

The Gull Island boundary extends from Point 1 to Point 2 along a straight line. It then extends along a straight line from Point 2 to the MHWL where a line defined by connecting Point 2 and Point 3 with a straight line intersects the MHWL. The boundary follows the MHWL eastward until it intersects the line defined by connecting Point 4 and Point 5 with a straight line. At that intersection, the boundary then extends from the MHWL to Point 5 along a straight line. The boundary then extends from Point 5 to Point 6 along a straight line.

Point	Latitude	Longitude
1 .....	33.96700° N	- 119.85000° W
2 .....	33.96700° N	- 119.88330° W
3 .....	33.86195° N	- 119.88330° W
4 .....	33.86195° N	- 119.80000° W
5 .....	33.96170° N	- 119.80000° W
6 .....	33.96700° N	- 119.85000° W

**Table B-8. Scorpion (Santa Cruz Island) Marine Reserve**

The Scorpion Marine Reserve (Scorpion) boundary is defined by NOAA's MHWL along Santa Cruz Island, the coordinates provided in Table B-8, and the following textual description.

The Scorpion boundary extends from Point 1 to Point 2 along a straight line. It then extends along a straight line from Point 2 to the MHWL along Santa Cruz Island where a line defined by connecting Point 2 and Point 3 with a straight line intersects the MHWL. The boundary follows the MHWL westward until it intersects the line defined by connecting Point 4 and Point 5 with a straight line. At that intersection, the boundary extends from the MHWL to Point 5 along a straight line.

Point	Latitude	Longitude
1 .....	34.04900° N	- 119.59170° W
2 .....	34.15450° N	- 119.59170° W
3 .....	34.15450° N	- 119.54670° W
4 .....	34.04670° N	- 119.54670° W
5 .....	34.04900° N	- 119.59170° W

**Table B-9. Footprint Marine Reserve**

The Footprint Marine Reserve boundary is defined by connecting in sequential order the coordinates provided in Table B-9.

Point	Latitude	Longitude
1 .....	33.98343° N	- 119.43311° W
2 .....	33.98343° N	- 119.51609° W
3 .....	33.90198° N	- 119.51609° W
4 .....	33.90198° N	- 119.43311° W

**Table B-10. Anacapa Island Marine Reserve**

The Anacapa Island Marine Reserve (Anacapa Island) boundary is defined by NOAA's MHWL along Anacapa Island, the coordinates provided in Table B-10, and the following textual description.

The Anacapa Island boundary extends from Point 1 to Point 2 along a straight line. It then extends along a straight line from Point 2 to the MHWL along Anacapa Island where a line defined by connecting Point 2 and Point 3 with a straight line intersects the

MHWL. The boundary follows the MHWL westward until it intersects the line defined by connecting Point 4 and Point 5 with a straight line. At that intersection, the boundary extends from the MHWL to Point 5 along a straight line.

Point	Latitude	Longitude
1 .....	34.00670° N	- 119.41000° W
2 .....	34.08330° N	- 119.41000° W
3 .....	34.08330° N	- 119.35670° W
4 .....	34.01670° N	- 119.35670° W
5 .....	34.00670° N	- 119.41000° W

**Table B-11. Santa Barbara Island Marine Reserve**

The Santa Barbara Island Marine Reserve (Santa Barbara) boundary is defined by NOAA's MHWL along Santa Barbara Island, the coordinates provided in Table B-11, and the following textual description.

The Santa Barbara Island boundary extends from Point 1 to Point 2 along a straight line. It then extends along a straight line from Point 2 to the MHWL along Santa Barbara Island where a line defined by connecting Point 2 and Point 3 with a straight line intersects the MHWL. The boundary follows the MHWL northeastward until it intersects the line defined by connecting Point 4 and Point 5 with a straight line. At that intersection, the boundary then extends from the MHWL to Point 5 along a straight line. The boundary then extends from Point 5 to Point 6 along a straight line.

Point	Latitude	Longitude
1 .....	33.47500° N	- 119.02830° W
2 .....	33.47500° N	- 118.90879° W
3 .....	33.36320° N	- 118.90879° W
4 .....	33.36320° N	- 119.03670° W
5 .....	33.46500° N	- 119.03670° W
6 .....	33.47500° N	- 119.02830° W

9. Add Appendix C to Subpart G to read as follows:

**Appendix C to Subpart G of Part 9222—Marine Conservation Area Boundaries**

**Table C-1. Painted Cave (Santa Cruz Island) Marine Conservation Area**

The Painted Cave Marine Conservation Area (Painted Cave) boundary is defined by NOAA's MHWL along Santa Cruz Island, the coordinates provided in Table C-1, and the following textual description.

The Painted Cave boundary extends from Point 1 to Point 2 along a straight line. It then extends along a straight line from Point 2 to the MHWL along Santa Cruz Island where a line defined by connecting Point 2 and Point 3 with a straight line intersects the MHWL. The boundary follows the MHWL westward until it intersects the line defined by connecting Point 4 and Point 5 with a straight line. At that intersection, the boundary extends from the MHWL to Point 5 along a straight line.

Point	Latitude	Longitude
1 .....	34.07500° N	- 119.88330° W
2 .....	34.08670° N	- 119.88330° W

Point	Latitude	Longitude
3 .....	34.08330° N	- 119.85000° W
4 .....	34.06670° N	- 119.85000° W
5 .....	34.07500° N	- 119.88330° W

**Table C-2. Anacapa Island Marine Conservation Area**

The Anacapa Island Marine Conservation Area (AIMCA) boundary is defined by NOAA's MHWL along Anacapa Island, the coordinates provided in Table C-2, and the following textual description.

The AIMCA boundary extends from Point 1 to Point 2 along a straight line. It then extends along a straight line from Point 2 to the MHWL of Anacapa Island where a line defined by connecting Point 2 and Point 3 with a straight line intersects the MHWL. The boundary follows the MHWL westward until it intersects the line defined by connecting Point 4 and Point 5 with a straight line. At that intersection, the boundary extends from the MHWL to Point 5 along a straight line.

Point	Latitude	Longitude
1 .....	34.01330° N	- 119.44500° W
2 .....	34.08330° N	- 119.44500° W
3 .....	34.08330° N	- 119.41000° W
4 .....	34.00670° N	- 119.41000° W
5 .....	34.01330° N	- 119.44500° W

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1310**

[Docket No. DEA-257P]

RIN 1117-AA93

**Changes in the Regulation of Iodine Crystals and Chemical Mixtures Containing Over 2.2 Percent Iodine**

**AGENCY:** Drug Enforcement Administration (DEA), U.S. Department of Justice.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This Notice of Proposed Rulemaking (NPRM) proposes changes in the regulation of the listed chemical iodine pursuant to the chemical regulatory provisions of the Controlled Substances Act (CSA). The Drug Enforcement Administration (DEA) believes that this action is necessary in order to remove deficiencies in the current regulatory controls, which are being exploited by drug traffickers who divert iodine (in the form of iodine crystals and iodine tincture) for the illicit production of methamphetamine in clandestine drug laboratories. This NPRM proposes (1) the movement of

iodine from List II to List I; (2) a reduction in the iodine threshold from 0.4 kilograms to zero kilograms; (3) the addition of import and export regulatory controls; and (4) the control of chemical mixtures containing greater than 2.2 percent iodine.

This NPRM proposes regulatory controls that will apply to iodine crystals and iodine chemical mixtures that contain greater than 2.2 percent iodine. This regulation will therefore control iodine crystals and strong iodine tinctures/solutions (e.g., 7 percent iodine) that do not have common household uses and instead have limited application in livestock, horses and for disinfection of equipment. Household products such as 2 percent iodine tincture/solution and household disinfectants containing iodine complexes will not be adversely impacted by this regulation.

If finalized as proposed, persons conducting regulated transactions involving iodine would need to be registered with the DEA, would be subject to import/export notification requirements of the CSA, and would be required to maintain records of all regulated transactions involving iodine regardless of size.

