

benefits of a new regulation or to determine whether the benefits of the proposed regulation outweigh its costs. Rather, Section 15(a) simply requires the Commission to "consider the costs and benefits" of its action.

Section 15(a) further specifies that costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission, in its discretion, may choose to give greater weight to any one of the five enumerated areas and determine that, notwithstanding its costs, a particular regulation is necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the Act. The Commission has evaluated the costs and benefits of its Proposal, in particular, new Regulation 3.10(d) in light of the specific considerations identified in Section 15(a) of the Act.

Regulation 3.10(d) concerns the registration of intermediaries, in particular, FCMs, IBs, CPOs, CTAs and LTMs. Specifically, it will require these intermediaries to complete an online annual review of their registration information, including disciplinary information, firm contacts and lists of authorized users. By ensuring that NFA, the self-regulatory organization that oversees the activities of these registrants, will have accurate and current information regarding registrants, Regulation 3.10(d) will maximize the protection of market participants and the public.

Such intermediaries already are under an ongoing obligation to provide updated information to NFA pursuant to Commission Regulation 3.31(a)(1). Regulation 3.10(d) will require these registrants to comply with an online review protocol established by NFA. This protocol will provide a straightforward process for registrants to electronically update their registration information. It will focus and guide registrants on the particular areas that need updating. By facilitating NFA's efforts to adopt this protocol, Regulation 3.10(d) will result in efficiency enhancements for registrants and NFA.

Regulation 3.10(d) also will have no effect on the following three enumerated areas: (1) Efficiency, competitiveness or the financial integrity of futures markets; (2) price discovery; and (3) sound risk management practices.

After considering these factors, the Commission has determined to adopt the amendment to Regulation 3.10 set forth below.

#### *C. Paperwork Reduction Act*

The Paperwork Reduction Act of 1995 ("PRA") imposes certain obligations on federal agencies, including the Commission, in connection with their conducting or sponsoring any collection of information as defined by the PRA.<sup>19</sup> In its Proposal, the Commission noted that the Proposed Amendment would require intermediaries to conduct an annual review of their registration information maintained with NFA and that this information is part of an approved collection of information. The Commission further noted that the Proposed Amendment would not result in any material modifications to this approved collection. Accordingly, for purposes of the PRA, the Commission certified that the Proposed Amendment did not impose any new reporting or recordkeeping requirements.

The Commission did not receive any comments regarding its analysis relative to the PRA.

#### **List of Subjects in 17 CFR Part 3**

Administrative practice and procedure, Brokers, Commodity futures, Reporting and recordkeeping requirements.

■ For the reasons discussed in the preamble, the Commission amends 17 CFR part 3 as follows:

#### **PART 3—REGISTRATION**

■ 1. The authority citation for part 3 continues to read as follows:

**Authority:** 5 U.S.C. 522, 522b; 7 U.S.C. 1a, 2, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6k, 6m, 6n, 6o, 6p, 8, 9, 9a, 12, 12a, 13b, 13c, 16a, 18, 19, 21, 23.

■ 2. Section 3.10 is amended by adding paragraph (d) to read as follows:

#### **§ 3.10 Registration of futures commission merchants, introducing brokers, commodity trading advisors, commodity pool operators and leverage transaction merchants.**

\* \* \* \* \*

(d) On a date to be established by the National Futures Association, and in accordance with procedures established by the National Futures Association, each registrant as a futures commission merchant, introducing broker, commodity trading advisor, commodity pool operator or leverage transaction merchant shall, on an annual basis, review and update registration information maintained with the

National Futures Association. The failure to complete the review and update within thirty days following the date established by the National Futures Association shall be deemed to be a request for withdrawal from registration, which shall be processed in accordance with the provisions of § 3.33(f).

■ 3. Section 3.33 is amended by revising paragraph (f) introductory text to read as follows:

#### **§ 3.33 Withdrawal from registration.**

\* \* \* \* \*

(f) A request for withdrawal from registration will become effective on the thirtieth day after receipt of such request by the National Futures Association, or earlier upon written notice from the National Futures Association (with the written concurrence of the Commission) of the granting of such request, unless prior to the effective date:

\* \* \* \* \*

Issued in Washington, DC, on June 26, 2007, by the Commission.

