reported 0.001 kilograms of use of ANPP as a reference standard.

Consumption and production of illegal fentanyl and fentanyl analogues in the EU

The European Drug Report - Trends and Developments 2017[1] of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) explains that "*In both Europe and North America, the recent emergence of highly potent new synthetic opioids, mostly fentanyl derivatives, is causing considerable concern. Since 2012, the EU Early Warning System has been receiving an increasing number of reports of these substances and of harms caused by them. These substances have been sold on online markets, and also on the illicit market. They have sometimes been sold as, or mixed with, heroin, other illicit drugs and even counterfeit medicines. Highly potent synthetic opioids present serious health risks, not only to those who use them, but also to those involved in their manufacture, as well as postal workers and law enforcement officers. With only small volumes needed to produce many thousands of doses, these substances are easy to conceal and transport. This poses a considerable challenge for drug control agencies. At the same time, they present a potentially attractive and profitable commodity for organised crime*." Although the exact total number of overdose deaths linked to illegal fentanyl and fentanyl analogues in the EU is unknown, some Member States, such as Estonia and Sweden, have reported more than 100 cases each in recent years.

[1] http://www.emcdda.europa.eu/system/files/publications/4541/TDAT17001ENN.pdf

Information on illegal fentanyl and fentanyl analogues production, also in the EU, is very scarce. According to the United Nations Office on Drugs and Crime (UNODC), two laboratories manufacturing fentanyl in the EU have been dismantled so far: one kitchen laboratory in Slovakia (2011) and one kitchen laboratory in Germany (2015). Additionally, Estonian authorities reported two seizures of NPP in 2016: in June a package arrived from China containing 10.24 kilograms and in August a package also from China containing 101.1 grams. It is likely that this substance was ordered and destined to be used for the illegal manufacture of fentanyl and its derivatives.

Impact of scheduling in Category 1 – Views of the main stakeholders

At the 20th meeting of the Group of Experts on Drug Precursors on 11 and 12 May 2017, representatives of the competent authorities of the EU Member States considered the question as to whether to schedule ANPP and NPP in the annexes of Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 on the basis of a summary document prepared by the Commission. All Member States that took the floor strongly supported the scheduling in Category 1. There was no Member State that opposed this view.

The Commission also consulted all the relevant European industry associations on this question. The European Chemical Industry Council (CEFIC) suggested to schedule in Category 1 in view of the overdose deaths related to illegal fentanyl production and as these substances are immediate precursors containing active ingredients. Moreover, the legal use of ANPP and NPP is already strictly monitored since they are almost exclusively used in the pharmaceutical industry (which needs to comply with many other requirements) and for the production of a controlled drug, namely fentanyl, for which also a strict legislative framework is in place. The additional burden on industry will therefore be limited. The European Association of Chemical Distributors (FECC) had no comments or suggestions. The European Federation of Pharmaceutical Industries and Associations (EFPIA) also had no particular views. It can thus be concluded that these federations do not oppose the scheduling in Category 1.

Conclusion - Scheduling in Category 1 of Regulation (EC) No 111/2005 and Regulation (EC) No 273/2004

In view of the following considerations:

- ANPP is an immediate precursor of fentanyl and acetyl fentanyl; NPP can either be used as a starting material for ANPP, which can subsequently be synthesized into fentanyl, or be a direct precursor to a number of fentanyl analogues; in other words, both substances can be easily converted into to the illegal narcotic drug or psychotropic substance fentanyl or fentanyl analogues;

- the misuse and abuse of fentanyl and fentanyl analogues are causing serious social and public health problems (overdose deaths) in some regions of the EU;

- there are indications that substantial illegal fentanyl manufacture on the basis of ANPP and NPP is taking place in the EU; to address this, import controls on ANPP and NPP would be legitimate;

- the legal production, trade and use of both substances is limited in the EU; consequently, scheduling in Category 1 would entail limited additional workload for economic operators and for the competent authorities in the EU;

- both substances are almost exclusively used in the pharmaceutical industry and for the production of a controlled drug which means that they are already strictly controlled (e.g. the authorisation systems of medicines, manufacturers and distributors and actors involved in Active Pharmaceutical Ingredients); this means that the additional requirements of Category 1, for instance that the substances should be stored in secured premises, will not create much additional burden;

- almost all stakeholders, in particular the competent authorities of the Member States and concerned economic operators, have a preference for scheduling ANPP and NPP in Category 1; and there are no stakeholders which oppose this proposal;

both 4-anilino-*N*-phenethylpiperidine (ANPP) and *N*-phenethyl-4-piperidone (NPP) should be scheduled in Category 1 of the Annex I to Regulation (EC) No 273/2004 and in Category 1 of the Annex to Regulation (EC) No 111/2005.