**DATES:** Written comments must be postmarked, and electronic comments must be sent, on or before October 10, 2006.

**ADDRESSES:** To ensure proper handling of comments, please reference "Docket No. DEA-257P" on all written and electronic correspondence. Written comments via regular mail should be sent to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters,

Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be sent directly to DEA electronically by sending an electronic message to [dea.diversion.policy@usdoj.gov](mailto:dea.diversion.policy@usdoj.gov).

Comments may also be sent electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this document is also available at the <http://www.regulations.gov> Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats. DEA will not accept any file format other than those specifically listed here.

**FOR FURTHER INFORMATION CONTACT:** Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537 at (202) 307-7183.

**SUPPLEMENTARY INFORMATION:**

**I. Background Information on Iodine**

Congress placed iodine in List II by amending Section 102(35) of the CSA (21 U.S.C. 802(35)) by passage of Public Law 104-237, the Comprehensive Methamphetamine Control Act of 1996 (MCA) on October 3, 1996. Iodine became a regulated chemical because of its use in the clandestine manufacture of the Schedule II controlled substances amphetamine and methamphetamine. Methamphetamine is the leading clandestinely manufactured controlled substance in the United States.

Faced with the growing threat of methamphetamine abuse in the United States and the ease with which methamphetamine is clandestinely

produced using iodine, the DEA is proposing to increase the regulatory controls on iodine in an effort to prevent the diversion of iodine to clandestine drug laboratories.

*Legitimate Uses of Iodine*

Iodine is important to the chemical and allied industries primarily as a chemical intermediate used to make new chemical products for industry and research. These products have application in sanitation (as disinfectants), animal feed, pharmaceuticals, as catalysts, heat stabilizers, and in various other industrial applications. Most iodine is consumed by industry. Those who purchase iodine for end use, whether they are individuals or businesses, would be subject to CSA chemical regulatory controls to the extent that they must present identification and provide other information that helps assure the seller that his or her proposed use of the chemical is legitimate. See 21 U.S.C. 830 and 21 CFR 1310.07.

Iodine has powerful bactericidal action and is used for disinfecting unbroken skin before surgery. Iodine also may be employed as a weak solution for the first-aid treatment of small wounds and abrasions.

The standard definition for iodine topical solutions, and other iodine containing products, is specified in the United States Pharmacopeia (U.S.P.). The U.S.P. lists two strengths of iodine solution and two strengths of iodine tincture. The U.S.P. specifies formulations for iodine topical solution, strong iodine solution, iodine tincture, and strong iodine tincture in the official monographs.

Commercially available iodine solutions and tinctures are summarized in the following table:

CONCENTRATION OF IODINE PRODUCTS PER 100 ML

	Iodine (gm.)	Sodium Iodide (gm.)	Potassium Iodide (gm.)
Iodine Topical (w/ water) .....	1.8-2.2	2.1-2.6	.....
Strong Iodine (w/ water) .....	4.5-5.5	.....	9.5-10.5
Iodine Tincture (w/ alcohol @ 44-50%) .....	1.8-2.2	2.1-2.6	.....
Strong Iodine Tincture (w/ alcohol @ 82.5-88.5%) .....	6.8-7.5	.....	4.7-5.5

As shown on the table, the solutions are formulated in two concentrations of iodine. They are specifically named as iodine topical solution and strong iodine solution. Iodine topical solution two percent U.S.P. is defined as having in each 100 ml, not less than 1.8 grams and not more than 2.2 grams of iodine, and not less than 2.1 grams and not

more than 2.6 grams of sodium iodide. Only water is used as the solvent. Strong iodine solution U.S.P. contains in each 100 ml, not less than 4.5 grams and not more than 5.5 grams of iodine and not less than 9.5 grams and not more than 10.5 grams of potassium iodine.

The U.S.P. defines iodine tincture as containing, in each 100 ml, not less than 1.8 grams and not more than 2.2 grams of iodine, and not less than 2.1 grams and not more than 2.6 grams of sodium iodide. The same weight amounts of iodine and sodium iodide are used as in the iodine topical solution except that alcohol is used in 44 to 50 percent

concentration. The target concentration of iodine is 2 percent. Strong iodine tincture is defined as containing, in each 100 ml, not less than 6.8 grams and not more than 7.5 grams of iodine and not less than 4.7 grams and not more than 5.5 grams of potassium iodide. The alcohol content is between 82.5 and 88.5 percent. The target iodine concentration is 7 percent.

Iodine two percent tincture and solution U.S.P. are sold at a wide variety of retail outlets and have household application as antiseptic and antimicrobial products. These products will not become regulated under the proposed regulation. In contrast, however, iodine crystals and iodine chemical mixtures containing over 2.2 percent iodine have no household use and are available only from specialty retailers. Iodine solutions (in excess of 2.2 percent iodine) are used as an antiseptic in the care of livestock and horses and as disinfectants for equipment and areas where livestock are kept. Some iodine solutions are used in saltwater aquariums, to test for the presence of starch, and as stains in some laboratory tests. This NPRM proposes regulating these chemical mixtures, but provides for the possibility of exemption as discussed later in this rule.

Iodine crystals have also been historically used by campers to purify water. Today, however, most of the water treatment products available to campers utilize iodide salts and are not the subject of this regulation. DEA, however, has identified two marketed products that contain iodine for water purification. Under this NPRM, these products would be subject to control.

There are other iodine containing products that have household use and are widely sold in retail settings. Iodine products classified as iodophors consist of iodine complexed with surfactant compounds (e.g. poloxamer-iodine complex) or with nonsurfactant compounds (e.g. polyvinyl pyrrolidone-iodine complex (povidone-iodine)). These complexes allow the iodine to be continually delivered. Such complex solutions in water or alcohol are better tolerated than iodine tincture and solutions with comparable efficacy. Considering the necessary time of application and the correct dilution, these complexes are used for general disinfection, hand disinfection, as well as for skin disinfection prior to surgery or venipuncture. Some of these iodine complexes are also used for the treatment of burns and of different skin lesions. Since these complex products do not have applicability as a source of iodine at clandestine drug laboratories,

DEA is proposing that these products be specifically exempted in 21 CFR 1310.12(d)(4). This provision would be automatically exempt from CSA controls "Iodine products classified as iodophors which exist as an iodine complex to include poloxamer-iodine complex, polyvinyl pyrrolidone-iodine complex (i.e. povidone-iodine), undecoylium chloride iodine, nonylphenoxypoly (ethyleneoxy) ethanol-iodine complex, iodine complex with phosphate ester of alkylaryloxy polyethylene glycol, and iodine complex with ammonium ether sulfate/polyoxyethylene sorbitan monolaurate."

DEA is aware that the element iodine is a constituent in certain pharmaceutical products (e.g. potassium iodide and others) sold over-the-counter or pursuant to a prescription. Potassium iodide is available for use in the event of a nuclear incident to protect the thyroid gland of exposed individuals. The element iodine is also a constituent in products sold as radioisotopes (e.g. radioactive iodine) which find widest use in the treatment of hyperthyroidism and in the diagnosis of certain disorders (e.g. thyroid dysfunction). The greatest use has been made of sodium iodide I<sup>131</sup>. DEA is also aware of other radiolabeled material, such as sodium iodide I<sup>123</sup>, which is available for scanning/imaging purposes in disease diagnosis. Note that these iodide compounds are not the subject of this NPRM. As such, the proposed regulatory controls will not apply to any of these iodide salts or radiolabeled iodine. Additionally, these proposed regulatory controls will not apply to any iodide material commonly dispensed pursuant to a prescription. Instead, this NPRM is limited only to the regulation of iodine crystals and chemical mixtures that contain iodine in the form of the iodine tinctures and iodine solutions described above.

This NPRM proposes regulatory controls that will apply to iodine crystals and iodine chemical mixtures that contain greater than 2.2 percent iodine. The vast majority of products having household application will not be adversely impacted by this regulation.

