List of Subjects in 12 CFR Part 747

Civil monetary penalties, Credit unions.

Melane Conyers-Ausbrooks,

Secretary of the Board.

For the reasons stated in the preamble, the Board amends 12 CFR part 747 as follows:

PART 747—ADMINISTRATIVE ACTIONS, ADJUDICATIVE HEARINGS, RULES OF PRACTICE AND PROCEDURE, AND INVESTIGATIONS

■ 1. The authority for part 747 continues to read as follows:

Authority: 12 U.S.C. 1766, 1782, 1784, 1785, 1786, 1787, 1790a, 1790d; 15 U.S.C. 1639e; 42 U.S.C. 4012a; Pub. L. 101–410; Pub. L. 104–134; Pub. L. 109–351; Pub. L. 114–74.

■ 2. Revise § 747.1001 to read as follows:

§ 747.1001 Adjustment of civil monetary penalties by the rate of inflation.

(a) The NCUA is required by the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note)), to adjust the maximum amount of each civil monetary penalty (CMP) within its jurisdiction by the rate of inflation. The following chart displays those adjusted amounts, as calculated pursuant to the statute:

U.S. Code citation	CMP description	New maximum amount
(1) 12 U.S.C. 1782(a)(3)	Inadvertent failure to submit a report or the inadvertent submission of a false or misleading report.	$4,146.
(2) 12 U.S.C. 1782(a)(3)	Non-inadvertent failure to submit a report or the non-inadvertent submission of a false or misleading report.	$41,463.
(3) 12 U.S.C. 1782(a)(3)	Failure to submit a report or the submission of a false or misleading report done knowingly or with reckless disregard.	$2,073,133 or 1 percent of the total assets of the credit union, whichever is less.
(4) 12 U.S.C. 1782(d)(2)(A)	Tier 1 CMP for inadvertent failure to submit certified statement of insured shares and charges due to the National Credit Union Share Insurance Fund (NCUSIF), or inadvertent submission of false or misleading statement.	$3,791.
(5) 12 U.S.C. 1782(d)(2)(B)	Tier 2 CMP for non-inadvertent failure to submit certified statement or submission of false or misleading statement.	$37,901.
(6) 12 U.S.C. 1782(d)(2)(C)	Tier 3 CMP for failure to submit a certified statement or the submission of a false or misleading statement done knowingly or with reckless disregard.	$1,895,095 or 1 percent of the total assets of the credit union, whichever is less.
(7) 12 U.S.C. 1785(a)(3)	Non-compliance with insurance logo requirements	$129.
(8) 12 U.S.C. 1785(e)(3)	Non-compliance with NCUA security requirements	$301.
(9) 12 U.S.C. 1786(k)(2)(A)	Tier 1 CMP for violations of law, regulation, and other orders or agreements.	$10,366.
(10) 12 U.S.C. 1786(k)(2)(B)	Tier 2 CMP for violations of law, regulation, and other orders or agreements and for recklessly engaging in unsafe or unsound practices or breaches of fiduciary duty.	$51,827.
(11) 12 U.S.C. 1786(k)(2)(C)	Tier 3 CMP for knowingly committing the violations under Tier 1 or 2 (natural person).	$2,073,133.
(12) 12 U.S.C. 1786(k)(2)(C)	Tier 3 CMP for knowingly committing the violations under Tier 1 or 2 (insured credit union).	$2,073,133 or 1 percent of the total assets of the credit union, whichever is less.
(13) 12 U.S.C. 1786(w)(5)(A)(ii)	Non-compliance with senior examiner post-employment restrictions	$341,000.
(14) 15 U.S.C. 1639e(k)	Non-compliance with appraisal independence requirements	First violation: $11,906. Subsequent violations: $23,811.
(15) 42 U.S.C. 4012a(f)(5)	Non-compliance with flood insurance requirements	$2,252.

(b) The adjusted amounts displayed in paragraph (a) of this section apply to civil monetary penalties that are assessed after the date the increase takes effect, including those whose associated violation or violations pre-dated the increase and occurred on or after November 2, 2015.

[FR Doc. 2020–29181 Filed 1–6–21; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 710, 712, and 745

[Docket No. 201211–0336]

RIN 0694–AH94

Chemical Weapons Convention Regulations and the Export Administration Regulations: Additions to Schedule 1(A) of the Annex on Chemicals to the Chemical Weapons Convention

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) is publishing this final rule to amend the Chemical Weapons Convention Regulations (CWCR) and the Export Administration Regulations (EAR) to reflect recent additions to Schedule 1(A) of the Annex on Chemicals to the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, also known as the Chemical Weapons Convention (CWC). This final rule also amends the definition of ''production'' in the CWCR to clarify the scope of this term as it applies to declarations regarding the production of ''Schedule 1,'' ''Schedule 2,'' or ''Schedule 3'' chemicals.

DATES: This rule is effective January 7, 2021.

FOR FURTHER INFORMATION CONTACT: For questions on the CWCR requirements for ''Schedule 1'' chemicals, contact Erica Sunyog, Treaty Compliance Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, U.S. Department of Commerce, Phone: (202) 482–6237.

SUPPLEMENTARY INFORMATION:

Background

The Chemical Weapons Convention (hereinafter, ''CWC'' or ''Convention''), which entered into force on April 29, 1997, is an international arms control treaty whose object and purpose is to eliminate an entire category of weapons of mass destruction by prohibiting the development, production, acquisition, stockpiling, retention, transfer or use of chemical weapons by States Parties. The CWC States Parties have agreed to destroy any stockpiles of chemical weapons they may hold and any facilities that produced them, as well as any chemical weapons they have abandoned on the territory of other States Parties. The CWC States Parties also have agreed to implement a comprehensive data declaration, notification, and inspection regime for those toxic chemicals and their precursors listed in Schedule 1, 2 or 3 in the CWC Annex on Chemicals to provide transparency and to verify that their public and private sectors are not engaged in activities prohibited under the CWC.