**Eileen Donovan,**

*Acting Secretary of the Commission.*

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**BILLING CODE 6351-01-P**

## **DEPARTMENT OF JUSTICE**

### **Drug Enforcement Administration**

#### **21 CFR Parts 1309 and 1310**

[Docket No. DEA-257F]

RIN 1117-AA93

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

**AGENCY:** Drug Enforcement Administration (DEA), Justice.

**ACTION:** Final rule.

**SUMMARY:** This rulemaking changes the regulation of the listed chemical iodine under the chemical regulatory provisions of the Controlled Substances Act (CSA). The Drug Enforcement Administration (DEA) believes that this action is necessary to remove deficiencies in the existing regulatory controls, which have been 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 rulemaking moves iodine from List II to List I; reduces the iodine threshold from 0.4 kilograms to zero kilograms; adds import and export regulatory controls; and controls

<sup>19</sup> 44 U.S.C. 3501 *et seq.*

chemical mixtures containing greater than 2.2 percent iodine.

This rulemaking establishes regulatory controls that will apply to iodine crystals and iodine chemical mixtures that contain greater than 2.2 percent iodine. This regulation therefore controls 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. Additionally, the final rule exempts transactions of up to one-fluid-ounce (30 ml) of Lugol's Solution.

Persons handling regulated iodine materials are required to register with DEA, are subject to the import/export notification requirements of the CSA, and are required to maintain records of all regulated transactions involving iodine regardless of size.

**DATES:** This rulemaking becomes effective on August 1, 2007. Persons seeking registration must apply on or before August 31, 2007 in order to continue their business pending final action by DEA on their application.

**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**

This rulemaking finalizes an August 11, 2006, Notice of Proposed Rulemaking (NPRM) [71 FR 46144] in which DEA proposed (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 action is being taken because of the continued use of iodine for the illicit production of the schedule II controlled substances amphetamine and methamphetamine. Methamphetamine is the leading controlled substance clandestinely manufactured 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 increasing the regulatory controls on

iodine in an effort to prevent the diversion of iodine to clandestine drug laboratories.

##### **Need for Increased Regulation**

This rulemaking changes the regulatory control of iodine in an effort to prevent the diversion of iodine for the illicit production of methamphetamine and amphetamine. The August 11, 2006, NPRM went into great detail regarding the scope of the domestic and international clandestine laboratory problem, use of iodine in the production of methamphetamine/amphetamine, and the need to increase regulatory controls on iodine.

As stated in the NPRM, 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.

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 Pub. L. 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 (solutions of iodine and iodide in alcohol), 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.

##### **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. These large-scale laboratories often rely upon a ready source of iodine. 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. DEA, therefore, believes that enhanced controls on iodine are necessary to prevent the diversion of iodine (in the form of iodine crystals and iodine tincture) for the illicit production of methamphetamine/amphetamine in clandestine drug laboratories.

#### *Comments*

In response to the August 11, 2006, NPRM, DEA received comments from thirteen interested parties. While commenters were generally supportive of DEA's need to prevent the diversion of iodine for the illicit production of methamphetamine, the comments raised concerns regarding the potential adverse impact upon the availability of specific iodine products intended for legitimate use.

#### *Comments Regarding Iodine Products Used for Nutritional Supplementation*

Twelve comments expressed concerns that the proposed regulations would adversely impact the availability of products for use as a dietary source of iodine. These comments detailed the use of iodine products as part of a nutritional program to supplement iodine levels for various health purposes (e.g., the normalization of thyroid function, prevention of breast cancer recurrence, or supplementation during pregnancy as a program to prevent autism in offspring.)

Eleven of these comments expressed concern that the regulation would adversely impact the availability of a specific formulation known as Lugol's Solution. Lugol's Solution is a 5 percent aqueous solution of iodine in combination with 10 percent potassium iodide.

