

EXEMPT ANABOLIC STEROID PRODUCTS—Continued

Trade Name	Company	NDC No.	Form	Ingredients	Quantity
Tilapia Sex Reversal Feed (Investigational).	Ziegler Brothers, Inc., Gardeners, PA.		Plastic bags ...	Methyltestosterone	60 mg/kg fish feed

Additional copies of this list may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537.

Plain Language Instructions

The Drug Enforcement Administration makes every effort to write clearly. If you have suggestions as to how to improve the clarity of this regulation, call or write Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307-7297.

Certifications*Regulatory Flexibility Act*

The Deputy Assistant Administrator, for the DEA Office of Diversion Control, in accordance with the Regulatory Flexibility Act [5 U.S.C. 605(b)], has reviewed this rule and by approving it, certifies that it will not have significant economic impact on a substantial number of small business entities. The granting of exempt status relieves persons who handle the exempt products in the course of legitimate business from the registration, labeling, records, reports, prescription, physical security, and import and export restrictions imposed by the CSA.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866, section 1(b). The Office of Management and Budget (OMB) reviewed the interim rule as a significant action; the DEA received no comments regarding the interim rule. This final rule falls into a category of regulatory actions which OMB has determined are exempt from regulatory review. Therefore, this action has not been reviewed by the OMB.

Executive Order 13132

This action has been analyzed in accordance with the principles and criteria in Executive Order 13132 and it has been determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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 \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under 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 costs 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.

PART 1308—[AMENDED]

Pursuant to the authority delegated to the Administrator of the DEA pursuant to 21 U.S.C. 871(a) and 28 CFR 0.100 and redelegated to the Deputy Assistant Administrator of the Drug Enforcement Administration Office of Diversion Control, pursuant to 28 CFR 0.104, appendix to subpart R, section 7(g), the Deputy Assistant Administrator of the Office of Diversion Control hereby adopts as a final rule, without change, the interim rule which was published at 65 FR 3124 on Jan. 20, 2000 and corrected at 65 FR 5024, on Feb. 2, 2000, amending the list described in 21 CFR 1308.34.

Dated: July 3, 2000.

John H. King,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 00-17915 Filed 7-13-00; 8:45 am]

Editorial Note: Due to numerous printing errors, rule document FR Doc. 00-17915 originally published at 65 FR 43690-43694, Friday, July 14, 2000 is being reprinted in its entirety.

[FR Doc. R0-17915 Filed 8-1-00; 8:45 am]

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DEPARTMENT OF JUSTICE**Drug Enforcement Administration****21 CFR Part 1310**

[DEA-156F]

RIN # 1117-AA43

Listed Chemicals; Final Establishment of Thresholds for Iodine and Hydrochloric Gas (Anhydrous Hydrogen Chloride)

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final Rule with request for comment.

SUMMARY: Effective October 3, 1996, the Comprehensive Methamphetamine Control Act of 1996 (MCA) established that iodine is a List II chemical; however, it was not made subject to import/export regulatory controls. While exports of the listed chemical hydrochloric acid (including anhydrous hydrogen chloride, referred to in the MCA as hydrochloric gas, which is a form of hydrogen chloride) were already regulated pursuant to 21 CFR 1310, the MCA had the practical effect of directing the DEA to place domestic controls on anhydrous hydrogen chloride. Since no domestic thresholds for iodine or anhydrous hydrogen chloride have been established prior to this Final Rule, all domestic transactions involving such chemicals have been subject to recordkeeping and reporting requirements under the Controlled Substances Act since October 3, 1996.

This rule establishes a domestic threshold of zero (0.0 kilograms) for anhydrous hydrogen chloride, and a domestic threshold of 0.4 kilograms for iodine. Import and export transactions in anhydrous chloride are unaffected by this rule. Iodine transactions involving amounts below the threshold will not be subject to recordkeeping and reporting requirements except for reporting of any unusual or excessive loss or disappearance as required by 21 U.S.C. 830(b)(1)(C).

