



Billing Code: 3510-33-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Docket No. 190215128-9128-01

RIN 0694-XC053

Impact of Proposed Additions to the “Annex on Chemicals” to the Chemical Weapons Convention (CWC) on Legitimate Commercial Chemical, Biotechnology, and Pharmaceutical Activities Involving “Schedule 1” Chemicals (including Schedule 1 Chemicals produced as Intermediates)

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of inquiry.

SUMMARY: The Bureau of Industry and Security (BIS) is seeking public comments on the impact on commercial activities of proposed additions to “Schedule 1” in the “Annex on Chemicals” to the Chemical Weapons Convention (CWC), as implemented through the Chemical Weapons Convention Implementation Act (CWCIA) and the Chemical Weapons Convention Regulations (CWCR). The purpose of this notice of inquiry is to collect information to assist BIS in assessing the likely impact on United States industry of the proposed addition of five chemical families to “Schedule 1” in the “Annex on Chemicals.”

DATES: Comments must be received by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION].

ADDRESSES: You may submit comments by any of the following methods (please refer to RIN 0694-XC053 in all comments and in the subject line of e-mail comments):

- Federal rulemaking portal (<http://www.regulations.gov>) – you can find this notice by searching on its regulations.gov docket number, which is BIS-2019-0002;
- E-mail: willard.fisher@bis.doc.gov – include the phrase “Schedule 1 Notice of Inquiry” in the subject line;
- Fax: (202) 482-3355 (Attn: Willard Fisher);
- By mail or delivery to Regulatory Policy Division, Bureau of Industry and Security, U.S. Department of Commerce, Room 2099B, 14th Street and Pennsylvania Avenue, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: For questions on the Chemical Weapons Convention requirements for “Schedule 1” chemicals, contact Douglas Brown, Treaty Compliance Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, U.S. Department of Commerce, Phone: (202) 482-2163. For questions on the submission of comments, contact Willard Fisher, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce, Phone: (202) 482-2440.

SUPPLEMENTARY INFORMATION:

Background

In providing its advice and consent to the ratification of the Convention on the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and Their Destruction, commonly called the Chemical Weapons Convention (CWC or “the Convention”), the Senate included, in Senate Resolution 75 (S. Res. 75, April 24, 1997), several conditions to its ratification. Condition 23, titled “Additions to the Annex on Chemicals,” calls for the President to submit a report to the Committee on Foreign Relations of the Senate,

detailing the likely impact of the proposed addition of a chemical or biological substance to a schedule in the “Annex on Chemicals.” This report shall include, inter alia, an assessment of the likely impact on United States industry of the proposed addition. President Trump, in his Memorandum of November 5, 2018 (83 FR 62679, December 4, 2018), delegated the authority to carry out this function to the Secretary of State, in coordination with other U.S. Government departments and agencies (including the Department of Commerce), consistent with the process described in National Security Presidential Memorandum-4 of April 4, 2017 (82 FR 16881, April 6, 2017).

The CWC is an international arms control treaty that contains certain verification provisions. In order to implement these verification provisions, the CWC established the Organization for the Prohibition of Chemical Weapons (OPCW). The CWC imposes certain obligations on countries that have ratified the Convention (i.e., States Parties), among which are the enactment of legislation to prohibit the production, storage, and use of chemical weapons, and the establishment of a National Authority to serve as the national focal point for effective liaison with the OPCW and other States Parties in order to achieve the object and purpose of the Convention and the implementation of its provisions. The CWC also requires each State Party to implement a comprehensive data declaration and inspection regime to provide transparency and to verify that both the public and private sectors of the State Party are not engaged in activities prohibited under the CWC.

“Schedule 1” chemicals consist of those toxic chemicals and precursors set forth in the CWC “Annex on Chemicals” and in SUPPLEMENT NO. 1 to PART 712 – SCHEDULE 1 CHEMICALS of the Chemical Weapons Convention Regulations (CWCR) (15 CFR parts 710-722). The CWC

identified these toxic chemicals and precursors as posing a high risk to the object and purpose of the Convention.