Most of these comments detailed the importance of Lugol's Solution as a source of milligram doses of iodine as part of a daily health program of disease prevention. Commenters noted how several drops of Lugol's Solution per day served as an inexpensive source of dietary iodine. Commenters detailed multiple uses for Lugol's Solution and expressed concerns that such material should remain available to end users in small quantities.

In response to comments, DEA conducted further review of the legitimate uses for Lugol's Solution. These uses include (1) the staining of slides in microbiology, (2) the staining of cervical and esophageal tissue in diagnosis of disease, (3) use in aquariums, (4) use in pre-treating the thyroid gland prior to ingestion of radiolabeled  $I^{131}$  so that the thyroid

gland will not take up large quantities of radioactive material, (5) use as a dietary source of iodine, and (6) use in educational science test kits for identification of starches. For each of these uses, the quantities of Lugol's Solution needed are small. In most cases, the Lugol's Solution is used in small 8 milliliter (ml) bottles or in one-fluid-ounce (30 ml) bottles. Because of the numerous legitimate uses and small quantities involved, DEA is adding a provision to this final rule that will exempt Lugol's Solution when packaged in bottles/containers of one-fluid-ounce (30 ml) or smaller, and involve distribution of only a single package per transaction. While this final rule provides an exemption for Lugol's Solution when packaged in small bottles, larger packages are subject to regulatory controls. DEA is aware of the availability of 16 fluid ounce bulk packages of Lugol's Solution. These larger bulk packages are subject to regulatory control provisions including registration, import/export notification, and recordkeeping.

DEA review indicates that only 2–6 drops a day of Lugol's Solution are used for nutritional purposes. Additionally, the quantities used in the healthcare field, microbiology, and in the testing of starches, require only very small amounts of Lugol's Solution and the sale of 8 ml and one-fluid-ounce (30 ml) bottles is common. When used in an aquarium, the labeled directions indicate that only 1 drop of Lugol's Solution per 25 gallons should be used weekly. Therefore, one-fluid-ounce package of Lugol's Solution should be adequate for most legitimate purposes. A one-fluid-ounce (30 ml) package size contains 1.5 grams of iodine and has potential utility for use in the illicit manufacture of methamphetamine. Therefore, DEA is adding the provision to exempt individual transactions involving one one-fluid-ounce (30 ml) package/bottle. Individuals that distribute more than one package/bottle of Lugol's Solution (of any size) per transaction, are subject to CSA recordkeeping and import/export requirements.

This final rulemaking includes a waiver of the registration requirement under 21 CFR 1309.24 for "Lugol's Solution (consisting of 5 percent iodine and 10 percent potassium iodide in an aqueous solution) in original manufacturer's packaging of one-fluid-ounce (30 ml) or less per package." Additionally, this rulemaking includes an exclusion from the definition of regulated transaction under 21 CFR 1310.08 for "Domestic and international transactions of Lugol's Solution

(consisting of 5 percent iodine and 10 percent potassium iodide in an aqueous solution) in original manufacturer's packaging of one-fluid-ounce (30 ml) or less, and no greater than one package/bottle per transaction."

DEA currently has no evidence that Lugol's Solution is diverted as a source of iodine for illicit purposes. However, should clandestine laboratory operators begin to exploit the exemption for small packages of Lugol's Solution as a source of iodine for the manufacture of methamphetamine, DEA may remove these exemption provisions.

One comment received from a physician expressed concerns regarding the possible control of an iodine product (Iodoral) that contains 5 milligrams iodine and 7.5 milligrams potassium iodide per tablet. The physician stated that this product is used in patients with thyroid disease and therefore requested that this product remain exempt from CSA regulatory provisions. In response to this comment, DEA obtained samples of Iodoral and determined that the concentration of iodine in the product is below the 2.2 percent concentration level for chemical mixtures as specified in 21 CFR 1310.12. Therefore, Iodoral 5 mg tablets are not subject to CSA regulatory control provisions following implementation of this final rule.

