



DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 231208-0291]

RIN 0694-XC103

Impact of the Implementation of the Chemical Weapons Convention (CWC) on Legitimate Commercial Chemical, Biotechnology, and Pharmaceutical Activities Involving “Schedule 1” Chemicals (including “Schedule 1” Chemicals produced as Intermediates) During Calendar Year 2023

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of inquiry.

SUMMARY: The Bureau of Industry and Security is seeking public comments on the impact that the implementation of the Chemical Weapons Convention, through the Chemical Weapons Convention Implementation Act of 1998 and the Chemical Weapons Convention Regulations, has had on commercial activities involving “Schedule 1” chemicals during calendar year 2023. The purpose of this notice of inquiry is to collect information to assist BIS in its preparation of the annual certification to the Congress on whether the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms are harmed by such implementation. This certification is required under Condition 9 of Senate Resolution 75 (April 24, 1997), in which the Senate gave its advice and consent to the ratification of the Chemical Weapons Convention.

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

ADDRESSES:

Comments on this rule may be submitted to the Federal rulemaking portal

<https://www.regulations.gov>. The regulations.gov ID for this rule is: BIS-2023-0039. Please refer to RIN 0694-XC103 in all comments.

All filers using the portal should use the name of the person or entity submitting the comments as the name of their files, in accordance with the instructions below. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential version of the submission.

For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters “BC.” Any page containing business confidential information must be clearly marked “BUSINESS CONFIDENTIAL” on the top of that page. The corresponding non-confidential version of those comments must be clearly marked “PUBLIC.” The file name of the non-confidential version should begin with the character “P.” Any submissions with file names that do not begin with either a “BC” or a “P” will be assumed to be public and will be made publicly available through <https://www.regulations.gov>.

Commenters submitting business confidential information are encouraged to scan a hard copy of the non-confidential version to create an image of the file, rather than submitting a digital copy with redactions applied, to avoid inadvertent redaction errors which could enable the public to read business confidential information.

FOR FURTHER INFORMATION CONTACT: For questions on the Chemical Weapons Convention requirements for “Schedule 1” chemicals, contact James Truske, Treaty Compliance Division, (202) 482-2509, E-mail: james.truske@bis.doc.gov. For questions on the submission of comments, contact Logan Norton, Regulatory Policy Division, E-mail: RPD2@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

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”) is an international arms control treaty that seeks to eliminate chemical weapons through requiring ratifying countries (States Parties) to prohibit the development, production,

acquisition, stockpiling, retention, and transfer of chemical weapons. The CWC imposes certain obligations on States Parties, among which are the enactment of legislation to implement the treaty's prohibitions. In the United States, the Chemical Weapons Convention Implementation Act of 1998, 22 U.S.C. 6701 *et seq.*, implements the provisions of the CWC. In providing its advice and consent to the ratification of the CWC, the Senate included, in Senate Resolution 75 (S. Res. 75, April 24, 1997), several conditions to its ratification. Condition 9, titled "Protection of Advanced Biotechnology," calls for the President to certify to Congress on an annual basis that "the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms in the United States are not being significantly harmed by the limitations of the Convention on access to, and production of, those chemicals and toxins listed in Schedule 1." On July 8, 2004, President George W. Bush, by Executive Order 13346, delegated his authority to make the annual certification to the Secretary of Commerce.

"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 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) 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. DOD maintains strict controls on "Schedule 1" chemicals produced at its facilities in order to ensure accountability for such chemicals, as well as their proper use, consistent with the Convention's objectives. Although this assignment of responsibility to DOD under PDD-70 effectively precluded commercial production of

“Schedule 1” chemicals for “protective purposes” in the United States, it did not 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 part 712) and in 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). Pursuant to CWC requirements, the CWCR restrict commercial production of “Schedule 1” chemicals to research, medical, or pharmaceutical purposes. The CWCR prohibit commercial production of “Schedule 1” chemicals for “protective purposes” because such production is effectively precluded per PDD-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) Prohibits the import of “Schedule 1” chemicals from States not Party to the Convention (15 CFR 712.2(b));
- (2) Requires annual declarations by certain 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) Provides for government approval of “declared Schedule 1” facilities (15 CFR 712.5(f));
- (4) Requires 200 days advance notification of the establishment of new “Schedule 1” production facilities producing greater than 100 grams aggregate of “Schedule 1” chemicals per calendar year (15 CFR 712.4);
- (5) Provides 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));
- (6) Requires 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) Prohibits 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* the definition of “production” in 15 CFR 710.1), the phrase “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. The phrase also encompasses the formation of a chemical through chemical reaction, including by a biochemical or biologically mediated reaction. “Production of a Schedule 1 chemical” 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.

Request for Comments

In order to assist in determining whether the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms in the United States are significantly harmed by the limitations of the Convention on access to, and production of, “Schedule 1” chemicals as described in this notice, BIS is seeking public comments on any effects that implementation of the CWC, through the Chemical Weapons Convention Implementation Act of 1998 and the CWCR, has had on commercial activities involving “Schedule 1” chemicals during calendar year 2023. To allow BIS to properly evaluate the significance of any harm to commercial activities involving “Schedule 1” chemicals, 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 and in accordance with the instructions provided herein. BIS will consider all comments received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

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