The CWC (Part VI of the “Verification Annex”) restricts the production of “Schedule 1” chemicals for protective purposes to two facilities per State Party: a single small-scale facility (SSSF) and a facility for production in quantities not exceeding 10 kg per year. The CWC Article-by-Article Analysis submitted to the Senate in Treaty Doc. 103-21 defined the term “protective purposes” to mean “used for determining the adequacy of defense equipment and measures.” Consistent with this definition and as authorized by Presidential Decision Directive (PDD)/NSC-70 (December 17, 1999), which specifies agency and departmental responsibilities as part of the U.S. implementation of the CWC, the Department of Defense (DOD) was assigned the responsibility to operate these two facilities. Although this assignment of responsibility to DOD per PDD/NSC-70 effectively precluded the commercial production of “Schedule 1” chemicals for protective purposes in the United States, it did not otherwise establish any limitations on “Schedule 1” chemical activities that are not prohibited by the CWC.

The provisions of the CWC that affect commercial activities involving “Schedule 1” chemicals are implemented in the CWCR (see 15 CFR 712) and in the Export Administration Regulations (EAR) (see 15 CFR 742.18 and 15 CFR 745), both of which are administered by the Bureau of Industry and Security (BIS). Pursuant to CWC requirements, the CWCR restrict commercial production of “Schedule 1” chemicals to research, medical, or pharmaceutical purposes only. The CWCR prohibit commercial production of “Schedule 1” chemicals for “protective purposes” because such production is effectively precluded per PDD/NSC-70, as described above – see 15 CFR 712.2(a). The CWCR also contain other requirements and

prohibitions that apply to “Schedule 1” chemicals and/or “Schedule 1” facilities. Specifically, the CWCR:

(1) Prohibit the import of “Schedule 1” chemicals from States not Party to the Convention (15 CFR 712.2(b));

(2) Require annual declarations by facilities engaged in the production of “Schedule 1” chemicals in excess of 100 grams aggregate per calendar year (i.e., declared “Schedule 1” facilities) for purposes not prohibited by the Convention (15 CFR 712.5(a)(1) and (a)(2));

(3) Provide for government approval of “declared Schedule 1” facilities (15 CFR 712.5(f));

(4) Provide that “declared Schedule 1” facilities are subject to initial and routine inspection by the OPCW (15 CFR 712.5(e) and 716.1(b)(1));

(5) Require 200 days advance notification of establishment of new “Schedule 1” production facilities producing greater than 100 grams aggregate of “Schedule 1” chemicals per calendar year (15 CFR 712.4);

(6) Require advance notification and annual reporting of all imports and exports of “Schedule 1” chemicals to, or from, other States Parties to the Convention (15 CFR 712.6, 742.18(a)(1) and 745.1); and

(7) Prohibit the export of “Schedule 1” chemicals to States not Party to the Convention (15 CFR 742.18(a)(1) and (b)(1)(ii)).

For purposes of the CWCR (see 15 CFR 710.1), “production of a Schedule 1 chemical” means the formation of “Schedule 1” chemicals through chemical synthesis, as well as processing to extract and isolate “Schedule 1” chemicals produced by a biochemical or biologically mediated reaction. Such production is understood, for CWCR declaration purposes, to include intermediates, by-products, or waste products that are produced and consumed within

a defined chemical manufacturing sequence, where such intermediates, by-products, or waste products are chemically stable and therefore exist for a sufficient time to make isolation from the manufacturing stream possible, but where, under normal or design operating conditions, isolation does not occur.

Proposed Addition of Five Families of Chemicals to “Schedule 1” in the CWC “Annex on Chemicals”

On October 16, 2018 the United States, Canada, and the Netherlands submitted a proposal to the OPCW Director General to add two families of chemicals to “Schedule 1” in the CWC “Annex on Chemicals.” On December 7, 2018, Russia submitted additional proposals to the Director General, which included adding three additional families to “Schedule 1.” However, the CWC States Parties have yet to reach agreement on adding the five chemical families to “Schedule 1” in the CWC “Annex on Chemicals.”

