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B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 211019–0210]

RIN 0694–AI64

Addition of Certain Entities to the Entity List

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This final rule amends the Export Administration Regulations (EAR) by adding four entities to the Entity List. These four entities have been determined by the U.S. Government to be acting contrary to the foreign policy and national security interests of the United States and will be listed on the Entity List under the destinations of Israel, Russia, and Singapore.

DATES: This rule is effective November 4, 2021.

FOR FURTHER INFORMATION CONTACT: Chair, End-User Review Committee, Office of the Assistant Secretary for Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–5991, Email: *ERC@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

Entity List

The Entity List (supplement no. 4 to part 744 of the EAR) identifies entities for which there is reasonable cause to believe, based on specific and articulable facts, that the entities have been involved, are involved, or pose a significant risk of being or becoming involved in activities contrary to the national security or foreign policy interests of the United States. The EAR (15 CFR parts 730–774) impose additional license requirements on, and limit the availability of most license exceptions for, exports, reexports, and transfers (in-country) to listed entities. The license review policy for each listed entity is identified in the ''License Review Policy'' column on the Entity List, and the impact on the availability of license exceptions is described in the relevant **Federal Register** document adding entities to the Entity List. Bureau of Industry and Security (BIS) places entities on the Entity List pursuant to part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR.

The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote and makes all decisions to remove or modify an entry by unanimous vote.

ERC Entity List Decisions

Additions to the Entity List

This rule implements the decision of the ERC to add four entities to the Entity List. The four entities are added based on § 744.11 (License requirements that apply to entities acting contrary to the national security or foreign policy interests of the United States) of the EAR. The four entities are located in Israel, Russia, and Singapore.

The ERC determined that NSO Group and Candiru be added to the Entity List based on § 744.11(b) of the EAR: Entities for which there is reasonable cause to believe, based on specific and articulated facts, that the entity has been involved, is involved, or poses a significant risk of being or becoming involved in activities that are contrary to the national security or foreign policy interests of the United States and those acting on behalf of such entities. Specifically, investigative information has shown that the Israeli companies NSO Group and Candiru developed and supplied spyware to foreign governments that used this tool to maliciously target government officials, journalists, businesspeople, activists, academics, and embassy workers.

The ERC determined that Positive Technologies, located in Russia, and Computer Security Initiative Consultancy PTE. LTD., located in Singapore, be added to the Entity List based on their engagement in activities counter to U.S. national security. Specifically, these entities traffic in cyber exploits used to gain access to information systems, threatening the privacy and security of individuals and organizations worldwide.

Pursuant to § 744.11(b) of the EAR, the ERC determined that the conduct of the above-described four entities raises sufficient concerns that prior review, via the imposition of a license requirement for exports, reexports, or transfers (in-country) of all items subject to the EAR involving these four entities and the possible issuance of license denials or the possible imposition of license conditions on shipments to these entities, will enhance BIS's ability to prevent violations of the EAR or otherwise protect U.S. national security or foreign policy interests. In addition, the ERC also determined that no license exceptions should be available for exports, reexports, or transfers (in-country) to the persons being added to the Entity List in this rule. The ERC imposed a license review policy of a presumption of denial for these four entities. The acronym ''a.k.a.,'' which is an abbreviation of 'also known as,' is used in entries on the Entity List to identify aliases, thereby assisting exporters, reexporters, and transferors in identifying entities on the Entity List.

For the reasons described above, this final rule adds the following four entities to the Entity List and includes, where appropriate, aliases:

Israel

- Candiru; *and*
- NSO Group

Russia

- Positive Technologies

Singapore

- Computer Security Initiative Consultancy PTE. LTD.

Savings Clause

Shipments of items removed from eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export, reexport, or transfer (in-country), on November 4, 2021, pursuant to actual orders for export, reexport, or transfer (in-country) to or within a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR).

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4801–4852). ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule.

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, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to or 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 regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications and commodity classification, and carries a burden estimate of 29.6 minutes for a manual or electronic submission for a total burden estimate of 31,835 hours. Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule.

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

4. Pursuant to section 1762 of ECRA, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date.

5. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by 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 in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 744—[AMENDED]

■ 1. The authority citation for 15 CFR part 744 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 15, 2021, 86 FR 52069 (September 17, 2021); Notice of November 12, 2020, 85 FR 72897 (November 13, 2020).

■ 2. Supplement No. 4 to part 744 is amended:

■ a. Under ISRAEL, by adding in alphabetical order entries for ''Candiru'' and ''NSO Group'';

■ b. Under RUSSIA, by adding in alphabetical order an entry for ''Positive Technologies''; and

■ c. Under SINGAPORE, by adding in alphabetical order an entry for ''Computer Security Initiative Consultancy PTE. LTD.''.

