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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1310**

**[Docket No. DEA-379]**

**RIN 1117-ZA04**

**Designation of Alpha-Phenylacetonitrile (APAAN), a Precursor Chemical Used in the Illicit Manufacture of Phenylacetone, Methamphetamine, and Amphetamine, as a List I Chemical**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** The Drug Enforcement Administration (DEA) is finalizing the designation of the chemical alpha-phenylacetonitrile (APAAN) and its salts, optical isomers, and salts of optical isomers, as a list I chemical under the Controlled Substances Act (CSA). The DEA proposed control of APAAN, due to its use in clandestine laboratories to illicitly manufacture the schedule II controlled substances phenylacetone (also known as phenyl-2-propanone or P2P), methamphetamine, and amphetamine. This rulemaking finalizes, without change, the control of APAAN as a list I chemical.

This action does not establish a threshold for domestic and international transactions of APAAN. As such, all transactions involving APAAN, regardless of size, shall be regulated. In addition, chemical mixtures containing APAAN are not exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical

mixtures containing any quantity of APAAN shall be regulated pursuant to the CSA. However, manufacturers may submit an application for exemption for those mixtures that do not qualify for automatic exemption.

**DATES:** *Effective date:* [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

**SUPPLEMENTARY INFORMATION:**

**Legal Authority**

The Controlled Substances Act (CSA) gives the Attorney General the authority to specify, by regulation, chemicals as list I or list II chemicals. 21 USC 802 (34) and (35). A “list I chemical” is a chemical that is used in manufacturing a controlled substance in violation of title II of the CSA, and is important to the manufacture of the controlled substance. 21 U.S.C. 802(34). A “list II chemical” is a chemical (other than a list I chemical) that is used in manufacturing a controlled substance in violation of title II of the CSA. 21 U.S.C. 802(35). The current list of all listed chemicals is published at 21 CFR 1310.02. Pursuant to 28 CFR 0.100(b), the Attorney General has delegated his authority to designate list I and list II chemicals to the Administrator of the Drug Enforcement Administration.

In addition, the United States is a Party to the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988 Convention). When the United States receives notification that a chemical has been added to Table I or Table II of the 1988 Convention pursuant to article 12, the United States is required to take measures it deems appropriate to monitor the manufacture and distribution of that chemical within the United States and to prevent its diversion. In addition, the 1988 Convention requires the United States to take other specified measures related to that chemical, including measures related to its international trade.

### **Background**

By a letter dated April 9, 2014, the Secretary-General of the United Nations informed the United States Government that the chemical alpha-phenylacetoacetonitrile (APAAN) was added to Table I of the 1988 Convention. This letter was prompted by a March 19, 2014, decision at the 57<sup>th</sup> Session of the United Nations Commission on Narcotic Drugs (CND) to add APAAN to Table I. As a Party to the 1988 Convention, the United States is obligated, pursuant to article 12, to take measures it deems appropriate to monitor the manufacture and distribution of APAAN within the United States and to prevent its diversion. Article 12 also obligates the United States to take other specified measures related to APAAN, including measures related to its international trade. By designating APAAN, which is a primary precursor for the manufacture of phenylacetone (also known as phenyl-2-propanone (P2P) or benzyl methyl ketone), methamphetamine, and

amphetamine, as a list I chemical, the United States will fulfill its obligations under the 1988 Convention.

### **Designation of APAAN and its Salts, Optical Isomers, and Salts of Optical Isomers as a List I Chemical**

On December 12, 2016, DEA published a Notice of Proposed Rulemaking (NPRM) proposing control of APAAN, due to its use in clandestine laboratories to illicitly manufacture the schedule II controlled substances phenylacetone (also known as phenyl-2-propanone or P2P), methamphetamine, and amphetamine. 81 FR 89402. In response to the NPRM, only one comment was received. This comment was supportive of the DEA's proposed control of APAAN. As such, this rulemaking finalizes the control of APAAN as a list I chemical.

On the effective date of this final rule, handlers of APAAN shall be subject to the chemical regulatory provisions of the CSA, including 21 CFR parts 1309, 1310, 1313, and 1316. Since even a small amount of APAAN can make a significant amount of P2P, this action does not establish a threshold for domestic and import transactions of APAAN in accordance with the provisions of 21 CFR 1310.04(g). Therefore, all APAAN transactions, regardless of size, will be regulated transactions as defined in 21 CFR 1300.02(b). As such, all APAAN transactions will be subject to recordkeeping, reporting, import and export controls, and other CSA chemical regulatory requirements. In addition, each regulated bulk manufacturer shall submit manufacturing, inventory, and use data on an annual basis.