#### *Why Traffickers Use Iodine*

Due to the regulatory controls placed on the listed chemical hydriodic acid, drug traffickers began using iodine as a substitute chemical in the illicit production of methamphetamine and amphetamine, both Schedule II controlled substances. Hydriodic acid became a regulated chemical upon enactment of the Chemical Diversion and Trafficking Act of 1988 (Pub. L.

100-690). Hydriodic acid, like iodine, was initially regulated as a List II chemical. Hydriodic acid was reclassified as a List I chemical by enactment of the Crime Control Act of 1990 (Pub. L. 101-647).

The Domestic Chemical Diversion Control Act of 1993 (DCDCA) (Pub. L. 103-200) required that handlers of List I chemicals be registered. This increased regulatory control and made it more difficult for traffickers to acquire hydriodic acid. Faced with this difficulty, traffickers began to substitute iodine for hydriodic acid for the illicit production of methamphetamine and amphetamine.

Iodine is commonly used with the List I chemicals phosphorus or hypophosphorous acid and ephedrine or pseudoephedrine to manufacture methamphetamine, which is now the most prevalent method used by traffickers. The List I chemicals phenylpropanolamine or norpseudoephedrine can be made into amphetamine by the same method.

#### *Current Regulatory Controls on Iodine and Need for Increased Regulation*

In response to the increased use of iodine in clandestine drug laboratories, Congress controlled iodine as a List II chemical by amending Section 102(35) of the CSA (21 U.S.C. 802(35)) by passage of Public Law 104-237, the Comprehensive Methamphetamine Control Act of 1996 (MCA) on October 3, 1996.

Although iodine became subject to CSA chemical regulatory controls, traffickers have exploited certain deficiencies in these controls to divert iodine. Only certain domestic distributions are regulated transactions, and distributions below the 0.4 kilogram cumulative threshold (about one pound), within a calendar month, are not regarded as regulated transactions. Import and export transactions of iodine are not regulated, regardless of the quantity distributed. Additionally, because iodine is a List II chemical, handlers of iodine are not required to register with DEA. These loopholes have been exploited by drug traffickers and the businesses that supply them.

While the regulatory controls placed on iodine apply to iodine crystals, they have not pertained to iodine tinctures (which are considered chemical mixtures). Drug traffickers are currently circumventing CSA regulatory controls via the diversion of iodine tinctures. Traffickers have learned that the tinctures can serve as a ready source of iodine crystals when the tincture is subjected to the appropriate chemical reaction.

Existing regulations pertaining to iodine have proved to be inadequate to prevent diversion. Traffickers have been able to make undocumented purchases of iodine crystals (up to the existing threshold of 0.4 kilograms), make unlimited purchases of iodine tincture, and make undocumented import and export shipments of iodine. Additionally, because iodine is a List II chemical and distributors are not registered, it is difficult for DEA to identify all handlers of regulated material.

This NPRM proposes changes to the regulatory control of iodine in an effort to prevent the diversion of iodine for the illicit production of methamphetamine and amphetamine.

#### *Use of Iodine in Clandestine Drug Laboratories*

Iodine is a major chemical used in the illicit manufacture of methamphetamine and amphetamine. DEA's El Paso Intelligence Center (EPIC) maintains the official U.S. database of clandestine laboratories seized by Federal, State, and local law enforcement. As reported by EPIC, the number of clandestine methamphetamine laboratories using iodine was 2243, 2774, 4015, 4326, and 4904 for the calendar years 1999, 2000, 2001, 2002, and 2003, respectively. The number of laboratories reported to have used hydriodic acid over the same years was 644, 661, 735, 746, and 650, respectively. The increased use of iodine over hydriodic acid is seen going back to 1997, the earliest year that such information is available from EPIC's database.

The data for clandestine labs seized only by federal authorities show similar trends. STRIDE (System to Retrieve Information on Drug Evidence) is a DEA maintained database that includes reports of clandestine laboratory seizures made primarily by DEA. STRIDE reports that between 1990 and 1994, the number of clandestine laboratories that used hydriodic acid was much greater than those using iodine. Although hydriodic acid became a List I chemical in 1990, handlers were not required to register until 1993. By 1994, the number of DEA cases involving iodine surpassed the number for hydriodic acid, and this has continued to the present time. This trend indicates that regulatory controls governing the handling of hydriodic acid were effective in causing traffickers to seek an alternate to hydriodic acid, in the form of iodine, which had less stringent regulatory controls.

Commercial iodine chemical mixtures, reported as iodine tincture, have also been identified as significant

sources of iodine in clandestine methamphetamine laboratories. The number of iodine tincture seizures reported by EPIC has steadily increased from 71 seizures in calendar year 1999, 397 seizures in calendar year 2000, 1154 seizures in calendar year 2001, 1679 seizures in calendar year 2002, to 2252 seizures in calendar year 2003. Thus, iodine and iodine tincture have increasingly been used as chemicals in the illicit production of controlled substances within the United States.

#### *International Scope of Problem*

The illicit production of methamphetamine is also an international problem. Mexican drug trafficking organizations operating out of Mexico and California began to dominate the illicit production and distribution of methamphetamine in the United States around 1994. This followed years of control by independent, regional outlaw motorcycle gangs, supplemented by numerous independent, smaller-scale producers. Mexican organizations now produce and supply the majority of the methamphetamine illicitly available in the United States, using large-scale laboratories based in Mexico and the Southwestern United States. Outlaw motorcycle gangs and small independent producers remain active in domestic methamphetamine production, but not on the same scale as the Mexican traffickers. The Mexican organizations' ready access to essential chemicals on the international market has greatly facilitated their ability to produce large amounts of methamphetamine.

Seizures along the Mexican border illustrate the need for import/export control of iodine. The United States Bureau of Immigration and Customs Enforcement (ICE) reports seizures at Southern California ports of entry. In Calendar Year 2001, ICE reported that there were 26 seizures of iodine totaling 2140 kilograms. In Calendar Year 2002, there were 20 seizures totaling 1605 kilograms, and in Calendar Year 2003, there were 19 seizures totaling 971 kilograms. The smuggling of iodine illustrates the need for additional international controls. Although iodine seizures have been declining, these quantities remain significant. The decrease may reflect a changing pattern of production by large methamphetamine manufacturing organizations, which have shifted some production, via large capacity clandestine labs, from California to Mexico.

## **II. Proposed Changes to the Regulation of Iodine**

### *Moving Iodine Into 21 CFR 1310.02(a) (List I)*

The Controlled Substances Act (CSA) and its implementing regulations, specifically 21 U.S.C. 802(35) and 21 CFR 1310.02(c), provide the Attorney General with the authority to specify, by regulation, the addition or deletion of any chemicals as listed chemicals if they are used in the manufacture of a controlled substance in violation of the CSA. This authority has been delegated to the Administrator of DEA by 28 CFR 0.100 and redelegated to the Deputy Administrator by 28 CFR 0.104 Appendix to Subpart R Section 12.

The definition in 21 CFR 1300.02(b)(19), defines "List II chemical" as a chemical, other than a List I chemical, specifically designated by the Administrator in 21 CFR 1310.02(b), that "is used in manufacturing a controlled substance in violation of the Act." 21 CFR 1300.02(b)(18) defines the term "List I chemical" to mean "a chemical specifically designated by the Administrator in 21 CFR 1310.02(a) \* \* \* that \* \* \* is used in manufacturing a controlled substance in violation of the Act and is important to the manufacture of a controlled substance."

The DEA is proposing to remove iodine from 21 CFR 1310.02(b) (List II) and to place it in 1310.02(a) (List I) because, based on the information provided above, iodine is a chemical that is important to the manufacture of the controlled substances methamphetamine and amphetamine. If placed in List I, 21 U.S.C. 822(a)(1) requires that persons who distribute iodine must be registered with DEA. Based on its experience with hydriodic acid and other List I chemicals, DEA believes that List I regulatory controls for iodine will help curtail its widespread use in the clandestine manufacture of methamphetamine and amphetamine. List I regulatory controls would dictate that handlers of iodine, including persons who manufacture, import, export, or distribute iodine, would be required to register with DEA. Retail and wholesale outlets that sell iodine crystals and covered tinctures/solutions would also be required to register.