#### *Comment Relating to Commercial Use of Iodine*

One comment was received from a manufacturer of injectable products and medical delivery systems. The commenter expressed support for the proposed exemption of iodophor products (iodine complexes), but requested clarification that the exemption includes organically bound iodine products which are non-ionic complexes. The commenter provided specific examples of organically bound products (e.g., iopamidol, iohexol and amiodarone.)

The proposed exemption for iodophors was intended to include organically bound iodine compounds. DEA has evaluated these products and determined that these organically bound compounds cannot serve as a source of iodine for methamphetamine laboratories and therefore are not at risk of diversion. As clarification, DEA has added a new paragraph under 21 CFR 1310.12(d)(5) which specifies that "Iodine products that consist of organically bound iodine (a non-ionic complex) (e.g., iopamidol, iohexol, and amiodarone)" are chemical mixtures that are automatically exempt from CSA regulatory provisions.

This commenter also requested that certain laboratory reagents (e.g., Karl Fischer Reagent and Aquastar Composite 5), be considered for exemption from regulation. The commenter stated it was not the manufacturer or distributor of such products, but used these reagents frequently for laboratory testing. The commenter expressed concern that the new regulation would potentially subject such reagents to CSA regulatory control. DEA conducted a review of such laboratory reagents, but the iodine concentration in these chemical mixtures appears to be proprietary and was not disclosed on product labeling.

DEA wishes to clarify that end users of such material are not subject to CSA regulatory requirements, except the requirement to provide identification for purchase of List I chemicals (21 CFR 1310.06), as long as they do not distribute regulated material. Such laboratory reagents would only be considered regulated material if they are chemical mixtures containing greater than 2.2 percent iodine, and not considered either an iodophor or organically bound iodine.

DEA recognizes that the 2.2 percent iodine concentration criteria cannot identify all mixtures that should receive exemption status. DEA notes that an application process already exists to exempt additional mixtures (21 CFR 1310.13). This application process was finalized in a previous final rule regarding chemical mixtures (68 FR 23195, 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)(vi)). Under these provisions, the manufacturer of these reagents may apply for exemption if their products are above the 2.2 percent iodine level.

Additionally, the commenter expressed concern regarding the ability to obtain iodine crystals for laboratory analytical use following implementation of this final rule. However, transactions involving iodine crystals have been regulated as List II chemicals since implementation of the Comprehensive Methamphetamine Control Act (MCA) in 1996. This final rule only requires that handlers of such material register with DEA and maintain records of transactions. Most of the chemical houses that supply high-grade material to analytical laboratories are already registered with DEA to handle List I chemicals. The regulatory requirement only pertains to distribution of regulated material. DEA does not believe that these regulations will adversely impact the availability of such material.

#### *Iodine Products Subject to This Final Rule*

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, will 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 the end user's 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 may also 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 IN 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

Source: U.S. Pharmacopoeia (U.S.P.)

As shown in 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 in water. 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 by the U.S.P. 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 are not subject to this regulation. In contrast, 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 (e.g., Lugol's Solution) are used in saltwater aquariums, used as a dietary source of iodine, used to test for the presence of starch, and as stains in some laboratory tests. This rulemaking exempts small transactions of these chemical mixtures, as discussed elsewhere 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 use 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 rulemaking, these products will be subject to control.

#### *Iodine Products Not Regulated Under This Rulemaking*

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 delivered continuously. 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 exempting these products in 21 CFR 1310.12(d)(4). This provision will 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), undecylm 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."

Additionally, DEA wishes to clarify that organically bound iodine products

that are non-ionic complexes (e.g., iopamidol, iohexol and amiodarone) are not subject to CSA regulatory controls. These organically bound compounds cannot serve as a source of iodine for methamphetamine laboratories and therefore are not at risk of diversion. As clarification, DEA has added a new paragraph under 21 CFR 1310.12(d)(5), which specifies that "Iodine products that consist of organically bound iodine (a non-ionic complex) (e.g., iopamidol, iohexol, and amiodarone)" are chemical mixtures that are automatically exempt from CSA regulatory provisions.