Although the threshold for anhydrous hydrogen chloride is established at 0.0 kilogram, DEA has concluded that certain transactions in anhydrous hydrogen chloride are not sources for

diversion. This rule also provides exemption from the recordkeeping and reporting requirements for both transactions involving pipeline distributions and distributions of 12,000 pounds (net weight) or more in a single container. Because these exemptions were not discussed in the Notice of Proposed Rulemaking published in September 30, 1997, DEA requests public comment with respect to the exemption for these two types of transactions involving anhydrous hydrogen chloride.

This rule reinserts the table in 21 CFR 1310.04(f)(2)(iv), listing thresholds for exports, transshipments, and international transactions to designated countries set forth in 21 CFR 1310.08(b). This table was inadvertently omitted from the DEA's final rule regarding implementation of the Domestic Chemical Diversion Control Act of 1993, published on June 22, 1995 (60 FR 32447). Finally, this final rule assigns the DEA chemical code number of 6699 for iodine.

DATES: This final rule is effective September 1, 2000, except that § 1310.08(h) and (i) are effective [insert date of publication]. Comments on § 1310.08(h) and (i) should be submitted by September 1, 2000.

ADDRESSES: Comments and objections should be submitted in triplicate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307-7183.

SUPPLEMENTARY INFORMATION:

1. Background

a. Effect of the Comprehensive Methamphetamine Control Act on Iodine and Anhydrous Hydrogen Chloride

Section 204 of The Comprehensive Methamphetamine Control Act of 1996 (MCA), which became effective on October 3, 1996, amended the definition of "List II chemicals" in Section 102(35) of the Controlled Substances Act (CSA) (21 U.S.C. 802(35)) to include iodide as a List II chemical. The MCA, however, did not control salts of iodine (e.g., potassium iodide or sodium iodide).

The listed chemical iodine is currently available as crystals, tinctures, and formulations (e.g., povidone-iodine and polozamer-iodine complexes).

Under this rule, only transactions involving at least 0.4 kg of iodine crystals will be subject to regulatory controls. Since iodine tinctures and formulations are considered chemical mixtures, transactions in these materials are not currently regulated and are not affected by this rule. However, DEA is conducting a separate rulemaking to develop regulations governing the distribution of any chemical mixtures that contain a listed chemical (63 FR 49506). As such, some chemical mixtures may soon be subject to recordkeeping and other chemical regulatory control provisions of the CSA.

This rule also relates to the chemical described in the MCA as "hydrochloric gas." This term refers to the chemical hydrogen chloride that is free of water. The DEA has adopted the term "anhydrous hydrogen chloride," which is the term used most commonly by the industrial and scientific communities to describe this chemical. Prior to passage of the MCA, hydrochloric acid was included as a listed chemical by regulation. The anhydrous form of hydrochloric acid, anhydrous hydrogen chloride, is a regulated form of hydrochloric acid (57 FR 43614). Prior to the MCA, domestic transactions in hydrochloric acid, including anhydrous hydrogen chloride, were excluded from the definition of "regulated transaction" (21 CFR 1310.08(a)). However, the MCA provides that domestic transactions in the anhydrous hydrogen chloride form of hydrochloric acid are regulated transactions, and subject to the recordkeeping and reporting requirements of 21 CFR 1310. This change does not affect other forms of hydrochloric acid.

b. Thresholds Used to Define Regulated Transaction

Not all transactions involving a listed chemical are necessarily regulated. For purposes of defining a regulated transaction (21 U.S.C. 802(39)), the CSA provides that the Attorney General may establish a threshold amount for each listed chemical. A threshold amount is established to determine whether a receipt, sale, importation or exportation within a calendar month or cumulative transactions by an individual within a calendar month are considered regulated transactions. Unless the Attorney General sets a threshold, the threshold is considered to be zero; this has been the case of iodine and anhydrous hydrogen chloride since passage of the MCA on October 3, 1996.