Prior to receiving a DEA chemical registration, handlers are subject to a pre-registration investigation by DEA in order to determine the legitimacy of the business per criteria specified under 21 U.S.C. 823(h). Registration also provides the DEA with the identity of all businesses that handle List I chemicals.

A business that sells a List I chemical in violation of the law or regulations can have its registration revoked and be prevented from handling List I chemicals. The registration requirement is a disincentive to casual handlers of iodine, who might be used unwittingly by methamphetamine cooks.

#### *Regulation of Import and Export Transactions*

When iodine was controlled as a listed chemical by the Comprehensive Methamphetamine Control Act of 1996, the bill specifically exempted it from import and export controls. The MCA, however, also explicitly provided that Congress was not limiting the authorization of the Attorney General to impose the import and export provisions of the CSA on iodine. See Public Law 104-237, Sec. 204. Because of the international flow of iodine in the production and distribution of methamphetamine, DEA has determined that the addition of import and export controls on iodine is necessary. Therefore, 21 CFR 1310.08 is proposed to be amended to remove imports and exports of iodine as excluded transactions. Thus, iodine would become subject to the import and export notification provisions of the CSA.

#### *Elimination of the Iodine Threshold*

Transactions involving listed chemicals—including cumulative transactions in a single calendar month—below a quantity threshold, specified pursuant to 21 U.S.C. 802(39)(A), are excluded from the definition of “regulated transaction.” Currently, the threshold for iodine is 400 grams (0.4 kilograms). Thresholds denote a quantity below which regulation is not necessary for law enforcement purposes. However, DEA has determined that the regulation of all transactions of regulated iodine products is necessary in order to prevent diversion. Thus, DEA is proposing to remove the threshold for iodine. Therefore, all transactions of regulated iodine products would be considered regulated transactions regardless of size.

Household uses for the regulated iodine products proposed to be controlled as List I chemicals by this NPRM are very limited. These regulated iodine materials (i.e. iodine crystals and tinctures and solution of greater than 2.2 percent iodine) are used in specialized applications, such as antiseptics in the care of large animals, sanitation for dairies, chemical lab tests, and as a source of iodine in saltwater aquariums. For some of the uses, two ounces can last several months.

DEA considered adjusting the threshold to exclude transactions of two ounces or below from regulatory control. However, the most common smaller size iodine container that DEA identified in clandestine laboratories is two ounces, which contains 56 grams of iodine. DEA estimates that 56 grams of iodine can produce over 50 grams of pure methamphetamine. Therefore, DEA determined that a 2-ounce quantity is useful to traffickers and should be regulated.

### **III. Proposed Regulation To Identify Exempt Iodine Chemical Mixtures**

#### *Definition of Chemical Mixtures*

The CSA (21 U.S.C. 802(40)) defines the term “chemical mixture” as “a combination of two or more chemical substances, at least one of which is not a List I chemical or a List II chemical, except that such term does not include any combination of a List I chemical or a List II chemical with another chemical that is present solely as an impurity.” Therefore, a chemical mixture contains any one or more listed chemical along with any number of non-listed chemicals.

DEA does not consider a chemical mixture to mean the combination of a listed chemical with an inert carrier. An inert carrier can be any chemical that does not interfere with the listed chemical’s function but is present to aid in the delivery of the listed chemical so it can be used in some chemical process. Examples include, but are not limited to, solutions of listed chemicals such as methylamine in water or hydrogen chloride dissolved in water or alcohol.

Iodine tinctures and solutions are considered chemical mixtures because they require the addition of iodine and an iodide salt into a water or water/alcohol solution. It is not simply iodine dissolved in an inert carrier. These iodine tinctures and solutions are therefore chemical mixtures in the regulatory sense.

#### *Regulation of Chemical Mixtures*

The Chemical Diversion and Trafficking Act of 1988 (Pub. L. 100-690)(CDTA) created the definition of “chemical mixture” (21 U.S.C. 802(40)), and exempted chemical mixtures from regulatory control. The CDTA established 21 U.S.C. 802(39)(A)(v) to exclude “any transaction in a chemical mixture” from the definition of a “regulated transaction.” This exemption of all chemical mixtures provided traffickers with an unregulated source for obtaining listed chemicals for use in the illicit manufacture of controlled substances.

The Domestic Chemical Diversion Control Act of 1993 (DCDCA), enacted in April 1994 subjected chemical mixtures containing listed chemicals to CSA regulatory requirements, unless specifically exempted by regulation. These requirements include recordkeeping, reporting, and security for all regulated chemical mixtures with the requirement added by the DCDCA of registration for handlers of regulated List I chemical mixtures.

The DCDCA also amended 21 U.S.C. 802(39)(A)(v) to provide the Attorney General with the authority to establish regulations exempting chemical mixtures from the definition of a “regulated transaction.” However, exclusion from this definition can only be made “based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered.” DEA has established the following three-tiered approach to identify which chemical mixtures qualify for automatic exemption: (1) The mixture contains a listed chemical at or below an established concentration limit; or (2) the mixture falls within a specifically defined category; or (3) the manufacturer of the mixture applies for and is granted a specific exemption for the product (68 FR 23195, May 1, 2003.)

This NPRM proposes regulations that identify which iodine chemical mixtures qualify for automatic exemption because they meet the requirements of 21 U.S.C. 802(39)(A)(v). Once finalized, those iodine chemical mixtures that do not qualify for automatic exemption would be regulated chemicals, unless the manufacturer has been granted specific exemption for their product(s) by DEA via an application process (21 CFR 1310.13).

#### *Federal Register Publications Addressing Iodine Chemical Mixtures*

Regulations regarding the exemption of chemical mixtures, including those containing iodine, were initially proposed by DEA on October 13, 1994, as part of its proposed regulations to implement the DCDCA (59 FR 51888). In response to industry concerns, the proposed regulations regarding the exemption process for chemical mixtures were withdrawn on December 9, 1994 (59 FR 63738). DEA proposed new regulations regarding the exemption of chemical mixtures by publishing a new NPRM entitled “Exemption of Chemical Mixtures” in

the **Federal Register** (63 FR 49506, September 16, 1998).

Iodine chemical mixtures, including iodine tinctures and solutions, were not a serious concern to law enforcement at the time DEA was drafting the 1998 proposed regulations regarding chemical mixtures. Therefore, a 20 percent concentration limit was proposed for iodine.

In addition to information obtained from DEA investigations, open sources, and communication with the regulated community, DEA also relies on comments to the NPRM to help establish final regulations. Comments to the NPRM "Exemption of Chemical Mixtures" informed DEA that seven percent iodine chemical mixtures are being used in the illicit manufacture of methamphetamine. Based on this information and the mounting evidence gathered by DEA that iodine is being extracted from these chemical mixtures for illicit purposes, DEA determined that the proposed concentration limit of 20 percent for iodine is too high compared to the concentration of iodine contained in mixtures being diverted by traffickers. Therefore, the final chemical mixture rulemaking published on December 15, 2004 [69 FR 74957], withdrew the iodine portion. Instead, DEA decided to address the iodine chemical mixture issue separately and is doing so under this NPRM. Since seven percent iodine tincture and solutions are the predominant iodine-containing chemical mixtures diverted by traffickers, DEA has determined that these chemical mixtures should be subject to CSA chemical regulatory controls. Two percent iodine tincture and solutions are also diverted, but DEA has not documented the frequent diversion of these materials at clandestine laboratories. Therefore, DEA does not intend to regulate the two percent iodine tincture or solution at this time.