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 under 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), and in general scientific research. 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 rulemaking. As such, the regulatory controls of the CSA do not apply to any of these iodide salts or radiolabeled iodine/iodide salts. Additionally, these regulatory controls do not apply to any iodide material commonly dispensed under a prescription. Instead, this regulation is limited only to iodine crystals and chemical mixtures that contain iodine in the form of the iodine tinctures and iodine solutions described above.

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

#### **II. Changes to the Regulation of Iodine as a Result of This Rulemaking**

##### *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(34) and (35) and 21 CFR 1310.02, provide the Attorney General with the authority to specify, by regulation, the addition or deletion of any chemicals as listed

chemicals. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances. Those classified as List II chemicals may be used to manufacture controlled substances in violation of the Act. 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, § 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."

In this final rule, the DEA is removing iodine from 21 CFR 1310.02(b) (List II) and placing it in 1310.02(a) (List I) because, based on the information provided above, and discussed in greater detail in the Notice of Proposed Rulemaking for this rule, iodine is a chemical that is important to the manufacture of the controlled substances methamphetamine and amphetamine in violation of the Act. Placement 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 dictate that handlers of iodine, including persons who manufacture, import, export, or distribute iodine, must register with DEA. Retail and wholesale outlets that sell iodine crystals and covered tinctures/solutions are also required to register.

Prior to receiving a DEA chemical registration, applicants are subject to a pre-registration investigation by DEA to determine whether their registration is consistent with the public interest pursuant to the criteria set forth in 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.

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

When iodine was controlled as a List II chemical by the Comprehensive Methamphetamine Control Act of 1996 (MCA), the law 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 Pub. L. 104-237, § 204. Because of the international commerce in iodine, and iodine's documented use in the clandestine production of methamphetamine, DEA has determined that the addition of import and export controls on iodine is necessary. Therefore, 21 CFR 1310.08 is amended to remove imports and exports of iodine as excluded transactions. Thus, iodine will 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." Historically, the threshold for iodine has been 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 to prevent diversion. Thus, DEA is removing the threshold for iodine under this final rule. Therefore, all transactions of regulated iodine products are considered regulated transactions regardless of size, unless specifically exempted.

#### *Iodine 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 chemicals 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.

#### *Regulation of Chemical Mixtures*

The Domestic Chemical Diversion Control Act of 1993 (DCDCA), enacted in April 1994, amended 21 U.S.C. 802(39)(A)(v) [current 21 U.S.C. 802(39)(A)(vi)] 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 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." As noted previously, 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 final rule implements regulations that identify which iodine chemical mixtures qualify for automatic exemption because they meet the requirements of 21 U.S.C. 802(39)(A)(vi). Those iodine chemical mixtures that do not qualify for automatic exemption are regulated chemicals, unless the manufacturer applies for, and is granted, specific exemption for their product(s) by DEA via an application process (21 CFR 1310.13).

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 is not regulating the two percent iodine tincture or solution at this time.

As discussed previously, DEA is also aware of other materials that contain iodine. Examples include iodophor complexes such as poloxamer-iodine and povidone-iodine and organically bound iodine complexes such as iopamidol, iohexol, and amiodarone. These materials are not of concern to DEA as a source of iodine for clandestine laboratories. This final rule specifies that these materials be specifically exempted from CSA chemical regulatory controls under 21 CFR 1310.12 by adding new paragraphs (d)(4) and (d)(5).

#### *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 a final rule (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)(vi)). An application may be for a single or a multiple number of formulations. All chemical mixtures that are granted exemption via the application process will be listed in 21 CFR 1310.13(i).

### **III. Requirements That Apply to Regulated List I Chemicals and Their Regulated Chemical Mixtures as a Result of This Rulemaking**

Any chemical mixture that is regulated because it contains greater than 2.2 percent iodine is treated as a List I chemical. Therefore, the same requirements for registration, records and reports, imports/exports, and administrative inspection, as outlined below, apply to handlers of regulated chemical mixtures.