The additions read as follows:

Supplement No. 4 to Part 744—Entity List

* * * * *

Country	Entity	License requirement	License review policy	**Federal Register** citation
*	* * *	*	* *	*
ISRAEL	* * *	*	* *	*
	Candiru, a.k.a., the following seven aliases: —Candiru Ltd.; —DF Associates Ltd.; —Grindavik Solutions Ltd.; —Taveta Ltd.; —Saito Tech Ltd.; —Greenwick Solutions; *and* —Tabatha Ltd. 21 Haarbaa, Tel Aviv-Yafo, Israel 6473921.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER] November 4, 2021.
	* * *	*	* *	*
	NSO Group, 22 Galgalei Haplada, Herzliya, Tel Aviv-Yafo, Israel 4672222.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER] November 4, 2021.
	* * *	*	* *	*
*	* * *	*	* *	*
RUSSIA	* * *	*	* *	*
	Positive Technologies, 8 Preobrzhenskaya Square, Moscow, Russia 107061.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER] November 4, 2021.
	* * *	*	* *	*

Country	Entity	License requirement	License review policy	Federal Register citation
*	* * *	*	* *	*
SINGAPORE	* * *	*	* *	*
	Computer Security Initiative Consultancy PTE. LTD., a.k.a., the following alias: —COSEINC. 102F Pasir Panjang Rd., #08–02, Citilink Warehouse Complex, Singapore 118530.	All items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	86 FR [INSERT FR PAGE NUMBER] November 4, 2021.
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Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2021–24123 Filed 11–3–21; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–631]

Schedules of Controlled Substances: Placement of Isotonitazene in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final amendment; final order.

SUMMARY: With the issuance of this final order, the Administrator of the Drug Enforcement Administration is permanently placing *N,N*-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine (commonly known as isotonitazene), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, in schedule I of the Controlled Substances Act. This scheduling action discharges the United States' obligations under the Single Convention on Narcotic Drugs (1961). This action continues to impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research or conduct instructional activities with, or possess), or propose to handle isotonitazene.

DATES: Effective December 6, 2021.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1961 United Nations Single Convention on Narcotic Drugs (Single Convention), March 30, 1961, 18 U.S.T. 1407, 570 U.N.T.S. 151, as amended by the 1972 Protocol. Article 3, paragraph 7 of the Single Convention requires that if the Commission on Narcotic Drugs (Commission) adds a substance to one of the schedules of such Convention, and the United States receives notification of such scheduling decision from the Secretary-General of the United Nations (Secretary-General), the United States, as a signatory Member State, is obligated to control the substance under its national drug control legislation. Under 21 U.S.C. 811(d)(1)), if control of a substance is required ''by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970,'' the Attorney General must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by 21 U.S.C. 811(a) or 812(b), and without regard to the procedures prescribed by 21 U.S.C. 811(a) and (b). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration (Administrator of DEA or Administrator). 28 CFR 0.100.

Background

On August 20, 2020, DEA issued a temporary scheduling order, placing isotonitazene (*N,N*-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine), in schedule I of the Controlled Substances Act (CSA). 85 FR 51342. That order was based on findings by the Acting Administrator of DEA (Acting Administrator) that the temporary scheduling of this substance was necessary to avoid an imminent hazard to the public safety; the order was codified at 21 CFR 1308.11(h)(48).

In November 2020, the Director-General of the World Health Organization recommended to the Secretary-General that isotonitazene be placed in Schedule I of the Single Convention, as this substance has an opioid mechanism of action and similarity to drugs that are controlled in Schedule I of the Single Convention (*i.e.,* isotonitazene is similar to drugs such as morphine and fentanyl), and has dependence and abuse potential. On June 10, 2021, the Secretary-General advised the Secretary of State of the United States, by letter, that during its 64th session in April 2021, the Commission voted to place isotonitazene in Schedule I of the Single Convention (CND Apr/64/1).

Isotonitazene

As discussed in the background section, isotonitazene is temporarily controlled in schedule I of the CSA upon the Acting Administrator's finding it poses imminent hazard to the public safety. Isotonitazene has a pharmacological profile similar to etonitazene (schedule I), fentanyl (schedule II), and other schedule I and II synthetic opioids that act as mu-opioid receptor agonists. Because of the pharmacological similarities of isotonitazene to etonitazene (a potent mu-opioid agonist), the use of isotonitazene presents a high risk of abuse and has negatively affected users and communities. The abuse of isotonitazene has been associated with