DEA is also aware of other materials that contain iodine. Examples include iodophor complexes such as poloxamer-iodine and povidone-iodine. These materials are not of concern to DEA as a source of iodine for clandestine laboratories. This NPRM proposes that these materials be specifically exempted from CSA chemical regulatory controls pursuant to 21 CFR 1310.12 by adding a new paragraph (d)(4) which will exempt "Iodine products classified as iodophors which exist as an iodine complex to include poloxamer-iodine complex, polyvinyl pyrrolidone-iodine complex (i.e. povidone-iodine), undecoylium chloride iodine, nonylphenoxypoly (ethyleneoxy) ethanol-iodine complex, iodine complex

with phosphate ester of alkylaryloxy polyethylene glycol, and iodine complex with ammonium ether sulfate/polyoxyethylene sorbitan monolaurate."

#### *Exemption by Application Process*

DEA recognizes that the 2.2 percent iodine concentration limit and category exemption criteria cannot identify all mixtures that should receive exemption status. DEA has implemented an application process to exempt additional mixtures (21 CFR 1310.13). This application process was finalized in the **Federal Register** Notice (68 FR 23195) published May 1, 2003. Under the application process, manufacturers may submit an application for exemption for those mixtures that do not qualify for automatic exemption. Exemption status can be granted if DEA determines that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and the listed chemical cannot be readily recovered (i.e., it meets the conditions in 21 U.S.C. 802(39)(A)(v)). An application may be for a single or a multiple number of formulations. All chemical mixtures which are granted exemption via the application process will be listed in 21 CFR 1310.13(i).

#### *Specific Requirements That Will Apply to Regulated Chemical Mixtures Containing Iodine*

DEA is proposing that a chemical mixture that is regulated because it contains greater than 2.2 percent iodine will be treated as a List I chemical. Therefore, the same requirements for registration, records and reports, imports/exports (except that pertaining to 21 U.S.C. 957), and administrative inspection, as outlined below, apply to handlers of regulated chemical mixtures.

#### *Requirements That Apply to Regulated List I Chemicals and Their Regulated Chemical Mixtures*

In light of the proposal to place iodine in 21 CFR 1310.02(a) (List I) and to control chemical mixtures containing greater than 2.2 percent iodine, the following requirements for List I chemicals are outlined. Chemical mixtures that are not exempt or excluded under any provision of these regulations, either by concentration limit, general category or as a result of DEA action on a specific application for exemption, shall be considered regulated chemical mixtures. Persons interested in handling List I chemicals, including regulated chemical mixtures containing List I chemicals, must comply with the following:

1. *Registration.* Any person who manufactures or distributes a List I chemical, or proposes to engage in the manufacture or distribution of a List I chemical, must obtain a registration pursuant to the CSA (21 U.S.C. 822). Regulations describing registration for List I chemical handlers are set forth in 21 CFR part 1309.

Separate registration is required for distribution, importing, and exporting. Different locations operated by a single entity require separate registration if any location is involved with the distribution, import, or export of a List I chemical. Any person distributing, importing, or exporting a regulated List I chemical mixture is subject to the registration requirement under the CSA. DEA recognizes, however, that it is not possible for persons who distribute, import, or export iodine, upon its placement in List I, to immediately complete and submit an application for registration and for DEA to issue registrations immediately for those activities. Therefore, to allow continued legitimate commerce in iodine, DEA is proposing to establish in 21 CFR 1310.09 a temporary exemption from the registration requirement for persons desiring to distribute, import, or export iodine, provided that DEA receives a properly completed application for registration on or before 60 days from the date of publication of a final rule. The temporary exemption for such persons will remain in effect until DEA takes final action on their application for registration.

The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, will remain in effect. Additionally, the temporary exemption does not suspend applicable federal criminal laws relating to iodine, nor does it supersede state or local laws or regulations. All handlers of iodine must comply with their state and local requirements in addition to the CSA and other federal regulatory controls.

2. *Records and Reports.* The CSA (21 U.S.C. 830) requires that certain records be kept and reports be made that involve listed chemicals. Regulations describing recordkeeping and reporting requirements are set forth in 21 CFR Part 1310. A record must be made and maintained for two years after the date of a transaction involving a listed chemical, provided the transaction is a regulated transaction.

Each regulated bulk manufacturer of a regulated mixture shall submit manufacturing, inventory and use data on an annual basis (21 CFR 1310.05(d)). Bulk manufacturers producing the

mixture solely for internal consumption, e.g., formulating a non-regulated mixture, are not required to submit this information. Existing standard industry reports containing the required information are acceptable, provided the information is readily retrievable from the report.

Title 21 CFR 1310.05 requires that each regulated person shall report to DEA any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the CSA.

3. *Import/Export.* All imports/exports of a listed chemical shall comply with the CSA (21 U.S.C. 957 and 971). Regulations for importation and exportation of List I chemicals are described in 21 CFR 1313. Separate registration is necessary for each activity (21 CFR 1309.22).

4. *Security:* All applicants and registrants shall provide effective controls against theft and diversion of chemicals as described in 21 CFR 1309.71.

5. *Administrative Inspection.* Places, including factories, warehouses, or other establishments and conveyances, where regulated persons may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of a regulated chemical/chemical mixture or where records relating to those activities are maintained, are controlled premises as defined in 21 CFR 1316.02(c). The CSA (21 U.S.C. 880) allows for administrative inspections of these controlled premises as provided in 21 CFR 1316 Subpart A.

The goal of this rulemaking is to deny traffickers unregulated access to iodine while minimizing the burden on legitimate industry. Persons who obtain a regulated chemical but do not distribute the chemical are end users. End users are not subject to CSA chemical regulatory control provisions such as registration or recordkeeping requirements. Some examples of end users are those who chemically react iodine and change it into a non-listed chemical, formulate iodine into an exempt chemical mixture or consume it in some industrial process, or use it for water treatment or sanitation.

### *Regulatory Certifications*

#### Regulatory Flexibility and Small Business Concerns

The Regulatory Flexibility Act (5 U.S.C. 600–612) requires agencies to determine whether a proposed rule will

have a significant economic impact on a substantial number of small entities (SEISNOSE). If an agency finds that there is a SEISNOSE, the agency must consider whether alternative approaches could mitigate the impact on small entities. The size criteria for small entities are defined by the Small Business Administration (SBA) in 13 CFR 121.201. As discussed below, DEA has researched the production and marketing of iodine to determine whether the proposed rule could have a SEISNOSE.

The majority of firms potentially subject to the proposed rule are considered small entities under the Small Business Administration definitions for the affected sectors.<sup>1</sup> The only firms for which the rule would have a significant economic impact are those with revenues or sales of less than about \$100,000 a year; the initial registration time and fee would represent one percent of their revenues. Economic Census data indicate that even the smallest firms in the affected sectors have sales well above the \$100,000 a year level.<sup>2</sup> Consequently, DEA concludes the proposed rule is unlikely to have a significant economic impact on a substantial number of small entities. DEA recognizes, however, that there may be a very small number of firms marketing specialty products that may be adversely affected because they offer no other products. DEA is seeking comment on whether there could be a significant economic impact on a substantial number of small entities.

#### *Initial Regulatory Flexibility Analysis*

##### Potential Universe of All Affected Entities

In broad terms, three companies produce iodine in bulk and distribute it to other companies that either use it in chemical manufacturing, purify it and repackage it, or simply repackage it for further sale. There may be a third step at the manufacturing level where iodine crystals or solutions are purchased in bulk from companies that purified it and are then repackaged for retail sales. Although some iodine products are likely to follow the normal distribution chain of manufacturer to wholesaler to retailer, others do not. Most chemical manufacturers are likely to purchase iodine directly from other manufacturers. Some of the “manufacturers” of iodine products appear to sell both to retail outlets and directly to consumers. Many of the

manufacturers offer catalogue and Internet sales.

In addition to the three manufacturers that produce iodine as a bulk chemical, DEA identified 43 firms that have developed material safety data sheets (MSDSs) for iodine products that would be covered by the proposed rule; five of these are already registered as chemical manufacturers. It is not possible to determine whether the DEA registrants produce iodine at registered locations or whether any of the 43 firms produce iodine products at multiple locations.<sup>3</sup> Eight other chemical manufacturers list iodine as a product; one of these is registered as a chemical importer and exporter. There may be other firms producing iodine for industrial uses whose MSDSs are not publicly available.<sup>4</sup> DEA is seeking comments on whether such information exists that could help in further identifying the entities the rule will potentially impact.