In addition, each State Party has agreed to adopt domestic legislation to implement its obligations under the Convention and to designate or establish a National Authority to serve as the national focal point for effective liaison with the Organization for the Prohibition of Chemical Weapons (OPCW) and other States Parties. The designated U.S. National Authority is the Bureau of Arms Control, Verification and Compliance, U.S. Department of State. The OPCW was established by the States Parties to achieve the object and purpose of the Convention, to ensure the implementation of its provisions (including those pertaining to international verification of compliance), and to provide a forum for consultation and cooperation among the States Parties. All CWC States Parties are members of the OPCW, which includes the Conference of the States Parties, the Executive Council, and the Technical Secretariat.

The provisions of the CWC that affect commercial activities involving scheduled chemicals (including ''Schedule 1'' chemicals) are implemented, pursuant to the Chemical Weapons Convention Implementation Act of 1998 (CWCIA) (22 U.S.C. 6701 *et seq.*) and Executive Order 13128 (64 FR 34703, June 28, 1999), by the Chemical Weapons Convention Regulations (CWCR) (see 15 CFR parts 710–722) and the Export Administration Regulations (EAR) (see 15 CFR 742.18 and 15 CFR part 745), both of which are administered by the Bureau of Industry and Security (BIS). Specifically, BIS maintains the list of ''Schedule 1'' chemicals identified in the CWC Annex on Chemicals in Supplement No. 1 to part 712 of the CWCR and as part of Supplement No. 1 to part 745 of the EAR. BIS also administers the CWC ''Schedule 1'' chemical declaration, reporting, notification, and verification requirements that are described in part 712 of the CWCR. In addition, § 745.1 of the EAR describes the advance notification and annual report requirements that apply to exports of ''Schedule 1'' chemicals.

The CWC identifies the toxic chemicals and immediate precursors listed under ''Schedule 1'' in the CWC Annex on Chemicals as posing a high risk to the object and purpose of the Convention. Consistent with Part VI of the CWC Verification Annex, the CWCR restrict commercial production of ''Schedule 1'' chemicals to research, medical, or pharmaceutical purposes only. See 15 CFR 710.1, at definition of *Purposes not prohibited by the CWC,* and 15 CFR 710.2(b), *Activities subject to the CWCR.* The CWCR prohibit commercial production of ''Schedule 1'' chemicals for ''protective purposes'' (see 15 CFR 712.2(a)) consistent with Presidential Decision Directive (PDD) 70 (December 17, 1999), which effectively limits production for such purposes to facilities operated by the Department of Defense. These CWCR restrictions and prohibitions apply to all persons and facilities located in the United States, except certain U.S. Government facilities—see 15 CFR 710.2(a). In addition to these general requirements and prohibitions pertaining to ''Schedule 1'' chemicals, the CWCR:

(1) Prohibit the import of ''Schedule 1'' chemicals from States not Party to the CWC (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 CWC (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 to the Technical Secretariat of the OPCW of all imports and exports of ''Schedule 1'' chemicals to, or from, other States Parties to the CWC (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 CWC (15 CFR 742.18(a)(1) and (b)(1)(ii)).

This final rule amends part 712 of the CWCR and part 745 of the EAR to reflect recent additions to Schedule 1(A) of the CWC Annex on Chemicals, as described below. In addition, this rule amends the definition of ''production'' in part 710 of the CWCR to clarify the scope of this term as it applies to declarations regarding the production of ''Schedule 1,'' ''Schedule 2,'' or ''Schedule 3'' chemicals.

This rule amends part 712 of the CWCR and part 745 of the EAR to add three ''Schedule 1'' chemical families and one individual ''Schedule 1'' chemical to both sets of regulations, consistent with two decisions adopted by the States Parties to the CWC during the OPCW's 24th Conference of the States Parties, held in The Hague, the Netherlands, from November 25–29, 2019. Based on two separate proposals submitted to the Director-General of the OPCW, one by the United States, Canada and the Netherlands, and the other by the Russian Federation, these decisions added three chemical families and one individual chemical to ''Schedule 1'' in the CWC Annex on Chemicals. The OPCW agreements are documented in OPCW Decisions C–24/DEC.4 and C–24/DEC.5 and may be obtained from the OPCW website (*http://www.opcw.org*). On December 10, 2019, the Director-General notified all States Parties and the Depositary of the CWC (*i.e.,* the Secretary-General of the United Nations) of the adoption of these decisions by the Conference of the States Parties. Pursuant to subparagraph 5(g) of Article XV of the CWC, these changes to the Annex on Chemicals entered into force for all States Parties 180 days after the date of this notification, that is, on June 7, 2020.

The additions to ''Schedule 1'' of the CWC Annex on Chemicals are as follows:

Schedule 1

A. Toxic chemicals:

(1) P-alkyl (H or ≤C_{10}, incl. cycloalkyl) N-(1-(dialkyl(≤C_{10}, incl. cycloalkyl)amino))alkylidene(H or ≤C_{10}, incl. cycloalkyl) phosphonamidic fluorides and corresponding alkylated or protonated salts

e.g. N-(1-(di-n-decylamino)-n-decylidene)-P-decylphosphonamidic fluoride (CAS No. 2387495–99–8)

Methyl-(1-(diethylamino)ethylidene) phosphonamidofluoridate (CAS No. 2387496–12–8)

(2) O-alkyl (H or ≤C_{10}, incl. cycloalkyl) N-(1-(dialkyl(≤C_{10}, incl. cycloalkyl)amino))alkylidene(H or ≤C_{10}, incl. cycloalkyl) phosphoramidofluoridates and corresponding alkylated or protonated salts

e.g. O-n-Decyl N-(1-(di-n-decylamino)-n-decylidene)phosphoramidofluoridate (CAS No. 2387496–00–4)

Methyl (1-(diethylamino)ethylidene) phosphoramidofluoridate (CAS No. 2387496–04–8)

Ethyl (1-(diethylamino)ethylidene) phosphoramidofluoridate (CAS No. 2387496–06–0)

(3) Methyl-(bis(diethylamino)methylene) phosphonamidofluoridate (CAS No. 2387496–14–0)

(4) Carbamates (quaternaries and bisquaternaries of dimethylcarbamoyloxypyridines)

Quaternaries of dimethylcarbamoyloxypyridines:

1-[N,N-dialkyl(≤C_{10})-N-(n-(hydroxyl, cyano, acetoxy)alkyl(≤C_{10})) ammonio]-n-[N-(3-dimethylcarbamoxy-α-picolinyl)-N,N-dialkyl(≤C_{10}) ammonio]decane dibromide (n=1–8)

e.g. 1-[N,N-dimethyl-N-(2-hydroxy)ethylammonio]-10-[N-(3-dimethylcarbamoxy-α-picolinyl)-N,N-dimethylammonio]decane dibromide (CAS No. 77104–62–2)

Bisquaternaries of dimethylcarbamoyloxypyridines:

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

e.g. 1,10-Bis[N-(3-dimethylcarbamoxy-α-picolyl)-N-ethyl-N-methylammonio]decane-2,9-dione dibromide (CAS No. 77104–00–8).