## **Chemical Mixtures of APAAN**

Under this final rulemaking, chemical mixtures containing APAAN shall not be exempt from regulatory requirements at any concentration, unless an application for exemption of a chemical mixture is submitted by an APAAN manufacturer, and the application is reviewed and accepted and the mixture exempted by the DEA under 21 CFR 1310.13. Therefore, all chemical mixtures containing any quantity of APAAN shall be subject to CSA control, unless the APAAN manufacturer is granted an exemption by the application process in accordance with 21 CFR 1310.13. This rule modifies the “Table of Concentration Limits” in 21 CFR 1310.12(c) to reflect the fact that chemical mixtures containing any amount of APAAN are subject to CSA chemical control provisions.

## **Exemption by Application Process**

The DEA has implemented an application process to exempt certain chemical mixtures from the requirements of the CSA and its implementing regulations. 21 CFR 1310.13. Manufacturers may submit an application for exemption for those mixtures that do not qualify for automatic exemption. Exemption status may be granted if the DEA determines that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance, and that the listed chemical or chemicals cannot be readily recovered. 21 CFR 1310.13(a) (1)–(2).

## **Requirements for Handling List I Chemicals**

The designation of APAAN as a list I chemical shall subject APAAN handlers (manufacturers, distributors, importers, and exporters) to all of the regulatory controls and administrative, civil, and criminal actions applicable to the manufacture, distribution, importing, and exporting of a list I chemical. Upon publication of this final rule, persons handling APAAN, including regulated chemical mixtures containing APAAN, shall be required to comply with the following list I chemical regulations:

1. *Registration.* Any person who manufactures, distributes, imports, or exports APAAN, or proposes to engage in the manufacture, distribution, importation, or exportation of APAAN, must obtain a registration pursuant to 21 U.S.C. 822, 823, 957, 958. Regulations describing registration for list I chemical handlers are set forth in 21 CFR part 1309.

Upon publication of this final rule, any person manufacturing, distributing, importing, or exporting APAAN or a chemical mixture containing APAAN will become subject to the registration requirement under the CSA. The DEA recognizes, however, that it is not possible for persons who are subject to the registration requirement to immediately complete and submit an application for registration and for the DEA to immediately issue registrations for those activities. Therefore, to allow continued legitimate commerce in APAAN, the DEA is establishing in 21 CFR 1310.09, a temporary exemption from the registration requirement for persons desiring to engage in activities with APAAN, provided that the DEA receives a properly completed application for registration or exemption of a chemical mixture on or before [INSERT DATE 30 DAYS AFTER

PUBLICATION IN THE FEDERAL REGISTER]. The temporary exemption for such persons will remain in effect until the DEA takes final action on their application for registration or application for exemption of a chemical mixture.

The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, would become effective on the effective date of this final rule. Therefore, all transactions of APAAN and chemical mixtures containing APAAN will be regulated while an application for registration or exemption is pending. This is necessary because not regulating these transactions could result in increased diversion of chemicals desirable to drug traffickers.

Additionally, the temporary exemption does not suspend applicable federal criminal laws relating to APAAN, nor does it supersede State or local laws or regulations. All handlers of APAAN must comply with applicable State and local requirements in addition to the CSA regulatory controls.

2. *Records and Reports.* Every DEA registrant must maintain records and reports with respect to APAAN pursuant to 21 U.S.C. 830 and in accordance with 21 CFR part 1310. Pursuant to 21 CFR 1310.04, a record must be made and maintained for two years after the date of a transaction involving a listed chemical, provided the transaction is a regulated transaction.

Each regulated bulk manufacturer of a listed chemical must submit manufacturing, inventory, and use data on an annual basis. 21 CFR 1310.05(d). Existing standard

industry reports containing the required information will be acceptable, provided the information is separate or readily retrievable from the report.

21 CFR 1310.05(a) requires that each regulated person shall report to the DEA any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the CSA and its corresponding regulations. Regulated persons are also required to report any proposed regulated transaction with a person whose description or other identifying characteristic the Administration has previously furnished to the regulated person; any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person; any in-transit loss in which the regulated person is the supplier; and any domestic regulated transaction in a tableting or encapsulating machine.