DEA identified 15 other manufacturers of iodine products. It is likely that these firms purchase iodine crystals and repackage them or purchase crystals or concentrated solutions and dilute them prior to repackaging. Because some of these firms may operate at multiple locations and because it is likely that not all manufacturers have been identified, the analysis estimates that there are between 75 and 90 manufacturers of iodine products.

Iodine products may be handled by a variety of wholesalers. The livestock and science kit products could be handled by drug, chemical, or agricultural wholesalers. Current Duns data indicate that 267 wholesalers distribute animal medicines; these are the wholesalers most likely to be distributing iodine products for horses. Some of these distributors may already be registered to handle controlled substances. The 2002 Economic Census for the wholesale industry indicated that about 1,115 agricultural wholesalers/retailers may carry tack shop materials. It is possible that other chemical wholesalers may be providing iodine to manufacturers of iodine products, but DEA considers it more likely that these manufacturers purchase iodine in bulk directly from chemical manufacturers. DEA has not identified

<sup>3</sup> The CSA requires that each location where a controlled substance or List I chemical is handled have a separate registration.

<sup>4</sup> OSHA requires the manufacturer of a chemical to develop an MSDS. Other firms that package or distribute the chemical must provide the MSDS, but generally use the MSDS acquired from the original manufacturer. MSDSs must be made available to employees and to firms that purchase the chemical, but publishing them for the general public is not required.

<sup>1</sup> See Table 3 for the SBA size standards for affected entities.

<sup>2</sup> See Table 3 for the average revenue for the smallest firms.

any data that indicate the number of wholesalers who distribute aquarium chemicals, but as there appears to be only one such covered product marketed specifically for aquariums (Kent Marine Lugol solution), it may not be handled by a large number of wholesalers. Similarly, Census classifications do not cover camping goods or science kits at the wholesale level. The Web site for Polar Pure lists only two wholesale distributors. Overall, DEA estimates that the number of wholesalers may range from 300 to 1,400. DEA seeks comments on such approximation.

At the retail level, tinctures are sold by tack shops; 2005 Duns data list about 4,080 such retailers. Agricultural retailers may also sell these products for livestock, but these are included in the wholesale estimate because the Census combines agricultural wholesalers and retailers in a single classification. Veterinarians may also sell the products, but would not be subject to registration because they are already registered to handle controlled substances.

The 2002 Census indicated that there were 5,039 pet stores that sold aquarium supplies. A check of two large chains, which have more than 1,400 stores between them, indicates that although both stock some iodine supplements, neither stock Lugol's solution. DEA estimates that between one percent and five percent of pet stores would carry iodine either as crystals or strong tinctures. Although nursery/garden retailers and building supplies/garden retailers sell pet supplies, it is unlikely that any of them carry covered iodine products.

The Census listed about 1,524 sporting good specialty stores that carry camping supplies. DEA has included 5 percent to 10 percent of them. Mail order and Internet outlets sell all of the iodine products. DEA has no basis for estimating how many of these outlets

sell iodine products without being associated with either wholesale or retail outlets that would be included in other counts. DEA has included 50 to 100 of these, but recognizes that these numbers could be either too low or too high. Table 1 presents the estimated low to high range of potentially regulated entities.

TABLE 1.—POTENTIALLY REGULATED UNIVERSE

	Low	High
New manufacturers .....	75	90
Wholesalers .....	300	1,400
Tack shops .....	2,040	4,080
Pet supplies .....	50	250
Camping supplies .....	75	150
Other .....	50	100
<b>Total .....</b>	<b>2,590</b>	<b>6,070</b>

The estimates in Table 1 represent the number of outlets that may currently handle products that would be subject to the proposed rule. In estimating the number of new registrants, however, DEA has to consider whether these outlets will elect to register and continue selling the products. For almost all of the entities listed in Table 1, iodine products are a minor item. The manufacturers, wholesalers, and mail order/Internet suppliers routinely collect the information DEA would require under the proposed rule; this information is necessary for them to ship the product. Other than the registration fees, the rule would not impose a burden on them although it is possible that some of these outlets may elect to drop iodine products rather than be subject to DEA rules.

Store retailers face a different situation. Not only are their revenues usually lower than those of manufacturers and wholesalers, but they are also unlikely to routinely collect all

of the information DEA requires for these transactions. Because the cost of the iodine products is low (\$5 to \$20), many of the transactions may be in cash. To teach their clerks what is required, explain to customers why the information is needed, transcribe the data, and maintain the record may be too great a burden for a specialty product that is unlikely to be in high demand and for which reasonable substitutes exist. DEA expects, therefore, that most store retailers will stop carrying these products and direct their customers to substitutes or to mail order or Internet sources. This shift would, in turn, likely reduce the number of wholesale distributors handling the products. Table 2 provides a more likely estimate of the potential number of new registrants, but even these estimates are likely to be high because most wholesale and retail outlets may elect to avoid DEA regulation.

TABLE 2.—POTENTIAL NUMBER OF REGISTRANTS

	Low	High
New manufacturers .....	75	90
Chemical wholesalers .....	150	700
Other .....	50	100
<b>Total .....</b>	<b>275</b>	<b>890</b>

Small Entities Likely To Be Affected by This Rule

The SBA standards for the potentially affected sectors are shown in Table 3 as are the average sales or value of shipments (for manufacturers) for the smallest firms reported in the 2002 Economic Census:

TABLE 3.—SMALL BUSINESS STANDARDS FOR SECTORS

	Size standard	Average sales/smallest firms**
Inorganic chemical manufacturers .....	1,000 FTE* .....	\$4.25 million.
Pharmaceutical manufacturers .....	750 FTE .....	\$824,000.
Miscellaneous manufacturers .....	500 FTE.	
Chemicals wholesalers .....	100 FTE .....	\$1 million.
Sporting goods and pet stores .....	\$6.5 million .....	\$345,000 (sporting) \$274,000 (pet).
Electronic/mail order shopping .....	\$23 million .....	\$528,000 (electronic) \$497,000 (mail).

\* FTE is an abbreviation for Full Time Equivalent (Employees).

\*\* 1 to 4 FTE except for inorganic chemical, where data available only for 5–9 FTE.

Because of the size standards, it is highly likely that a substantial number of the firms that will be regulated will be considered small businesses. DEA has no information on the number of potentially regulated entities that would be classified as small and is seeking comment on this issue.

The three main manufacturers of iodine are large firms; two of the three are also foreign-owned and the third is a joint venture with foreign firms.

**Specific Requirements Imposed That Would Impact Small Entities**

Firms that handle iodine will be required to register with DEA. At present, the registration fee is \$595; the

reregistration fee is \$477. Each of the firms will also be required to become familiar with DEA's regulations, to maintain records of each sale, and to report to DEA on unusual sales and thefts/losses. Bulk manufacturers must file annual reports, but these reports already apply to iodine as a List II chemical, so impose no new burden. DEA specifies that normal business records may be used to meet the requirements of records of sales. Importers and exporters would be required to file an advance notification for each importation or exportation.

DEA estimates that it takes a firm a half hour to complete and submit a registration, which can be done online.

In addition, DEA estimates that it will take four hours to become familiar with the regulations that apply. DEA assumes that rule familiarization and registration will be done by managerial staff. The cost for initial compliance for firms in manufacturing, wholesale, and retail sectors is shown in Table 4. Wage rates are based on November 2004 BLS industry data and loaded with fringe and overhead. Fringe rates are based on BLS "Employer Costs for Employee Compensation—December 2005" for management for goods producing and service industries, as applicable. Overhead is loaded at 56 percent of compensation, based on the most recent Grant Thornton survey.