When an amount of listed chemical distributed to any "person" in a calendar month is equal to or greater

than the threshold, the transaction is a regulated transaction. Thereafter, all transactions within the calendar month to those persons involving the listed chemical are regulated transactions. If the transaction is considered a regulated transaction, recordkeeping and reporting requirements as specified in 21 CFR Part 1310 apply. A "person" is defined in 21 CFR 1300.02(21) as "any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity." This includes any consumer who takes possession of a product, even as a free sample.

c. Notice of Proposed Rulemaking and the Comment Period

Prior to this Rule, thresholds had not been established for iodine or anhydrous hydrogen chloride. Therefore, all domestic distributions involving these chemicals became regulated effective October 3, 1996. In order to establish thresholds, the DEA published a notice of proposed rulemaking on September 30, 1997, (62 FR 51072) that proposed domestic thresholds for anhydrous hydrogen chloride and iodine of 0.0 kilograms and 0.4 kilograms, respectively. Interested persons were invited to comment.

The proposed domestic threshold of anhydrous hydrogen chloride is based on several factors: Nature of its legitimate use in industry; quantities used by legitimate industry; and quantities of anhydrous hydrogen chloride seized at clandestine laboratories. DEA learned that most transactions of anhydrous hydrogen chloride involve thousands of pounds, whereas clandestine laboratories use containers holding quantities as small as 0.5 pounds. Since the majority of anhydrous hydrogen chloride transactions involved large quantities, and to ensure the most effective controls on the diversion of this chemical, the DEA proposed a domestic threshold of 0.0 kilograms.

The comment period lasted for 60 days after publication of the proposed rule in the **Federal Register**. Interested persons who might be affected by the proposed thresholds responded. The DEA considered each of the seven comments received as well as the concerns of law enforcement and the provisions of the MCA.

2. Comments

a. Comments Related To the Iodine Threshold

A total of seven comments were received with two of the seven comments referring to iodine. One

requested that the threshold be raised from 0.4 kilograms to 3 kilograms. The other comment encouraged DEA to take into account recognized industrial standards for iodine distribution and to reduce the reporting burden for all legitimate suppliers and consumers of iodine. The standard for iodine distribution refers to the iodine package size used in distributions.

b. Anhydrous Hydrogen Chloride Threshold

All seven comments mentioned anhydrous hydrogen chloride. These comments mostly requested clarification while one requested that the threshold be set at 5 pounds. The comments also included a description of types of transactions in anhydrous hydrogen chloride that the commenters stated should not be subject to regulation.

c. Exemption Request for Some Transactions in Anhydrous Hydrogen Chloride

Three comments described transactions involving very large amounts of anhydrous hydrogen chloride. These transactions involve a special form of anhydrous hydrogen chloride referred to as refrigerated liquid. The material is distributed via large tank trucks, tank cars or by pipeline. The DEA agrees that these transactions should not be subject to regulation. However, the Notice of Proposed Rulemaking did not propose that these methods of distribution be exempted from regulation. Therefore, the DEA will exempt these forms of transactions via this notice as an interim final rule. The rule will be in effect upon publication but the DEA will allow for a comment period.

This final rule will: (1) Establish the iodine threshold, (2) establish the anhydrous hydrogen chloride thresholds, and (3) serve as an interim rule that exempts certain transactions in anhydrous hydrogen chloride. Due to the complexity of this final rule, it will be broken into three parts.

Part I Iodine

a. Iodine Is a Listed Chemical Under the MCA

The majority of clandestine laboratory seizures in the United States are those manufacturing methamphetamine, a Schedule II controlled substance. From 1993 through calendar year 1998, the DEA has participated in more than 4,740 methamphetamine laboratory seizures in the United States. This number does not include thousands of additional methamphetamine laboratory seizures by state and local authorities.