3. *Importation and Exportation.* All importation and exportation of APAAN must comply with 21 U.S.C. 957, 958, and 971 and be in accordance with 21 CFR part 1313.

4. *Security.* All applicants and registrants must provide effective controls against theft and diversion in accordance with 21 CFR 1309.71–1309.73.

5. *Administrative Inspection.* Places, including factories, warehouses, or other establishments and conveyances, where registrants or other regulated persons may lawfully hold, manufacture, distribute, or otherwise dispose of a list I chemical or where records relating to those activities are maintained, are controlled premises as defined in 21 U.S.C. 880(a) and 21 CFR 1316.02(c). The CSA (21 U.S.C. 880) allows for



administrative inspections of these controlled premises as provided in 21 CFR part 1316, subpart A.

6. *Liability.* Any activity involving APAAN not authorized by, or in violation of, the CSA, will be unlawful, and may subject the person to administrative, civil, and/or criminal action.

## **REGULATORY ANALYSES**

### *Executive Orders 12866 and 13563*

This final rulemaking, which adds APAAN as a list I chemical, has been developed in accordance with the principles of Executive Orders 12866 and 13563. The DEA followed the principles of these Executive Orders, even though it has been determined that this action is not a significant regulatory action.

To determine whether this action is a significant regulatory action, the DEA utilized a least cost option analysis. At the outset, the DEA determined that the primary costs of this rule would come from complying with the registration, recordkeeping, reporting, and export and import requirements set forth in the CSA. Therefore, under the least cost option, an entity would choose to discontinue the sale of APAAN if proceeds from the sale are less than the cost of complying with the rule.

The DEA has not identified any industrial uses of APAAN by domestic entities and its potential usage appears to be limited to research. Based on independent research following a 2013 United Nations Questionnaire/Survey on APAAN, the DEA identified three entities that have each imported APAAN. Two of the three entities had average

annual sales of APAAN totaling \$13 during the analysis period. The third entity had average annual sales of APAAN totaling \$1,440 during the same period. Other chemical distributors list APAAN in their chemical catalogs. However, these entities do not manufacture APAAN, instead opting to purchase APAAN from international sources to fill special orders. These entities do not stock APAAN in inventory and the vast majority had no previous sales of APAAN.

The registration fee for importers of a list I chemical is \$1,523 per year. Based on the least cost option, these three entities would choose to discontinue the sale of APAAN because complying with the rule is more costly. Thus, the annual economic impact of the rule is \$1,467 (total annual sales of APAAN from the three affected entities). Therefore, this is evidence that this rule will not have an annual effect on the economy of \$100 million or more and is not a significant regulatory action.

#### *Executive Order 13771*

Executive Order 13771, titled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017 and published in the Federal Register on February 3, 2017. 82 FR 9339. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations, to the extent permitted by law, be offset by the elimination of existing costs

associated with at least two prior regulations. The interim guidance from the Office of Management and Budget (OMB), issued on February 2, 2017, explains that for Fiscal Year 2017 the above requirements only apply to each new “significant regulatory action that imposes costs.” Because the DEA has determined that this final rulemaking is not a “significant regulatory action,” the requirements of Executive Order 13771 have not been triggered.

*Executive Order 12988*

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

*Executive Order 13132*

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

*Executive Order 13175*

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

*Regulatory Flexibility Act*

The Acting Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, has reviewed this rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this rule is to designate APAAN as a list I chemical under the CSA. No less restrictive measures (i.e., non-control or control in list II) would enable the DEA to meet its statutory obligation under the CSA and its international obligations of the 1988 Convention. The DEA estimates that this rule affects three small entities. As discussed above, the DEA compared the dollar value of APAAN sales to the cost of registration. Further, the DEA assumed that if the cost of registration is more than the dollar value of APAAN sales, then each entity would discontinue the sale of APAAN.

Two entities earned \$13 in annual sales of APAAN while the third entity earned \$1,440 in annual sales of APAAN. The cost of registration alone is \$1,523 for each entity. Therefore, the DEA anticipates that each entity will discontinue the sale of APAAN because the cost of compliance is greater than the annual sales. As a result, the annual economic impact of the rule is \$1,467.