TABLE 4.—INITIAL COMPLIANCE COST PER FIRM

Sector	Wage rate	Total labor	Total cost with fee
Manufacturing .....	\$127	\$573	\$1,168
Wholesale .....	98	442	1,037
Retail .....	60	269	864
Mail order/Electronic .....	91	408	1,003

A comparison of the initial compliance costs in Table 4 with the annual revenues or sales of the smallest firms shown in Table 3 indicates that the costs do not approach one percent of sales or revenues of the smallest firms in each sector and, therefore, do not impose a significant economic burden on firms. The recurring costs for renewal are lower (a half hour of labor plus the reregistration fee). DEA estimates that completing the advance notification (Form 486) for imports and exports requires less than 15 minutes. DEA is seeking comments on these estimates.

**Reporting and Recordkeeping Requirements**

Firms subject to the rule will be required to maintain records of sales. The records required include the date of the sale; the name, quantity, and form of packaging of the chemical; the method of transfer; and the type of identification used by the purchaser and any unique number on that identification. Routine sales records for credit card or mail order sales will include the required information. Manufacturers and wholesalers, which normally sell products through purchase orders, will not have to create any additional records. As noted above, retailers that have cash sales would have to create new records if they continue to sell the products. Because these products represent such a small percentage of any store's sales and there

are products that can be substituted for them, DEA considers that it is unlikely that retailers will register and continue to sell iodine products.

Importers and exporters would have to file a Form 486 15 days in advance of any importation or exportation. If the importer meets the requirements to be a regular importer, the person must file the form on or before the date of importation, but does not require DEA approval. Similarly, exporters that have an established business relationship with a foreign customer need to file the form by the date of exportation.

**Alternatives**

Pursuant to the requirements of the RFA, DEA has evaluated alternatives to this proposed rule and determined that no reasonable alternatives exist. This NPRM proposes changes to the regulatory control of iodine in an effort to prevent the diversion of iodine for the illicit production of methamphetamine and amphetamine. Providing small businesses with alternatives and/or exemptions from the proposed rule would eliminate the regulatory objective behind the rule. DEA has proposed ways to lessen the regulations' economic impact on all entities covered by the rule. This NPRM proposes regulatory controls that will apply to iodine crystals and iodine chemical mixtures that contain greater than 2.2 percent iodine thereby eliminating the majority of products that use iodine from the requirements of this

regulation.<sup>5</sup> Also, this proposed rule allows manufacturers to seek exemption for additional mixtures of iodine that do not qualify for automatic exemption under 21 CFR 1310.13. DEA seeks comments on reasonable alternatives to this rule that will serve to lessen its impact on small businesses while maintaining the regulatory objective of regulating iodine crystals and strong tinctures and chemical mixtures containing over 2.2 percent iodine.

**Additional Impact Issues Raised**

DEA expects that most store retailers will elect not to sell iodine crystals or strong tinctures rather than registering and maintaining sales records. Most iodine products with household applications would not be subject to the rule. DEA considered whether the loss of product sales would have a significant economic impact on retailers. DEA will seek comment on this issue, but in general does not expect an impact. These products make up a very small part of the sales of any pet or sporting goods store. Eliminating the product line is unlikely to have a noticeable effect on sales even if customers continue to seek the products from on line or mail order sources. In most cases, customers will be able to purchase substitutes that are no more expensive, and in some cases, are less expensive. DEA, therefore, expects that

<sup>5</sup> See the section in this regulation on the legitimate uses of iodine.

the impact on sales at the retail level will be minimal.

The impact on manufacturers, with one possible exception, is also likely to be minimal. DEA's research indicates that the manufacturers who produce iodine tinctures and crystals for use with livestock and fish also produce and market the substitutes. If sales of these iodine products decline, it is likely that the sales of substitutes will increase. Many of these companies also sell directly to customers through catalogues and on line. Because the sales records required under the rules are the same records the companies create for mail order or on line sales, there would be no burden beyond registration for these firms to meet these requirements. The one exception is a small company that apparently markets a single product using iodine crystals. To the extent that in-store sales of its product decline and are not replaced with on line sales, the rule could have a significant impact on the firm.

#### *Executive Order 12866*

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with Executive Order 12866, Section 1(b). It has been determined that this rule is a "significant regulatory action". Therefore, this action has been reviewed by the Office of Management and Budget.

This proposed rule would impose new regulatory requirements on businesses choosing to handle iodine tinctures, iodine crystals and chemical mixtures containing iodine including registration with DEA, recordkeeping, the submission of certain reports regarding import and export transactions to DEA, and security requirements. DEA believes that the requirement of recordkeeping for regulated transactions involving iodine tinctures, crystals and chemical mixtures containing iodine are already accomplished through the maintenance of business records as a usual and customary business practice. Likewise, security occurs as a normal part of good business practice. DEA believes these new regulatory requirements are necessary to prevent the diversion of iodine to the illicit production of methamphetamine and amphetamine.

Based on the costs and number of regulated entities discussed in the previous section, DEA estimates that the total cost of initial compliance with the proposed rule would range from \$293,000 to \$931,000; annual costs thereafter could range from \$146,000 to \$469,000.

#### *Costs of Methamphetamine Abuse/ Benefits of Rulemaking*

Methamphetamine is the most prevalent controlled substance illicitly synthesized in the United States. The clandestine manufacture, distribution and abuse of methamphetamine are serious public health problems. Despite considerable efforts by Federal, state, and local law enforcement, the illicit trafficking and abuse of methamphetamine continue.

According to the 2003 National Survey on Drug Use and Health, approximately 12.3 million Americans ages 12 and older reported trying methamphetamine at least once during their lifetimes, representing 5.2% of the population ages 12 and older. Approximately 1.3 million (0.6%) reported past year methamphetamine use and 607,000 (0.3%) reported past month methamphetamine use. In 2004, the Monitoring the Future Study which assesses the extent of drug use among adolescents (8th, 10th and 12th graders) indicated that 6.2 percent of high school seniors reported some prior lifetime use of methamphetamine, statistically unchanged from 2003. Some prior lifetime use of methamphetamine was reported by 5.3 percent of 10th grade students.

The consequences of methamphetamine use appear to be trending upward. The Drug Abuse Warning Network (DAWN) data indicate that the estimated number of emergency department (ED) mentions for methamphetamine increased steadily, from 10,447 in 1999, to 13,505 in 2000, to 14,923 in 2001, and to 17,696 in 2002, although the percentage increase from 2001 to 2002 is not statistically significant. Similarly, the estimated rate of ED mentions per 100,000 population has increased from 4 in 1999, to 5 in 2000, to 6 in 2001, to 7 in 2002. Statistically significant increases in methamphetamine ED mentions were reported by San Francisco (19.4%), Seattle (35.3%), and Atlanta (39.0%) between 2001 and 2002. (Note: A visit to the emergency department is referred to as an episode, and every time a drug is involved in an episode it is counted as a mention.) According to the DAWN 2002 mortality data, areas with the highest number of methamphetamine drug-related deaths were those in the Midwest and Western areas, including Phoenix (132), San Diego (81), Las Vegas (72), Dallas (46), and San Francisco (38).

The El Paso Intelligence Center (EPIC) reports that there were 10,349 methamphetamine laboratories seized in the U.S. in FY 2004 (as reported through April 12, 2006). Another rising cost of

the methamphetamine problem is the cost of cleaning up the toxic side effects of methamphetamine production. Clandestine laboratory sites must be remediated and chemicals seized at clandestine laboratories must be removed, and that removal is very expensive. During FY 2004, DEA administered 10,061 state and local clandestine laboratory cleanups at a cost of \$18.6 million.

The total social and monetary costs from trafficking and abuse of methamphetamine are abundant. Costs include those incurred to treat medical consequences of abuse, loss of life and injury to users and by users to bystanders, abandonment of the children of methamphetamine abusers (and corresponding cost of social services), theft and property damage resulting from abuse, loss of employment and productivity, increased costs to law enforcement, cost of prosecution and incarceration for crimes associated with drug use, and increased costs due to cleanups of lab sites. Benefits obtained from implementation of iodine controls, to counter illicit methamphetamine production, greatly exceed costs necessary to implement such controls. However, DEA is seeking public comment on any effect this rule may have on markets.