In light of the placement of 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, are 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 manufacturing, distribution, importing, and exporting. Different locations operated by a single entity require separate registration if any location is involved with the manufacture, distribution, import, or export of a List I chemical. Any person manufacturing, 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 manufacture, 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 establishing in 21 CFR 1310.09 a temporary exemption from the registration requirement for persons desiring to manufacture, distribute, import, or export iodine, provided that DEA receives a properly completed application for registration on or before August 31, 2007. 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.

Section 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 part 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) where original or other records or documents required under the Act, are kept or required to be kept. The CSA (21 U.S.C. 880) allows for administrative inspections of these controlled premises as provided in 21 CFR part 1316 subpart A.

The goal of this rulemaking is to deny traffickers 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 rule will have a significant economic impact on a substantial number of small entities. If an agency finds that there is a significant economic impact on a substantial number of small entities, 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 this rulemaking could have a significant economic impact on a substantial number of small entities.

The majority of firms potentially subject to this rulemaking are considered small entities under the Small Business Administration definitions for the affected sectors.<sup>1</sup> The only firms for which the rulemaking would have a significant economic impact are those with revenues or sales of less than about \$125,000 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 \$125,000 a year level.<sup>2</sup> Consequently, DEA concludes that this rulemaking will not 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 alternative products. DEA sought comments on whether there could be a significant economic impact on a substantial number of small entities in the NPRM. DEA did not receive any comments on this issue from any distributors of such products.

<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.



*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 will be covered by this 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 for which MSDSs are not publicly available.<sup>4</sup> DEA sought comments on whether such information exists that could help in further identifying the entities this final rule will potentially impact. The only comments received were from end-users.

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. Distributors of science kits will still need to keep records if quantities exceed a single one-fluid-ounce package of Lugol's Solution per transaction.

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 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's Solution), it may not be handled by a large number of wholesalers. DEA has exempted distributors of Lugol's Solution in the manufacturers' packages containing 1 fluid ounce (30 ml) or less from registration, so these distributors will simply have to retain normal sales records.

Census classifications do not cover camping goods at the wholesale level. The web site for Polar Pure, a water purification system involving iodine regulated by this rule, lists only two wholesale distributors. Overall, DEA estimates that the number of wholesalers may range from 300 to 1,400.

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. Since DEA has provided for the unregulated sale of single small packages of Lugol's Solution, the potential impact upon pet stores should be greatly reduced or eliminated.

The Census listed about 1,524 sporting good specialty stores that carry camping supplies. DEA has included 5 percent to 10 percent of them in its estimates regarding the impact of this rule. 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
Total .....	2,590	6,070

The estimates in Table 1 represent the number of outlets that may currently handle products that are subject to this rule. The regulated universe will likely be smaller (especially for pet supplies, given that DEA has provided the exemption for single small packages of Lugol's Solution in this final 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 this rule; this information is necessary for them to ship the product. Other than the registration fees, the rulemaking would not impose a burden on them

<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.



although it is possible that some of these outlets may elect to drop iodine products rather than be subject to DEA regulations.

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 collect all of the information DEA requires for these transactions routinely. 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
Total .....	275	890

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	Av. 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 will be classified as small and did not receive any comments 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 Will Impact Small Entities

Firms that handle iodine will be required to register with DEA. At present, the registration fee for

manufacturers is \$2,293 and for distributors is \$1,147. 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 will 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 application, which can be

done online, and a half hour to become familiar with the rule. 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 May 2005 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 .....	\$126	\$126	\$2,419
Wholesale .....	98	98	1,245
Retail .....	62	62	1,209
Mail order/Electronic .....	93	93	1,240

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 slightly lower (a half hour of labor plus the registration fee). DEA estimates that completing the advance

notification (Form 486) for imports and exports requires less than 15 minutes.

## Reporting and Recordkeeping Requirements

Firms subject to this rulemaking 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. Retailers that have cash sales will 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 other than exempted quantities of Lugol's Solution.