Using 1% of annual revenue as the criteria for significant economic impact, the DEA estimates that none of the three small entities will experience a significant economic impact. The cost of the rule as a percentage of annual revenue for the three entities is, 0.00044%, 0.00036%, and 0.038%, respectively, which is less than 1% of the entities’

annual income. Therefore, the rule will not have a significant effect on a substantial number of small entities.

*Unfunded Mandates Reform Act of 1995*

On the basis of information contained in the “Regulatory Flexibility Act” section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, that this action would not result in any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA of 1995.

*Paperwork Reduction Act*

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. The DEA does not anticipate that it will receive new registration applications for the purpose of engaging in transactions involving this chemical. The transactions in this chemical of which the DEA is aware are very small, and it does not appear to the DEA that it would be economically justifiable because DEA believes there is no legitimate market for manufacturing or engaging in commercial transactions in this chemical. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not

required to respond to, a collection of information unless it displays a currently valid OMB control number.

*Congressional Review Act*

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of \$100 million or more. It will not cause a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign based companies in domestic and export markets. However, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

**List of Subjects in 21 CFR Part 1310**

Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, for the reasons set forth in the preamble, part 1310 of title 21 of the Code of Federal Regulations is amended as follows:

**PART 1310-- RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES; IMPORTATION AND EXPORTATION OF CERTAIN MACHINES**

1. The authority citation for part 1310 continues to read as follows:

**Authority:** 21 U.S.C. 802, 827(h), 830, 871(b), 890.

2. Amend § 1310.02 by redesignating paragraphs (a)(1) through (a)(30) as paragraphs (a)(2) through (a)(31), respectively, and adding a new paragraph (a)(1) to read as follows:

**§ 1310.02 Substances covered.**

\* \* \* \* \*

(a) \* \* \*

(1) Alpha-phenylacetoacetonitrile and its salts, optical isomers, and salts of optical isomers (APAAN).....8512

\* \* \* \* \*

3. Amend § 1310.04 by redesignating paragraphs (g)(1)(i) through (g)(1)(x) as paragraphs (g)(1)(ii) through (g)(1)(xi), respectively, and adding a new paragraph (g)(1)(i) to read as follows:

**§ 1310.04 Maintenance of records.**

\* \* \* \* \*

(g) \* \* \*

(1) \* \* \*

(i) Alpha-phenylacetoacetonitrile and its salts, optical isomers, and salts of optical isomers (APAAN)

\* \* \* \* \*

4. Amend § 1310.09 by adding paragraph (n) to read as follows:

**§ 1310.09 Temporary exemption from registration.**

\* \* \* \* \*

(n)(1) Each person required under sections 302 and 1007 of the Act (21 U.S.C. 822, 957) to obtain a registration to manufacture, distribute, import, or export regulated alpha-phenylacetonitrile (APAAN) and its salts, optical isomers, and salts of optical isomers, including regulated chemical mixtures pursuant to § 1310.12, is temporarily exempted from the registration requirement, provided that the DEA receives a properly completed application for registration or application for exemption for a chemical mixture containing alpha-phenylacetonitrile (APAAN) and its salts, optical isomers, and salts of optical isomers, pursuant to §1310.13 on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports or exports a chemical mixture containing alpha-phenylacetonitrile (APAAN) and its salts, optical isomers, and salts of optical isomers whose application for exemption is subsequently denied by the DEA must obtain a registration with the DEA. A temporary exemption from the registration requirement will also be provided for those persons whose applications for exemption are denied, provided that the DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that



the application for exemption has been denied. The temporary exemption for such persons will remain in effect until the DEA takes final action on their registration application.

5. Amend § 1310.12(c) by adding in alphabetical order an entry “Alpha-phenylacetoacetonitrile, and its salts, optical isomers, and salts of optical isomers.

(APAAN)” in the table “Table of Concentration Limits” to read as follows:

**§ 1310.12 Exempt chemical mixtures.**

\* \* \* \* \*

(c) \* \* \*

TABLE OF CONCENTRATION LIMITS

DEA chemical code number	Concentration	Special conditions
*****		
Alpha-phenylacetonitrile, and its salts, optical isomers, and salts of optical isomers. (APAAN).....	8512	Not exempt at any concentration. Chemical mixtures containing any amount of APAAN are not exempt.
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\* \* \* \* \*

Dated: July 10, 2017

Chuck Rosenberg,

*Acting Administrator.*

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