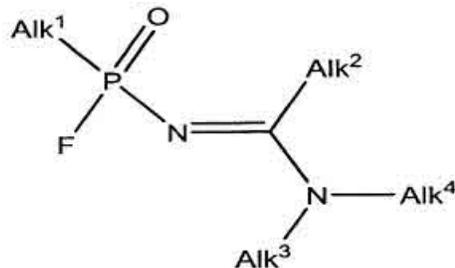
The following five “Schedule 1” chemical families are under consideration for being listed as toxic chemicals in “Schedule 1” (the addition of the first two chemical families to “Schedule 1” was proposed by the United States, Canada, and the Netherlands; the addition of the other three chemical families was proposed by Russia):

- (1) P-alkyl-N-fluorophosphonyl amidines

Generic name:

P-Alkyl (H or \leq C10, incl. cycloalkyl) *N*-(1-(dialkyl(\leq C10, incl. cycloalkyl)amino))alkylidene(H or \leq C10, incl. cycloalkyl) phosphoramidic fluorides and corresponding alkylated or protonated salts

Generic structure:



Example:

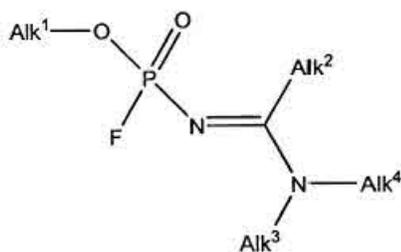
N-(1-(di-*n*-decylamino)-*n*-decylidene)-*P*-decylphosphonamidic fluoride
(No CAS Number)

(2) O-Alkyl-N-fluorophosphorylamidines

Generic name:

O-alkyl (H or \leq C10, incl. cycloalkyl) *N*-(1-(dialkyl(\leq C10, incl. cycloalkyl)amino))alkylidene(H or \leq C10, incl. cycloalkyl) phosphoramidofluoridates and corresponding alkylated or protonated salts

Generic structure:



Example:

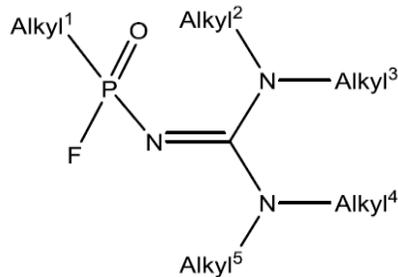
O-*n*-decyl *N*-(1-(di-*n*-decylamino)-*n*-decylidene) phosphoramidofluoridate
(No CAS Number)

3) P-alkyl-N-fluorophosphonyl guanidines

Generic name:

P-Alkyl (H or \leq C10, incl. cycloalkyl)-(bis((alkyl (H or \leq C10, incl. cycloalkyl)alkyl(H or \leq C10, incl. cycloalkyl)amino))methylene) phosphoramidofluoridates and corresponding alkylated or protonated salts

Generic structure:



Example:

Methyl-(bis(diethylamino)methylene)phosphoramidofluoridate
(No CAS Number)

4) Carbamates (quaternaries and bisquaternaries of dimethylcarbamoyloxy pyridines)

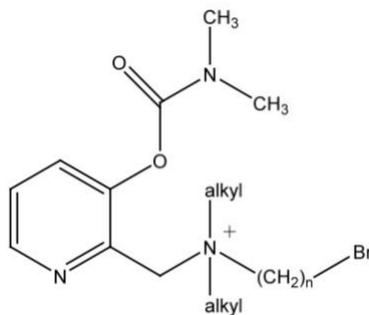
Generic names:

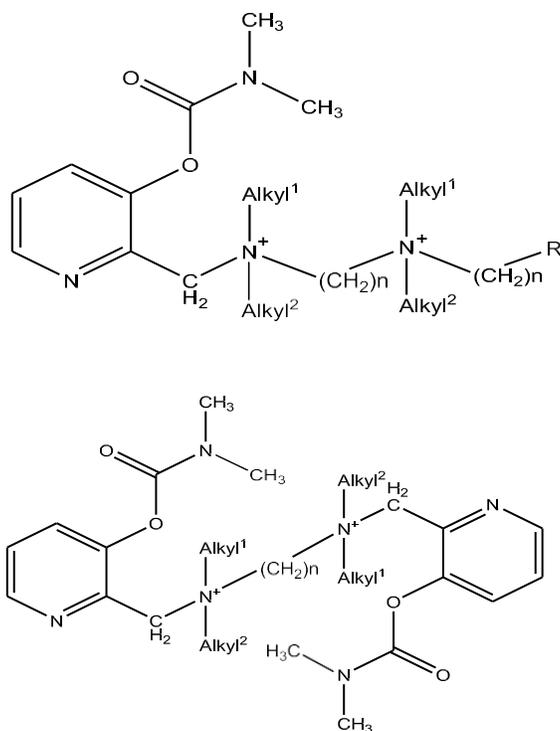
N-(n-Bromo (Alkyl)-N-(3-dimethylcarbamoy- α -picolinyl)-N,N- (C_nH_{2n-1}, n=1,2,3) ammonium bromide (n=1-10)