#### *Executive Order 12988*

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

#### *Executive Order 13132*

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

#### *Paperwork Reduction Act*

This rule proposes changes to the regulation of iodine and proposes regulations to identify iodine chemical mixtures that are exempt from CSA regulatory controls pertaining to chemicals. Under this proposal, persons who handle chemical mixtures with concentration levels of iodine 2.2 percent and less will not be subject to CSA regulatory controls, including the requirement to register with DEA.

This Notice of Proposed Rulemaking would require persons handling iodine crystals, strong iodine tinctures and chemical mixtures containing iodine to

register with DEA and to report import and export transactions involving regulated transactions in these chemicals to DEA.

For purposes of this proposed rulemaking, DEA has estimated the population of persons potentially required to register with DEA to handle iodine and its chemical mixtures to be between 275 and 890. However, some of these persons may already be registered with DEA and others may decide to no longer handle such products rather than registering. Therefore, DEA is specifically seeking input from industry regarding the number of persons who might be affected by this rulemaking. DEA will not be amending its information collection regarding chemical registration [OMB information collection 1117-0031 "Application for Registration under Domestic Chemical Diversion Control Act of 1993 and Renewal Application for Registration under Domestic Chemical Diversion Control Act of 1993"] pending receipt of comments regarding the impact of this regulation. DEA will amend its information collection, as warranted, based on the public comment received.

Further, this NPRM would require persons importing and exporting products containing iodine crystals, tinctures and chemical mixtures controlled by this rule to report such imports and exports to DEA. DEA cannot accurately estimate how many such transactions occur annually and, thus, the impact of this reporting requirement to the regulated industry. DEA is seeking comment from the regulated industry regarding the impact of this proposed regulation and will amend its information collection regarding the reporting of import and export transactions [OMB information collection 1117-0023 "Import/Export Declaration: Precursor and Essential Chemicals"], as warranted, based on the public comment received.

DEA is also soliciting comments on the impact of recordkeeping requirements upon handlers of regulated iodine products and any potential impact upon public health given any reduction in availability of regulated products, especially where it can be quantified.

*Unfunded Mandates Reform Act of 1995*

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$114,000,000 or more in any one year, and will not significantly or uniquely affect small

governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

*Small Business Regulatory Enforcement Fairness Act of 1996*

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

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

Drug traffic control, Exports, Imports, List I and List II chemicals, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1310 is proposed to be amended as follows:

**PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES [AMENDED]**

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

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

2. Section 1310.02 is amended by adding a new paragraph (a)(28) and removing paragraph (b)(11) to read as follows:

**§ 1310.02 Substances covered.**

\* \* \* \* \*

(a) \* \* \*

(28) Iodine 6699

\* \* \* \* \*

3. Section 1310.04 is amended by removing paragraph (f)(2)(ii)(H); redesignating (f)(2)(ii)(I) as (f)(2)(ii)(H); and adding a new paragraph (g)(1)(vi) to read as follows:

**§ 1310.04 Maintenance of records.**

\* \* \* \* \*

(g) \* \* \*

(1) \* \* \*

(vi) iodine

\* \* \* \* \*

**§ 1310.08 [Amended]**

4. Section 1310.08 is amended by removing paragraph (f) and redesignating paragraphs (g) through (l) as paragraphs (f) through (k).

5. Section 1310.09 is amended by adding new paragraph (h) to read as follows:

**§ 1310.09 Temporary exemption from registration.**

\* \* \* \* \*

(h) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export regulated iodine, including regulated iodine chemical mixtures pursuant to §§ 1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption for a chemical mixture containing iodine on or before [60 days from date of publication of a final rule]. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, and 1313 of this chapter remain in full force and effect. Any person who distributes, imports or exports a chemical mixture containing iodine whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for these persons, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has not been approved. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

6. Section 1310.12 is amended by revising the introductory text of paragraph (c), by adding an entry for "Iodine" in alphabetical order in the table of paragraph (c), and adding new paragraph (d)(4) to read as follows:

**§ 1310.12 Exempt chemical mixtures.**

\* \* \* \* \*

(c) Mixtures containing a listed chemical in concentrations equal to or less than those specified in the "Table of Concentration Limits" are designated as exempt chemical mixtures for the purpose set forth in this section. The concentration is determined for liquid-liquid mixtures by using the volume or weight and for mixtures containing solids or gases by using the unit of weight.

TABLE OF CONCENTRATION LIMITS

List I chemicals	DEA chemical code number	Concentration (percent)	Special conditions
Iodine .....	6699	2.2	*

(d) \* \* \*  
\* \* \* \* \*

(4) Iodine products classified as iodophors which exist as an iodine complex to include poloxamer-iodine complex, polyvinyl pyrrolidone-iodine complex (i.e. povidone-iodine), undecylium chloride iodine, nonylphenoxy poly (ethyleneoxy) ethanol-iodine complex, iodine complex with phosphate ester of alkylaryloxy polyethylene glycol, and iodine complex with ammonium ether sulfate/ polyoxyethylene sorbitan monolaurate.

Dated: July 6, 2006.  
**Michele M. Leonhart,**  
*Deputy Administrator.*  
 [FR Doc. E6-12353 Filed 8-10-06; 8:45 am]  
**BILLING CODE 4410-09-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Bureau of Customs and Border Protection**

**8 CFR Parts 212 and 235**

[USCBP 2006-0097]

RIN 1651-AA66

**DEPARTMENT OF STATE**

**22 CFR Parts 41 and 53**

RIN 1400-AC10

**Documents Required for Travelers Arriving in the United States at Air and Sea Ports-of-Entry From Within the Western Hemisphere**

**AGENCY:** Bureau of Customs and Border Protection, Department of Homeland Security; Bureau of Consular Affairs, Department of State.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Intelligence Reform and Terrorism Prevention Act of 2004 provides that by January 1, 2008, United States citizens and nonimmigrant aliens may enter the United States only with passports or such alternative documents as the Secretary of Homeland Security may designate as satisfactorily

establishing identity and citizenship. This notice of proposed rulemaking (NPRM) is the first phase of a joint Department of Homeland Security and Department of State plan to implement these new requirements. This NPRM proposes that, beginning January 8, 2007, United States citizens and nonimmigrant aliens from Canada, Bermuda, and Mexico entering the United States at air ports-of-entry and most sea ports-of-entry, with certain limited exceptions, will generally be required to present a valid passport. This NPRM does not propose to change the requirements for United States citizens and nonimmigrant aliens from Canada, Bermuda, and Mexico entering the United States at land border ports-of-entry and certain types of arrivals by sea (ferries and pleasure vessels) which will be addressed in a separate, future rulemaking.

**DATES:** Written comments must be submitted on or before September 25, 2006.

**ADDRESSES:** Comments, identified by docket number USCBP 2006-0097, must be submitted by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Comments by mail are to be addressed to the Bureau of Customs and Border Protection, Office of Regulations and Rulings, Border Security Regulations Branch, 1300 Pennsylvania Avenue, NW., Washington, DC 20229. Submitted comments by mail may be inspected at the Bureau of Customs and Border Protection at 799 9th Street, NW., Washington, DC. To inspect comments, please call (202) 572-8768 to arrange for an appointment.

**Instructions:** All submissions must include the agency name and docket number USCBP 2006-0097. All comments will be posted without change to <http://www.regulations.gov>, including any personal information sent with each comment. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Participation in Rulemaking Process"

heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or submitted comments, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Department of Homeland Security: Robert Rawls, Office of Field Operations, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Room 5.4-D, Washington, DC 20229, telephone number (202) 344-2847.

**Department of State:** Consuelo Pachon, Office of Passport Policy, Planning and Advisory Services, Bureau of Consular Affairs, telephone number (202) 663-2662.

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