Clandestine laboratory operators most frequently use the ephedrine/pseudoephedrine reduction method to synthesize methamphetamine. This method utilizes hydriodic acid, which is a List I chemical with a domestic threshold of one liter. Because of increased controls on hydriodic acid, clandestine laboratory operators are resorting to producing their own hydriodic acid. They produce hydriodic acid from iodine, either in a separate step or by using iodine directly in the synthesis of methamphetamine.

b. Legal Uses for Iodine

Iodine is used largely in the form of a complex, salt, or as part of some chemical, that contains iodine. Iodine may be found dissolved in some disinfectants. Iodine does not dissolve well in water and so needs to be bound to a stabilizer or in some way converted to a water stable form to be used in disinfectants. Iodine crystals have very limited direct use and are mostly restricted to laboratory settings.

The major end uses of iodine are in catalysts, stabilizers and animal feeds. DEA has identified that farriers use iodine crystals. It can be purchased from either veterinary supply stores, feed and tack/farm supply stores or chemical distributors.

c. Determining the Iodine Threshold

The reasons cited in the proposed rule for the 0.4 kilogram threshold included legitimate use in industry, including quantities normally required for such uses; quantities purchased by clandestine laboratory operators; quantities seized at clandestine laboratory sites; and iodine's use in the production of methamphetamine. The majority of clandestine laboratories that produce methamphetamine do so in less than one-half kilogram quantities. The DEA cannot determine the source of all of the iodine seized at the clandestine laboratories due to operators removing the original labels or transferring the iodine to other unmarked containers. At those sites where iodine was seized in its original containers, DEA identified that the iodine was being purchased from either veterinary supply stores, feed and tack/farm supply stores or chemical distributors. The DEA has determined that a 2-ounce bottle of iodine would last a rancher or a farrier several months and that, typically, an individual would purchase at the most three 2-ounce bottles (approximately 0.2 kilograms).

Based on the above information, the DEA proposed a domestic threshold of 0.4 kilograms for iodine. This would subject transactions of 1 pound package

size or larger to recordkeeping requirements and would ensure the most effective controls on the diversion of iodine while minimizing the impact on industry, particularly for small businesses such as veterinary, feed, and farm supply stores.

d. Comments Pertaining to the Iodine Threshold

One comment suggested that the threshold be raised to 3 kilograms for iodine. The perceived substantial burden that the threshold will place on certain retailers, namely those associated with supplying the research community, is cited as the reason for this suggested threshold. The DEA believes that implementing a 3 kilogram threshold for iodine would allow current diversion of this chemical to continue mostly unabated. The DEA has queried suppliers of iodine to walk-in customers regarding the amounts of iodine that these customers would reasonably require for legitimate purposes and found that a 2 ounce bottle (approximately 60 grams) would last a typical purchaser several months. Additionally, the DEA has evidence that indicates that iodine is diverted for use at illicit methamphetamine laboratories often in one pound sizes. The DEA is aware that many legitimate distributors devote a good deal of effort to prevent their products from being sold to traffickers. However, some distributors sell to the general public under the pretense that the chemicals are to be used solely for research purposes without regard to how these chemicals are actually used. Based on these findings, the DEA concluded that the 0.4 kilogram threshold for iodine would impact traffickers while minimizing the burden upon legitimate industry.

DEA estimates that approximately 75 grams (0.17 pounds) of methamphetamine can be produced from 0.4 kilograms of iodine that has been converted into hydriodic acid. Approximately 563 grams (over 1 pound) of methamphetamine can be produced from 3 kilograms of iodine converted by hydriodic acid. The amount of 0.4 kilograms is twice the amount identified as the normal quantity range sold in legitimate face-to-face transactions. These factors contribute to setting the threshold at 0.4 kilograms.