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, appropriate and transparent consultations, including at expert level, have been carried out in the preparation of this delegated act. The relevant documents have been transmitted in a timely and appropriate manner to the European Parliament and to the Council. The Group of Experts on Drug Precursors was consulted in the meeting held on 11 and 12 May 2017 and via written procedure from 14 November 2017 to 15 December 2017. Additionally, the proposal has been posted on the Better Regulation Portal of the European Commission for feedback within 4 weeks from 15 November 2017 to 13 December 2017.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Regulations 111/2005 and 273/2004 are closely linked. They jointly implement the measures envisaged by Article 12 of the 1988 UN Convention. Common implementing rules for Regulations 111/2005 and 273/2004 have been adopted through Commission Delegated Regulation (EU) 2015/1011 and Commission Implementing Regulation (EU) 2015/1013.

In the light of the above, the bundling of two different 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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(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[2], 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[3], and in particular Article 30a thereof,

Whereas:

(1) 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 60/12 and 60/13 of the Commission on Narcotic Drugs of the United Nations, taken at its sixtieth session on 16 March 2017, 4-anilino-*N*-phenethylpiperidine (ANPP) and *N*-phenethyl-4-piperidone (NPP) have been added to Table I of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 19 December 1988[4] (the '1988 UN Convention').

(3) The purpose of Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 is to implement Article 12 of the 1988 UN Convention in the Union. ANPP and NPP should consequently be added to Annex I to Regulation (EC) No 273/2004 and to the Annex to Regulation (EC) No 111/2005.

(4) The scheduled substances listed in those Annexes 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. For example, substances of category 1 need to be stored in secured premises and each operator dealing with these substances needs a licence.

(5) ANPP is an immediate precursor of fentanyl and acetyl fentanyl. NPP can either be used as a starting material for ANPP, which can subsequently be synthesised into fentanyl, or it can be a direct precursor of a number of fentanyl analogues. In other words, both substances can be easily transformed into fentanyl or fentanyl analogues.

[2] OJ L 47, 18.2.2004, p. 1.
[3] OJ L 22, 26.1.2005, p. 1.
[4] OJ L 326, 24.11.1990, p. 57.

(6) The misuse and abuse of fentanyl and fentanyl analogues are causing serious social and public health problems (in particular, a growing number of overdose deaths) in some regions of the Union. There are indications that substantial illegal fentanyl manufacture on the basis of ANPP and NPP is taking place in the Union. To address this problem, import controls on ANPP and NPP should be introduced.

(7) There is only limited lawful production, trade and use of ANPP and NPP in the Union. The scheduling of these substances in category 1 would consequently entail only a limited extra administrative burden for economic operators and competent authorities in the Union. Moreover, consultation with economic operators and Member States showed that there is a clear preference for listing both substances as category 1 substances in the Regulations.

(8) In the light of the considerations in recitals 5, 6 and 7, ANPP and NPP should be scheduled as category 1 substances in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005.

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

(10) Given there is some lawful production, trade and use of ANPP and NPP in the Union, economic operators and competent authorities should be given sufficient time to adapt to the amendments made by this Regulation.

(11) Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 jointly implement certain provisions of the 1988 UN Convention. In view of the close material link between those two Regulations it is justified to adopt the amendments by way of one single delegated act,

HAS ADOPTED THIS REGULATION:

Article 1
Amendment to Regulation (EC) No 273/2004

In Annex I to Regulation (EC) No 273/2004, in the table for Category 1 scheduled substances, the following entries are inserted in the list of substances in the appropriate place sequentially according to their CN Code:

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'.

Article 2
Amendment to Regulation (EC) No 111/2005

In the Annex to Regulation (EC) No 111/2005, in the table for Category 1 scheduled substances, the following entries are inserted in the list of substances in the appropriate place sequentially according to their CN Code:

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'.

Article 3
Entry into force and application

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

It shall apply from …

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

Done at Brussels, 26.2.2018

For the Commission
The President
Jean-Claude JUNCKER