Importers and exporters will 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 Regulatory Flexibility Account, DEA evaluated alternatives to this rulemaking and determined that no reasonable alternatives exist. This rulemaking establishes 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 this rulemaking would eliminate the regulatory objective behind the rule. DEA has explored ways to lessen the regulations' economic impact on all entities covered by the rule. This rulemaking establishes regulatory controls that 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> DEA, after reviewing comments, has also provided an exemption for individual transactions involving small packages of

Lugol's Solution. Additionally, this rulemaking allows manufacturers to seek exemption for additional mixtures of iodine that do not qualify for automatic exemption under 21 CFR 1310.13. DEA sought comments on reasonable alternatives to this rulemaking that would 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. DEA has incorporated new the exemption for individual transactions involving one-fluid-ounce (30 ml) packages of Lugol's Solution in response to these comments.

## 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 will not be subject to the rule. DEA considered whether the loss of product sales would have a significant economic impact on retailers. These products make up a very small part of the sales of any 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 online 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 the impact on sales at the retail level will be minimal. Where cost effective substitutes were not available DEA has provided an exemption (i.e., individual transactions involving one-fluid-ounce (30 ml) packages of Lugol's Solution, where certain alternative products cost more than ten times that of Lugol's Solution).

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 online. Because the sales records required under the rules are the same records the companies create for mail order or online sales, there is 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 online sales, the rulemaking 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 rulemaking is a "significant regulatory action". Therefore, this action has been reviewed by the Office of Management and Budget.

This final rule imposes 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 final rule ranges from \$430,000 to \$1.21 million; annual costs thereafter range from \$416,000 to \$1.16 million.

## 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 2005 National Survey on Drug Use and Health, approximately 10.36 million Americans ages 12 and older reported trying methamphetamine at least once during their lifetimes, representing 4.3% of the population ages 12 and older. Approximately 1.3 million (0.5%) reported past year methamphetamine use and 512,000 (0.2%) reported past month methamphetamine use. In 2005, the Monitoring the Future Study which assesses the extent of drug use among

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

adolescents indicated that 3.1 percent of 8th graders, 4.1 percent of 10th graders and 4.5 percent of 12th graders reported some prior lifetime use of methamphetamine. The Drug Abuse Warning Network (DAWN) data indicate that the estimated number of emergency department (ED) visits for methamphetamine was 108,905 in 2005.

The El Paso Intelligence Center (EPIC) reports that there were 12,484 methamphetamine laboratories seized (including laboratories, dump sites and equipment seizures) in the U.S. in CY2005 (as reported through November 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 cleaned up and chemicals seized at clandestine laboratories must be removed, and that removal is very expensive. During FY 2005, DEA administered 8,639 state and local clandestine laboratory cleanups at a cost of \$17 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.

#### *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 rulemaking implements changes in the regulation of iodine and

implements regulations to identify iodine chemical mixtures that are exempt from CSA regulatory controls pertaining to chemicals. Under this rulemaking, 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 rulemaking will 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 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. DEA notes that it solicited, but did not receive, comment regarding the number of persons who would be required to register with DEA as a result of this rule. Accordingly, by separate notice, DEA is 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"] to increase the burden associated with this collection by 275 respondents annually.

Further, this rulemaking will require persons importing and exporting products containing iodine crystals, tinctures, and chemical mixtures controlled by this rulemaking to report such imports and exports to DEA. DEA sought comment from the regulated industry regarding the impact of this regulation; however, no comments addressed this issue. Therefore by separate notice DEA is amending its information collection regarding the reporting of import and export transactions [OMB information collection 1117-0023 "Import/Export Declaration: List I and List II Chemicals"] to estimate that DEA will receive new DEA Forms 486 annually. DEA notes that DEA already receives DEA Forms 486 for the importation and exportation of iodine; the only new reporting results from chemical mixtures containing over 2.2 percent iodine.