It should be noted that to help lessen the burden of recordkeeping, 21 CFR 1310.06(b) provides that normal business records shall be considered adequate, provided they contain information described in 21 CFR 1310.06(a) and are readily retrievable from other business records. These

records can be those already required by other federal, state and local regulatory agencies.

e. Conclusion

DEA has determined that increasing the iodine threshold from 0.4 to 3 kilograms will not be sufficient to prevent diversion of iodine for illegitimate reasons. Therefore, the threshold for iodine will be set at 0.4 kilograms.

Part II Anhydrous Hydrogen Chloride Threshold

1. Background

a. What Is Anhydrous Hydrogen Chloride?

The statutory term "hydrochloric gas" is a form of hydrogen chloride more properly called anhydrous hydrogen chloride. Anhydrous hydrogen chloride is hydrogen chloride that is free from water. When in the form of a gas it is free of water. At ambient temperature and normal atmospheric pressure, anhydrous hydrogen chloride exists as a gas. Therefore, sometime anhydrous hydrogen chloride is referred to as hydrogen chloride gas or hydrochloric gas.

When the atmospheric pressure is increased and/or the temperature is decreased, anhydrous hydrogen chloride can change from a gas to a liquid. This is sometime referred to as refrigerated hydrogen chloride. Refrigerated hydrogen chloride is the same as anhydrous hydrogen chloride even though the physical state has been changed from a gas to a liquid.

Anhydrous hydrogen chloride is often dissolved in water. When dissolved it is usually referred to as hydrochloric acid. A commercial name for hydrochloric acid is muriatic acid. Because it is mixed with water, the term anhydrous cannot be used.

b. Past and Current Regulation of Anhydrous Hydrogen Chloride

Was Anhydrous Hydrogen Chloride a List II Chemical Prior to the MCA?

Yes. Prior to the MCA, by regulation, all forms of hydrochloric acid, which included anhydrous hydrogen chloride, were a list II chemical (21 CFR 1310.02(b)(8)). However, all domestic and import transactions of hydrochloric acid were excluded from the definition of "regulated transaction" (21 CFR 1310.08(a)). In addition, by regulation, all exports, transshipments and international transactions of anhydrous hydrogen chloride, except those to all South American countries and Panama above a threshold of 27 kilograms, had

similarly been excluded from the definition of "regulated transaction" (21 CFR 1310.08(b)). This may have given the appearance that anhydrous hydrogen chloride was a non-regulated form of the chemical. Prior to enactment of the MCA, only exports to all South American countries and Panama above a threshold of 27 kilograms had been regulated transactions (21 CFR 1310.08(b)).

How Does the MCA Affect Transactions of Anhydrous Hydrogen Chloride?

The CSA amendment by the MCA had the practical effect of directing DEA to place domestic controls on anhydrous hydrogen chloride. As a result, domestic transactions and the already controlled exports, transshipments and international transactions of anhydrous hydrogen chloride to designated countries are regulated transactions. These designated countries are listed in 21 CFR 1310.08(b).

How Is Hydrochloric Acid Affected by This New Regulation?

Hydrochloric acid, that is, hydrogen chloride dissolved in water, is not affected by these regulations. Domestic and import transactions involving that form of the chemical are not regulated transactions. Only export transactions of threshold amounts to those countries designated in 21 CFR 1310.08(b) are regulated transactions.

C. Uses for Anhydrous Hydrogen Chloride

i. Legal uses. According to information gathered by the DEA, the major legitimate uses of anhydrous hydrogen chloride are in the cotton industry, the electronic/silicon industry, the pharmaceutical industry and other industries for use in chemical syntheses. All of those industries use large quantities of anhydrous hydrogen chloride for their manufacturing processes. Generally, thousands of pounds are involved in a single transaction with the exception of smaller quantities (i.e., single or multiple cylinders) being used by research, analytical or synthetic laboratories.

ii. Illicit uses. Anhydrous hydrogen chloride can be used to convert an illicitly produced controlled substance from the "base" form to the "salt" form. These two forms have different physical characteristics. It is the salt form that is typically sold and used by individuals for abuse purposes.