Notice of Inquiry on the Impact of Proposed Additions to CWC ''Schedule 1''

Pursuant to Condition 23 to Senate Resolution 75 (S. Res. 75, April 24, 1997), and as delegated from the President, the Secretary of State, in coordination with other U.S. Government departments and agencies, including the Department of Commerce, must submit a report to the Senate Committee on Foreign Relations detailing, *inter alia,* the likely impact on United States industry of the proposed addition of a chemical or biological substance to a schedule in the CWC Annex on Chemicals. Consistent with Condition 23, on August 14, 2019, BIS published a notice of inquiry (84 FR 40389) that requested public comments as to 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 certain chemical families that had been proposed for addition to ''Schedule 1'' in the CWC Annex on Chemicals.

BIS did not receive any public comments in response to this notice of inquiry. Of the chemical families at issue, three families of chemicals and one individual chemical from a fourth family, as described above, were added to ''Schedule 1'' by the decisions adopted at the Conference of the States Parties in November 2019. These additions to ''Schedule 1'' are reflected in the amendments to the CWCR and the EAR described below.

Amendments to Supplement No. 1 to Part 712 of the CWCR (Schedule 1 Chemicals)

Supplement No. 1 to part 712 of the CWCR identifies ''Schedule 1'' chemicals listed in the CWC Annex on Chemicals. This rule amends Supplement No. 1 to: (1) Include the three chemical families and one individual chemical that were added to ''Schedule 1;'' and (2) add a Note 3 following the list of chemicals to explain that the numerical sequence of the ''Schedule 1'' Toxic Chemicals and Precursors specified therein is not consecutive so as to align with the December 23, 2019, consolidated textual changes to the Annex on Chemicals, which reflect the decisions adopted by the CWC Conference of the States Parties in November 2019. Specifically, the chemicals listed in ''Schedule 1(A),'' Toxic Chemicals, are numbered 1–8 and 13–16 (the latter includes 16.1 and 16.2), while the chemicals listed in ''Schedule 1(B),'' Precursors, are numbered 9–12.

This rule does not amend any of the declaration, advance notification, reporting or verification requirements in part 712 of the CWCR that apply to ''Schedule 1'' chemicals or facilities involved in the production of such chemicals. Although the newly added ''Schedule 1'' chemicals are now subject to these requirements, BIS estimates that the amendments made by this rule will not significantly affect the public burden imposed by these requirements because very few (if any) commercial facilities in the United States produce these chemicals. Consistent with this estimate, BIS did not receive any responses to its August 2019 notice of inquiry requesting public comments on the impact on U.S. industry of the proposed addition of the families of chemicals at issue to ''Schedule 1'' of the CWC Annex on Chemicals. As further evidence of the limited scope of any potential commercial applications, these chemicals are defense articles subject to the export licensing jurisdiction of the U.S. Department of State (as described below).

Amendments to Supplement No. 1 to Part 745 of the EAR (Schedules of Chemicals)

Supplement No. 1 to part 745 of the EAR includes the three schedules of Chemicals (Schedules 1, 2 and 3) contained in the CWC Annex on Chemicals. This rule amends ''Schedule 1'' in Supplement No. 1 to reflect the decisions adopted at the November 2019 CWC Conference of the States Parties to add three chemical families and one individual chemical to ''Schedule 1'' in the CWC Annex on Chemicals. In addition, this rule revises the formats of ''Schedule 2 and ''Schedule 3'' for consistency with the format of ''Schedule 1,'' as amended by this rule. This rule also adds a Note following the list of chemicals in Supplement No. 1 to explain that the numerical sequence of the ''Schedule 1'' Toxic Chemicals and Precursors specified therein is not consecutive so as to align with the December 23, 2019, consolidated textual changes to the Annex on Chemicals, which reflect the decisions adopted by the CWC Conference of the States Parties in November 2019. Specifically, the chemicals listed in ''Schedule 1(A),'' Toxic Chemicals, are numbered 1–8 and 13–16 (the latter includes 16.1 and 16.2), while the chemicals listed in ''Schedule 1(B),'' Precursors, are numbered 9–12.

This rule does not amend the advance notification and reporting requirements for exports of ''Schedule 1'' chemicals described in § 745.1 of the EAR, which are, for all practical purposes, a cross-reference to (or general restatement of) the requirements in § 712.6 of the CWCR (except that the CWCR requirements

also apply to imports of ''Schedule 1'' chemicals). Furthermore, these newly added ''Schedule 1'' chemicals are not subject to the export licensing jurisdiction of BIS under the EAR. All ''Schedule 1'' chemicals, except ricin and saxitoxin (which are controlled under Export Control Classification Number 1C351 on the Commerce Control List in Supplement No. 1 to part 774 of the EAR), are subject to the export licensing jurisdiction of the Directorate of Defense Trade Controls, Department of State, under the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120–130). Consequently, the conforming amendments made by this rule will not affect the burden imposed on the public by the ''Schedule 1'' chemical advance notification and reporting requirements described in § 745.1 of the EAR.