DEA also solicited 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. The majority of comments addressed these issues. In response, DEA is providing an exemption for individual transactions involving Lugol's Solution in small packages so that such product will remain available to end-users.

#### *Unfunded Mandates Reform Act of 1995*

This rulemaking will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$118,000,000 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.

#### *Congressional Review Act*

This rulemaking is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rulemaking 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**

##### *21 CFR Part 1309*

Administrative practice and procedure, Drug Traffic Control, List I and List II chemicals, Reporting and recordkeeping requirements.

##### *21 CFR Part 1310*

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

■ For the reasons set out above, 21 CFR parts 1309 and 1310 are amended as follows:

#### **PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS [AMENDED]**

■ 1. The authority citation for part 1309 continues to read as follows:

**Authority:** 21 U.S.C. 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 958.

■ 2. § 1309.24 is amended by redesignating paragraphs (h) through (k) as paragraphs (i) through (l) and by adding a new paragraph (h) to read as follows:

**§ 1309.24 Waiver of registration requirement for certain activities.**

\* \* \* \*

(h) The requirement of registration is waived for any person whose activities with respect to List I chemicals are limited solely to the distribution of Lugol's Solution (consisting of 5 percent iodine and 10 percent potassium iodide in an aqueous solution) in original manufacturer's packaging of one fluid ounce (30 ml) or less.

\* \* \* \*

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

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

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

■ 4. § 1310.02 is amended by adding a new paragraph (a)(28), removing paragraph (b)(11), and redesignating paragraph (b)(12) as paragraph (b)(11) to read as follows:

**§ 1310.02 Substances covered.**

\* \* \* \*

(a) \* \* \*

(28) Iodine ..... 6699

\* \* \* \*

■ 5. § 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

\* \* \* \*

■ 6. § 1310.08 is amended by revising paragraph (f) to read as follows:

**§ 1310.08 Excluded transactions.**

\* \* \* \*

(f) Domestic and international transactions of Lugol's Solution (consisting of 5 percent iodine and 10 percent potassium iodide in an aqueous solution) in original manufacturer's packaging of one-fluid-ounce (30 milliliters) or less, and no greater than one package per transaction.

\* \* \* \*

■ 7. § 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 manufacture, 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 the Administration receives a proper application for registration or application for exemption for a chemical mixture containing iodine on or before August 31, 2007. 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 the Administration must obtain a registration with the Administration. A temporary exemption from the registration requirement will also be provided for these persons, provided that the Administration receives a properly completed application for registration on or before 30 days following the date of official Administration notification that the application for exemption has not been approved. The temporary exemption for such persons will remain in effect until the Administration takes final action on their registration application.

■ 8. § 1310.12 is amended by adding an entry for "iodine" in alphabetical order in the table of paragraph (c), and adding new paragraphs (d)(4) and (d)(5) to read as follows:

**§ 1310.12 Exempt chemical mixtures.**

\* \* \* \*

(c) \* \* \*

**TABLE OF CONCENTRATION LIMITS**

List I chemicals	DEA chemical code No.	Concentration (percent)	Special conditions
* * * *	* * * *	* * * *	* * * *
Iodine .....	6699	2.2	Calculated as weight/volume (w/v).
* * * *	* * * *	* * * *	* * * *

(d) \* \* \*

(4) Iodine products classified as iodophors that exist as an iodine complex to include poloxamer-iodine complex, polyvinyl pyrrolidone-iodine complex (i.e., povidone-iodine), undecylmethyl ammonium 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.

(5) Iodine products that consist of organically bound iodine (a non-ionic

complex) (e.g., iopamidol, iohexol, and amiodarone.)

\* \* \* \*

Dated: June 19, 2007.

Michele M. Leonhart,

Deputy Administrator.

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**DEPARTMENT OF DEFENSE****Department of the Air Force****32 CFR Part 841****[No. USAF-2007-0010]****Licensing Government-Owned Inventions in the Custody of the Department of the Air Force**

**AGENCY:** Department of the Air Force, DoD.

**ACTION:** Final rule.