1-[N,N-Dialkyl(C_≤10)-N-(n-(hydroxyl, cyano, acetoxy)alkyl(C_≤10)ammonio]-n-[N-(3-methyl-carbamoy- α -picolinyl)-N,N-dialkyl(C_≤10)ammonio]decane dibromide (n=1-8)

1,n-Bis[N-(3-dimethylcarbamoy- α -picolyl)-N,N-dialkyl(C_≤10)ammonio]-alkane-(2,(n-1)-dione) dibromide (n=2-12)

Generic structures:





Examples:

N-(10-Bromodecyl)-N-(3-dimethylcarbamoyl- α -picolinyl)-N,N-dimethylammonium bromide

1-[N,N-Dimethyl-N-(2-hydroxy)ethylammonio]-10-[N-(3-dimethyl-carbamoyl- α -picolinyl)-N,N-dimethylammonio]decane dibromide
(CAS number: 77104-62-2)

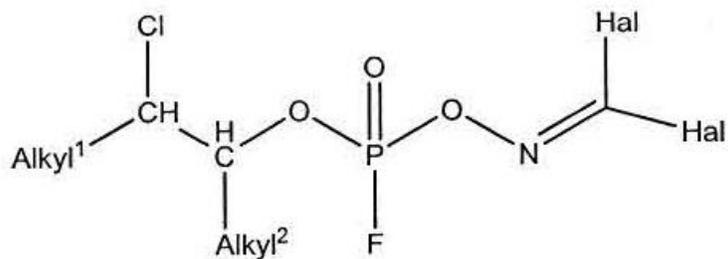
1,10-Bis[N-(3-dimethylcarbamoyl- α -picolyl)-N-ethyl-N-methylammonio]-decane-2,9-dione dibromide
(CAS number: 77104-00-8)

- 5) Fluorophosphoryl dihaloformaldoximes (also referred to as substituted ((alkylidene)amino)oxy-phosphates and phosphonates)

Generic name:

O-(1-Alkyl(H, Me)-2-alkyl(H, Me)-2-chloroethyl)-(((dihalo(F, Cl)methylene)amino)-oxy)phosphorofluoridates

Generic structure:



Examples:

2-Chloroethyl(((chloro fluoro- methylene)amino)oxy)phosphoro- fluoridate
(CAS number: 26102-97-6)

1-Chloropropan-2-yl(((chloro fluoro- methylene)amino)oxy)phosphoro- fluoridate
(CAS number: 26102-98-7)

3-Chlorobutan-2-yl(((chloro fluoro- methylene)amino)oxy)phosphoro- fluoridate
(CAS number: 26102-99-8)

Request for Comments

BIS is seeking public comments to assist in determining whether the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms in the United States would be significantly harmed by the limitations that would be imposed on access to, and production of, the compounds included in the five chemical families identified above, if the CWC States Parties were to agree to add these chemical families to “Schedule 1” in the CWC “Annex on Chemicals.” To allow BIS to properly evaluate the significance of any harm to commercial activities involving the proposed “Schedule 1” chemical families, public comments submitted in response to this notice of inquiry should include both a quantitative and qualitative assessment of the impact of the CWC on such activities.

Submission of Comments

All comments must be submitted to one of the addresses indicated in this notice.

The Department requires that all comments be submitted in written form. BIS will

consider all comments received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. All comments (including any personally identifying information or information for which a claim of confidentiality is asserted either in those comments or their transmittal e-mails) will be made available for public inspection and copying. Parties who wish to comment anonymously may do so by submitting their comments via Regulations.gov, leaving the fields that would identify the commenter blank and including no identifying information in the comment itself.

Dated: August 6, 2019.

Richard E. Ashooh

Assistant Secretary

for Export Administration

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