Clarification of the Definition of ''Production'' in Part 710 of the CWCR

This final rule amends the definition of ''*production*'' in § 710.1 of the CWCR to clarify its application to the CWCR's declaration requirements concerning the production of ''Schedule 1,'' ''Schedule 2,'' or ''Schedule 3'' chemicals. Specifically, this rule clarifies the definition consistent with §§ 712.5(d), 713.2(a)(2)(ii) and 714.1(a)(2)(ii) of the CWCR (as amended by the April 27, 2006, CWCR final rule (81 FR 24918)), whereby ''Schedule 1,'' ''Schedule 2,'' or ''Schedule 3'' chemicals that are intermediates, but not transient intermediates, must be considered when determining if a chemical is subject to the declaration requirements in the CWCR. (See the OPCW Conference of the States Parties Decisions that form the basis of this treatment of such intermediates: C–10/DEC.12, November 10, 2005, ''Understanding Relating to the Concept of 'Captive Use' in Connection with Declarations of Production and Consumption Under Part VI of the Verification Annex to the Convention;'' and C–9/DEC.6, November 30, 2004, ''Understanding of the Concept of 'Captive Use' in Connection with Declarations of Production and Consumption Under Parts VII and VIII of the Verification Annex to the Chemical Weapons Convention.'')

As amended by this rule, the definition of ''production'' in § 710.1 of the CWCR is understood (for purposes of the ''Schedule 1,'' ''Schedule 2,'' and ''Schedule 3'' chemical declaration requirements in the CWCR) 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.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including: Potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits and of reducing costs, harmonizing rules, and promoting flexibility. This final rule has been determined to be not significant for purposes of Executive Order 12866. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule contains the following collections of information subject to the requirements of the PRA. These collections have been approved by OMB under control numbers 0694–0091 (Chemical Weapons Convention Declaration and Report Handbook and Forms & Chemical Weapons Convention Regulations (CWCR)) and 0694–0117 (Chemical Weapons Convention Provisions of the Export Administration Regulations (EAR)). The approved information collection under OMB control number 0694–0091 includes CWCR declarations, reports, notifications, and on-site inspections of chemical facilities and carries a total burden estimate of 14,813 hours. The approved information collection under OMB control number 0694–0117 includes Schedule 1 chemical advance notifications and annual reports, Schedule 3 chemical End-Use Certificates, and exports of ''technology'' to produce certain Schedule 2 and Schedule 3 chemicals and carries a total burden estimate of 42 burden hours.

BIS estimates that the overall increase in costs and burdens due to the implementation of the changes made by this final rule will be minimal, based on the fact that there are very few, if any, commercial applications for the ''Schedule 1'' chemicals added by this rule to Supplement No. 1 to part 712 of the CWCR and Supplement No. 1 to part 745 of the EAR. Consistent with this estimate, BIS did not receive any responses to its August 2019 notice of inquiry described herein. Additional evidence of the limited scope of potential commercial applications is that the chemicals at issue are defense articles subject to the export licensing jurisdiction of the Department of State. Also, pursuant to § 710.2(a) of the CWCR, certain U.S. Government facilities (*e.g.,* Department of Defense and Department of Energy facilities) are not subject to the CWCR and, consequently, the costs and burdens of the requirements described therein do not apply to such facilities.

In addition, although the newly added ''Schedule 1'' chemicals are subject to the declaration, advance notification, reporting or verification requirements in part 712 of the CWCR, the fact that these chemicals have few potential commercial applications will, as a practical matter, limit the impact of these requirements. Consequently, the amendments made by this rule will not significantly alter the costs and burdens imposed on the public by such CWCR requirements. Furthermore, because these newly added ''Schedule 1'' chemicals are defense articles subject to the export licensing jurisdiction of the Department of State under the ITAR, the conforming amendments made by this rule do not add to, or otherwise affect, any export licensing requirements in the EAR; nor, as a practical matter, will they significantly alter the costs and burdens imposed on the public by the reporting and advance notification requirements described in § 745.1 of the EAR.

Written comments and recommendations for the information collections referenced above should be sent within 30 days of the publication of this final rule to: *www.reginfo.gov/public/do/PRAMain.* The public may locate these particular information collections by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed

rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (see 5 U.S.C. 553(a)(1)). Immediate implementation of these amendments is non-discretionary and fulfills the United States' international obligations under the CWC. The CWC is an international arms control treaty prohibiting the development, production, acquisition, stockpiling, retention, transfer or use of chemical weapons by States Parties in order to eliminate an entire category of weapons of mass destruction. The 193 CWC States Parties have agreed to, among other things, implement a comprehensive data declaration, notification, and inspection regime for those toxic chemicals and their precursors listed in Schedules 1, 2 or 3 in the CWC Annex on Chemicals (the Annex). The amendments set forth in this rule implement two decisions adopted by the States Parties during the OPCW's 24th Conference of the States Parties, held in The Hague, the Netherlands, from November 25–29, 2019, and clarify a definition in the CWCR to ensure consistency with the CWCR's declaration requirements regarding the production of ''Schedule 1,'' ''Schedule 2,'' or ''Schedule 3'' chemicals.

These provisions of the Administrative Procedure Act also are waived for good cause, as unnecessary and contrary to the public interest (see 5 U.S.C. 553(b)(B)). This rule brings the CWCR and the EAR into conformity with recent updates to ''Schedule 1'' in the Annex by amending Supplement No. 1 to part 712 of the CWCR and Supplement No. 1 to part 745 of the EAR. These changes to the Annex entered into force, with respect to all States Parties to the CWC, on June 7, 2020. As a State Party, the United States became obligated to apply the declaration, advance notification, reporting and verification requirements in part 712 of the CWCR to these newly added ''Schedule 1'' chemicals as of that date.

Because these obligations will have already come into effect by the time this rule is published, a delay of this rulemaking to allow for notice and opportunity for public comment would be unnecessary. As indicated above, the U.S. has no discretion in this matter—it must implement these changes as a State Party.

Even if these changes were discretionary, a delay of this rulemaking to allow for notice and opportunity for public comment would be unnecessary. Based on the lack of any responses to BIS's August 14, 2019, notice of inquiry requesting public comments on the impact of the addition of these chemicals (together with others) to the Annex, it does not appear that there any many (if any) chemical, biotechnology, or pharmaceutical firms in the U.S. that would be adversely affected by the substance of this rule. Moreover, these chemicals are defense articles subject to the export licensing jurisdiction of the Department of State under the ITAR and, consequently, have few potential commercial applications.

Similarly, a delay of this rulemaking to provide notice and opportunity for public comment would be contrary to the public interest, as would a 30-day delay in effective date, given the fact that the restrictions associated with the addition of these chemicals to the Annex have already come into force for CWC States Parties as of June 7, 2020. Providing notice and opportunity for public comment and a 30-day delay in effectiveness would not only impair the ability of the United States to fulfill its obligations as a State Party in a timely manner, it also might lead the public to mistakenly assume that these changes are discretionary. Such measures might also have a significant adverse impact upon the ability of U.S. companies to comply in a timely fashion with the declaration, advance notification, reporting, and other requirements that apply to these newly added ''Schedule 1'' chemicals, as they would have to wait until the amendments adding these chemicals to the CWCR and the EAR have taken effect. Consequently, any further delay in implementation would adversely impact the ability of the United States to meet its ''Schedule 1'' chemical declaration, notification, and reporting obligations to the OPCW with respect to these newly added ''Schedule 1'' chemicals. Conversely, timely publication of these regulatory changes, with immediate effectiveness, would provide U.S. companies with adequate time to adjust their recordkeeping and other activities in advance of any deadlines that would apply to the submission of declarations, advance notifications, or reports associated with the newly added ''Schedule 1'' chemicals, thereby making it possible for the U.S. to meet its CWC obligations in this regard.

For similar reasons, application of the APA's notice and comment and 30-day delay in effectiveness requirements to the clarification to the definition of ''production'' set forth in § 710.1 of the CWCIA made as part of this rule would be unnecessary and contrary to the public interest. The clarification merely conforms the definition to language already set forth in the CWCIA's declaration requirements that apply to ''Schedule 1,'' ''Schedule 2,'' and ''Schedule 3'' chemicals.

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by the APA or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

List of Subjects

15 CFR Part 710

Chemicals, Exports, Foreign trade, Imports, Treaties.

15 CFR Part 712

Chemicals, Exports, Foreign trade, Imports, Reporting and recordkeeping requirements.

15 CFR Part 745

Administrative practice and procedure, Chemicals, Exports, Foreign trade, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, parts 710 and 712 of the Chemical Weapons Convention Regulations (15 CFR parts 710–722) and part 745 of the Export Administration Regulations (15 CFR parts 730–774) are amended as follows:

PART 710—GENERAL INFORMATION AND OVERVIEW OF THE CHEMICAL WEAPONS CONVENTION REGULATIONS (CWCR)

■ 1. The authority citation for 15 CFR part 710 continues to read as follows:

Authority: 22 U.S.C. 6701 *et seq.;* E.O. 13128, 64 FR 36703, 3 CFR 1999 Comp., p. 199.

■ 2. In § 710.1, the definition of ''Production'' is revised to read as follows:

§ 710.1 Definitions of terms used in the Chemical Weapons Convention Regulations (CWCR).

* * * * *

Production. Means the formation of a chemical through chemical reaction, including biochemical or biologically mediated reaction (see supplement no. 2 to this part).

(1) Production of Schedule 1 chemicals means formation through chemical synthesis as well as processing to extract and isolate Schedule 1 chemicals.

(2) Production of a Schedule 2 or Schedule 3 chemical means all steps in

the production of a chemical in any units within the same plant through chemical reaction, including any associated processes (*e.g.,* purification, separation, extraction, distillation, or refining) in which the chemical is not converted into another chemical. The exact nature of any associated process (*e.g.,* purification, etc.) is not required to be declared.

(3) Production of a Schedule 1, Schedule 2 or Schedule 3 chemical is understood, for 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.

* * * * *

PART 712—ACTIVITIES INVOLVING SCHEDULE 1 CHEMICALS

■ 3. The authority citation for 15 CFR part 712 continues to read as follows:

Authority: 22 U.S.C. 6701 *et seq.;* 50 U.S.C. 1601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950, as amended by E.O. 13094, 63 FR 40803, 3 CFR, 1998 Comp., p. 200; E.O. 13128, 64 FR 36703, 3 CFR 1999 Comp., p. 199.

■ 4. Supplement No. 1 to part 712 is amended by revising the table and adding a Note 3 to the Notes to Supplement No. 1 to read as follows:

SUPPLEMENT NO. 1 TO PART 712—SCHEDULE 1 CHEMICALS

	CAS registry No.
A. Toxic Chemicals:	
1. *Family:* O-Alkyl(≤C_{10}, incl. cycloalkyl) alkyl (Me, Et, n-Pr or i-Pr)- phosphonofluoridates	
Not limited to the following examples:	
Sarin: O-Isopropyl methylphosphonofluoridate	107–44–8
Soman: O-Pinacolyl methylphosphonofluoridate	96–64–0
2. *Family:* O-Alkyl (≤C_{10}, incl. cycloalkyl) N,N-dialkyl (Me, Et, n-Pr or i-Pr) phosphoramidocyanidates	
Not limited to the following example:	
Tabun: O-Ethyl N,N-dimethyl phosphoramidocyanidate	77–81–6
3. *Family:* O-Alkyl (H or ≤C_{10}, incl. cycloalkyl) S-2-dialkyl (Me, Et, n-Pr or i-Pr)-aminoethyl alkyl (Me, Et, n-Pr or i-Pr) phosphonothiolates and corresponding alkylated or protonated salts	
Not limited to the following example:	
VX: O-Ethyl S-2-diisopropylaminoethyl methyl phosphonothiolate	50782–69–9
4. Sulfur mustards:	
2-Chloroethylchloromethylsulfide	2625–76–5
Mustard gas: Bis(2-chloroethyl)sulfide	505–60–2
Bis(2-chloroethylthio)methane	63869–13–6
Sesquimustard: 1,2-Bis(2-chloroethylthio)ethane	3563–36–8
1,3-Bis(2-chloroethylthio)-n-propane	63905–10–2
1,4-Bis(2-chloroethylthio)-n-butane	142868–93–7
1,5-Bis(2-chloroethylthio)-n-pentane	142868–94–8
Bis(2-chloroethylthiomethyl)ether	63918–90–1
O-Mustard: Bis(2-chloroethylthioethyl)ether	63918–89–8
5. Lewisites:	
Lewisite 1: 2-Chlorovinyldichloroarsine	541–25–3
Lewisite 2: Bis(2-chlorovinyl)chloroarsine	40334–69–8
Lewisite 3: Tris(2-chlorovinyl)arsine	40334–70–1
6. Nitrogen mustards:	
HN1: Bis(2-chloroethyl)ethylamine	538–07–8
HN2: Bis(2-chloroethyl)methylamine	51–75–2
HN3: Tris(2-chloroethyl)amine	555–77–1
7. Saxitoxin	35523–89–8
8. Ricin	9009–86–3
13. *Family:* P-alkyl (H or ≤C_{10}, incl. cycloalkyl) N-(1-(dialkyl(≤C_{10}, incl. cycloalkyl)amino))alkylidene(H or ≤C_{10}, incl. cycloalkyl) phosphonamidic fluorides and corresponding alkylated or protonated salts	
Not limited to the following examples:	
N-(1-(di-n-decylamino)-n-decylidene)-P-decylphosphonamidic fluoride	2387495–99–8
Methyl-(1-(diethylamino)ethylidene)phosphonamidofluoridate	2387496–12–8
14. *Family:* O-alkyl (H or ≤C_{10}, incl. cycloalkyl) N-(1-(dialkyl(≤C_{10}, incl. cycloalkyl)amino))alkylidene(H or ≤C_{10}, incl. cycloalkyl) phosphoramidofluoridates and corresponding alkylated or protonated salts	
Not limited to the following examples:	
O-n-Decyl N-(1-(di-n-decylamino)-n decylidene)phosphoramidofluoridate	2387496–00–4
Methyl (1-(diethylamino)ethylidene)phosphoramidofluoridate	2387496–04–8
Ethyl (1-(diethylamino)ethylidene)phosphoramidofluoridate	2387496–06–0
15. Methyl-(bis(diethylamino)methylene)phosphonamidofluoridate	2387496–14–0
16. Carbamates (quaternaries and bisquaternaries of dimethylcarbamoyloxypyridines)	
16.1. *Family:* Quaternaries of dimethylcarbamoyloxypyridines: 1-[N,N-dialkyl(≤C_{10})-N-(n-(hydroxyl, cyano, acetoxy)alkyl(≤C_{10})) ammonio]-n-[N-(3-dimethylcarbamoxy-α-picolinyl)-N,N-dialkyl(≤C_{10}) ammonio]decane dibromide (n=1-8)	
Not limited to the following example:	
1-[N,N-dimethyl-N-(2-hydroxy)ethylammonio]-10-[N-(3-dimethylcarbamoxy-α-picolinyl)-N,N-dimethylammonio]decane dibromide	77104–62–2
16.2. *Family:* Bisquaternaries of dimethylcarbamoyloxypyridines:1,n-Bis[N-(3-dimethylcarbamoxy-α-picolyl)-N,N-dialkyl(≤C_{10}) ammonio]-alkane-(2,(n-1)-dione) dibromide (n=2-12)	
Not limited to the following example:	

SUPPLEMENT NO. 1 TO PART 712—SCHEDULE 1 CHEMICALS—Continued

	CAS registry No.
1,10-Bis[N-(3-dimethylcarbamoxy-α-picolyl)-N-ethyl-N- methylammonio]decane-2,9-dione dibromide	77104–00–8
B. Precursors:	
9. *Family:* Alkyl (Me, Et, n-Pr or i-Pr) phosphonyldifluorides	
Not limited to the following example:	
DF: Methylphosphonyldifluoride	676–99–3
10. *Family:* O-Alkyl (H or ≤C_{10}, incl. cycloalkyl) O-2-dialkyl (Me, Et, n-Pr or i-Pr)-aminoethyl alkyl (Me, Et, n-Pr or i-Pr) phosphonites and corresponding alkylated or protonated salts	
Not limited to the following example:	
QL: O-Ethyl O-2-diisopropylaminoethyl methylphosphonite	57856–11–8
11. Chlorosarin: O-Isopropyl methylphosphonochloridate	1445–76–7
12. Chlorosoman: O-Pinacolyl methylphosphonochloridate	7040–57–5

Notes to Supplement No. 1

* * * * *

NOTE 3: The numerical sequence of the ''Schedule 1'' Toxic Chemicals and Precursors is not consecutive so as to align with the December 23, 2019, consolidated textual changes to ''Schedule 1'' of the Annex on Chemicals to the Chemical Weapons Convention (CWC), which reflect the decisions adopted by the CWC Conference of the States Parties in November 2019.

PART 745—CHEMICAL WEAPONS CONVENTION REQUIREMENTS

■ 5. The authority citation for 15 CFR part 745 is revised to read as follows:

Authority: 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950); 22 U.S.C. 6701 *et seq.;* E.O. 13128, 64 FR 36703, 3 CFR 1999 Comp., p. 199; 50 U.S.C. 4801–4852; Notice of November 12, 2019, 84 FR 61817 (November 13, 2019).

■ 6. Supplement No. 1 to part 745 is revised to read as follows:

SUPPLEMENT NO. 1 TO PART 745—SCHEDULES OF CHEMICALS

	CAS registry No.
Schedule 1	
A. Toxic Chemicals:	
1. *Family:* O-Alkyl(≤C_{10}, incl. cycloalkyl) alkyl (Me, Et, n-Pr or i-Pr)- phosphonofluoridates	
Not limited to the following examples:	
Sarin: O-Isopropyl methylphosphonofluoridate	107–44–8
Soman: O-Pinacolyl methylphosphonofluoridate	96–64–0
2. *Family:* O-Alkyl (≤C_{10}, incl. cycloalkyl) N,N-dialkyl (Me, Et, n-Pr or i-Pr) phosphoramidocyanidates	
Not limited to the following example:	
Tabun: O-Ethyl N,N-dimethyl phosphoramidocyanidate	77–81–6
3. *Family:* O-Alkyl (H or ≤C_{10}, incl. cycloalkyl) S-2-dialkyl (Me, Et, n-Pr or i-Pr)-aminoethyl alkyl (Me, Et, n-Pr or i-Pr) phosphonothiolates and corresponding alkylated or protonated salts	
Not limited to the following example:	
VX: O-Ethyl S-2-diisopropylaminoethyl methyl phosphonothiolate	50782–69–9
4. *Sulfur mustards:*	
2-Chloroethylchloromethylsulfide	2625–76–5
Mustard gas: Bis(2-chloroethyl)sulfide	505–60–2
Bis(2-chloroethylthio)methane	63869–13–6
Sesquimustard: 1,2-Bis(2-chloroethylthio)ethane	3563–36–8
1,3-Bis(2-chloroethylthio)-n-propane	63905–10–2
1,4-Bis(2-chloroethylthio)-n-butane	142868–93–7
1,5-Bis(2-chloroethylthio)-n-pentane	142868–94–8
Bis(2-chloroethylthiomethyl)ether	63918–90–1
O-Mustard: Bis(2-chloroethylthioethyl)ether	63918–89–8
5. *Lewisites:*	
Lewisite 1: 2-Chlorovinyldichloroarsine	541–25–3
Lewisite 2: Bis(2-chlorovinyl)chloroarsine	40334–69–8
Lewisite 3: Tris(2-chlorovinyl)arsine	40334–70–1
6. *Nitrogen mustards:*	
HN1: Bis(2-chloroethyl)ethylamine	538–07–8
HN2: Bis(2-chloroethyl)methylamine	51–75–2
HN3: Tris(2-chloroethyl)amine	555–77–1
7. Saxitoxin	35523–89–8
8. Ricin	9009–86–3
13. *Family:* P-alkyl (H or ≤C_{10}, incl. cycloalkyl) N-(1-(dialkyl(≤C_{10}, incl. cycloalkyl)amino))alkylidene(H or ≤C_{10}, incl. cycloalkyl) phosphonamidic fluorides and corresponding alkylated or protonated salts	
Not limited to the following examples:	
N-(1-(di-n-decylamino)-n-decylidene)-P-decylphosphonamidic fluoride	2387495–99–8
Methyl-(1-(diethylamino)ethylidene)phosphonamidofluoridate	2387496–12–8
14. *Family:* O-alkyl (H or ≤C_{10}, incl. cycloalkyl) N-(1-(dialkyl(≤C_{10}, incl. cycloalkyl)amino))alkylidene(H or ≤C_{10}, incl. cycloalkyl) phosphoramidofluoridates and corresponding alkylated or protonated salts	
Not limited to the following examples:	

SUPPLEMENT NO. 1 TO PART 745—SCHEDULES OF CHEMICALS—Continued

	CAS registry No.
O-n-Decyl N-(1-(di-n-decylamino)-n decylidene)phosphoramidofluoridate	2387496–00–4
Methyl (1-(diethylamino)ethylidene)phosphoramidofluoridate	2387496–04–8
Ethyl (1-(diethylamino)ethylidene)phosphoramidofluoridate	2387496–06–0
15. Methyl-(bis(diethylamino)methylene)phosphonamidofluoridate	2387496–14–0
16. Carbamates (quaternaries and bisquaternaries of dimethylcarbamoyloxypyridines)	
16.1. *Family:* Quaternaries of dimethylcarbamoyloxypyridines: 1-[N,N-dialkyl($\leq C_{10}$)-N-(n-(hydroxyl, cyano, acetoxy)alkyl($\leq C_{10}$)) ammonio]-n-[N-(3-dimethylcarbamoxy-α-picolinyl)-N,N-dialkyl($\leq C_{10}$) ammonio]decane dibromide (n=1–8)	
Not limited to the following example:	
1-[N,N-dimethyl-N-(2-hydroxy)ethylammonio]-10-[N-(3-dimethylcarbamoxy-α-picolinyl)-N,N-dimethylammonio]decane dibromide	77104–62–2
16.2. *Family:* Bisquaternaries of dimethylcarbamoyloxypyridines:1,n-Bis[N-(3-dimethylcarbamoxy-α-picolyl)-N,N-dialkyl($\leq C_{10}$) ammonio]-alkane-(2,(n-1)-dione) dibromide (n=2–12).	
Not limited to the following example:	
1,10-Bis[N-(3-dimethylcarbamoxy-α-picolyl)-N-ethyl-N- methylammonio]decane-2,9-dione dibromide	77104–00–8
B. Precursors:	
9. *Family:* Alkyl (Me, Et, n-Pr or i-Pr) phosphonyldifluorides	
Not limited to the following example:	
DF: Methylphosphonyldifluoride	676–99–3
10. *Family:* O-Alkyl (H or $\leq C_{10}$, incl. cycloalkyl) O-2-dialkyl (Me, Et, n-Pr or i-Pr)-aminoethyl alkyl (Me, Et, n-Pr or i-Pr) phosphonites and corresponding alkylated or protonated salts	
Not limited to the following example:	
QL: O-Ethyl O–2-diisopropylaminoethyl methylphosphonite	57856–11–8
11. *Chlorosarin:* O-Isopropyl methylphosphonochloridate	1445–76–7
12. *Chlorosoman:* O-Pinacolyl methylphosphonochloridate	7040–57–5
Schedule 2	
A. Toxic Chemicals:	
1. *Amiton:* O,O-Diethyl S-[2-(diethylamino)ethyl] phosphorothiolate and corresponding alkylated or protonated salts	78–53–5
2. PFIB: 1,1,3,3,3-Pentafluoro-2-(trifluoromethyl)-1-propene	382–21–8
3. *BZ:* 3-Quinuclidinyl benzilate	6581–06–2
B. Precursors:	
4. *Family:* Chemicals, except for those listed in Schedule 1, containing a phosphorus atom to which is bonded one methyl, ethyl or propyl (normal or iso) group but not further carbon atoms,	
Not limited to the following examples:	
Methylphosphonyl dichloride	676–97–1
Dimethyl methylphosphonate	756–79–6
Exemption: Fonofos: O-Ethyl S-phenyl ethylphosphonothiolothionate	944–22–9
5. *Family:* N,N-Dialkyl (Me, Et, n-Pr or i-Pr) phosphoramidic dihalides	
6. *Family:* Dialkyl (Me, Et, n-Pr or i-Pr) N,N-dialkyl (Me, Et, n-Pr or i-Pr)-phosphoramidates	
7. Arsenic trichloride	7784–34–1
8. 2,2-Diphenyl-2-hydroxyacetic acid	76–93–7
9. Quinuclidine-3-ol	1619–34–7
10. *Family:* N,N-Dialkyl (Me, Et, n-Pr or i-Pr) aminoethyl-2-chlorides and corresponding protonated salts	
11. *Family:* N,N-Dialkyl (Me, Et, n-Pr or i-Pr) aminoethane-2-ols and corresponding protonated salts	
Exemptions: N,N-Dimethylaminoethanol and corresponding protonated salts	108–01–0
N,N-Diethylaminoethanol and corresponding protonated salts	100–37–8
12. *Family:* N,N-Dialkyl (Me, Et, n-Pr or i-Pr) aminoethane-2-thiols and corresponding protonated salts	
13. Thiodiglycol: Bis(2-hydroxyethyl)sulfide	111–48–8
14. *Pinacolyl alcohol:* 3,3-Dimethylbutane-2-ol	464–07–3
Schedule 3	
A. Toxic Chemicals:	
1. *Phosgene:* Carbonyl dichloride	75–44–5
2. Cyanogen chloride	506–77–4
3. Hydrogen cyanide	74–90–8
4. *Chloropicrin:* Trichloronitromethane	76–06–2
B. Precursors:	
5. Phosphorus oxychloride	10025–87–3
6. Phosphorus trichloride	7719–12–2
7. Phosphorus pentachloride	10026–13–8
8. Trimethyl phosphite	121–45–9
9. Triethyl phosphite	122–52–1
10. Dimethyl phosphite	868–85–9
11. Diethyl phosphite	762–04–9
12. Sulfur monochloride	10025–67–9
13. Sulfur dichloride	10545–99–0
14. Thionyl chloride	7719–09–7
15. Ethyldiethanolamine	139–87–7

SUPPLEMENT NO. 1 TO PART 745—SCHEDULES OF CHEMICALS—Continued

	CAS registry No.
16. Methyldiethanolamine	105–59–9
17. Triethanolamine	102–71–6

Note to Supplement 1: The numerical sequence of the ''Schedule 1'' Toxic Chemicals and Precursors is not consecutive so as to align with the December 23, 2019, consolidated textual changes to ''Schedule 1'' of the Annex on Chemicals to the Chemical Weapons Convention (CWC), which reflect the decisions adopted by the CWC Conference of the States Parties in November 2019.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2020–27759 Filed 1–6–21; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 742 and 774

[Docket No. 201208–0330]

RIN 0694–AI09

Commerce Control List: Clarifications to the Scope of Export Control Classification Number 1C991 To Reflect Decisions Adopted at the June 2019 Australia Group Plenary Meeting

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) publishes this final rule to amend the Export Administration Regulations (EAR) to clarify the scope of the export controls that apply to certain vaccines and medical products, consistent with the release (*i.e.,* exclusion) notes contained in the Australia Group (AG) ''Human and Animal Pathogens and Toxins for Export Control'' common control list.

DATES: This rule is effective January 7, 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Kimberly Orr, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482–4201, Email: *Kimberly.Orr@bis.doc.gov.*

SUPPLEMENTARY INFORMATION: The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to clarify the scope of the export controls that apply to certain vaccines, consistent with the vaccine release (*i.e.,* exclusion) note contained in the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control'' common control list, as updated by a decision made at the AG Plenary meeting held in Paris, France, in June 2019. The AG is a multilateral forum consisting of 42 participating countries and the European Union that maintain export controls on a list of chemicals, biological agents, and related equipment and technology that could be used in a chemical or biological weapons program. The AG periodically reviews items on its control list to enhance the effectiveness of participating governments' national controls and to achieve greater harmonization among these controls.

The AG specifically excludes certain vaccines from control under its ''List of Human and Animal Pathogens and Toxins for Export Control'' and the associated Warning List. However, prior to the June 2019 Plenary changes to this AG common control list, it was not clear if the release note therein applied not only to vaccines containing those human and animal pathogens and toxins identified on the list, but also to vaccines containing the genetic elements and genetically modified organisms identified therein. Recent changes to this AG common control list, based in part on a decision made at the June 2019 Plenary meeting, clarify that this release note applies to vaccines containing the genetic elements and genetically modified organisms identified on this list, as well as vaccines containing the viruses, bacteria, and toxins identified on this list.

Specifically, this rule amends Export Control Classification Number (ECCN) 1C991 on the Commerce Control List (CCL) to indicate that it includes vaccines containing, or designed for use against, any of the items identified in ECCN 1C351, 1C353 or 1C354. Prior to the effective date of this final rule, ECCN 1C991 indicated that it controlled vaccines ''against'' such items, but was not specific about whether all vaccines ''containing'' such items were controlled, irrespective of whether the vaccines were designed for use ''against'' such items.

This rule also expands the scope of medical products controlled under ECCN 1C991 to include those containing genetically modified organisms and genetic elements described in ECCN 1C353.a.3. In addition, this rule clarifies the definition of 'immunotoxin' that appears in ECCN 1C351 and ECCN 1C991 and removes the definition of 'subunit' from ECCN 1C351.

Finally, this rule renumbers ECCN 1C991.c and .d by listing medical products that are subject to chemical/biological (CB) controls, as well as anti-terrorism (AT) controls, under ECCN 1C991.c and listing medical products that are subject only to AT controls under ECCN 1C991.d. A conforming amendment is made to § 742.2(a)(3) of the EAR to reflect this change in paragraph sequencing.

ECCN 1C991 (Vaccines, Immunotoxins, Medical Products, Diagnostic and Food Testing Kits)

This final rule amends ECCN 1C991 on the Commerce Control List (CCL) (Supplement No. 1 to part 774 of the EAR) to make the description of the vaccines controlled by this ECCN more closely reflect the scope of the vaccine release note contained in the AG ''List of Human and Animal Pathogens and Toxins for Export Control.'' ECCN 1C991 does not control any of the human and animal pathogens and toxins or genetic elements and genetically modified organisms identified on this AG list; however, it does control vaccines, immunotoxins, medical products, and diagnostic and food testing kits that contain certain of these AG-listed items.

The amendments contained in this final rule are intended to clarify the scope of the vaccine controls described in ECCN 1C991. Prior to the effective date of this final rule, the control text for vaccines described in ECCN 1C991.a indicated that this ECCN controlled ''vaccines against items controlled by ECCN 1C351, 1C353 or 1C354.'' The use of the term ''against'' in the control text created some uncertainty concerning the extent to which ECCN 1C991.a applied to vaccines that ''contain'' items controlled by ECCN 1C351, 1C353 or