Hydrochloric acid can also be used to isolate the base by forming the salt. However, using hydrochloric acid is not as easy as using anhydrous hydrogen

chloride and requires the proper solvents and laboratory technique. Hydrochloric acid has advantages in the illicit processing of cocaine and heroin. Anhydrous hydrogen chloride is the preferred chemical for the manufacture of methamphetamine into a usable form.

2. Comments for Anhydrous Hydrogen Chloride

Seven responses were received; two responses came from membership organizations. All seven comments requested clarifications or exemptions for specific types of transactions. One comment requested that the threshold be raised to 5 pounds. The DEA has carefully reviewed and considered the comments received in response to the Notice of Proposed Rulemaking. These will be discussed below.

a. Clarification as to the Form of Hydrogen Chloride Being Addressed in This Rulemaking

Five comments requested that the DEA clarify what is meant by hydrochloric gas. In response, DEA notes that the chemical being addressed in this rulemaking is the form of hydrochloric acid that is free of water. This substance is anhydrous hydrochloric acid or anhydrous hydrogen chloride. The DEA has responded to these concerns by revising 21 CFR 1310.02 and 1310.04 to include the term "anhydrous hydrogen chloride," thereby specifying the form of the chemical for which domestic transactions are regulated.

Two comments stated that the designations (e.g., UN 1050, UN 1789 and UN 2186) used by the United Nations (UN) should be adopted to identify the different forms of the acid. The DEA agrees that this is an efficient means to identify the acid for industrial commerce. However, the introduction of these numbers into the CFR would not be advantageous. DEA believes that introducing new designations to the CFR may cause confusion and imply that a new chemical has been placed in list II.

Anhydrous forms of hydrochloric acid being addressed in this rulemaking are anhydrous hydrogen chloride (designated as UN 1050; Anhydrous gas) and refrigerated anhydrous hydrogen chloride (designated as UN 2186; anhydrous refrigerated liquid). These forms of hydrochloric acid are free from water and thus included as anhydrous hydrogen chloride. The form that is dissolved in water is hydrochloric acid (designated as UN 1789) which has been addressed under a separate rulemaking published on September 22, 1992, (57 FR 43614). That final rule identifies

anhydrous hydrogen chloride as a form of hydrochloric acid regulated under the chemical designation of hydrochloric acid (DEA chemical code number 6545).

The DEA does not treat the different forms of hydrogen chloride as separate listed chemicals with distinct DEA chemical code numbers (57 FR 43614). Certain transactions in hydrochloric acid, including domestic distributions, have been exempt from the recordkeeping and reporting requirements (21 CFR 1310.08(a)(b)). The MCA directed DEA to impose controls on domestic transactions of the anhydrous form of hydrochloric acid but not the form dissolved in water. However, no new chemical is being addressed. The use of UN numbers in the CFR may imply that new chemicals are being added to the list of regulated chemicals.

Introducing the UN numbers to the regulatory language would create additional problems. Reference to each form of the chemical will need to be made via UN numbers everywhere the chemical is mentioned. Because UN numbers may not be understood by all who use the CFR, it may cause confusion. The DEA would need to define the UN numbers in the CFR to make use of them.

b. Clarification of the Forms of Hydrochloric Acid in 21 CFR 1310.02(b)

Two comments raised the issue of including anhydrous hydrogen chloride in 21 CFR 1310.02(b)(8), which lists hydrochloric acid. The comments noted that if the different forms are named in the same subsection, then any time a reference in the regulation mentions hydrochloric acid, it also should include anhydrous hydrogen chloride. It was suggested that these different forms be listed separately in List II. The DEA concluded that this might imply that a new substance is being placed on the list. All forms of hydrogen chloride, as finalized in 57 FR 43614, are List II chemicals and currently regulated in 21 CFR 1310.02(b). To clarify, 21 CFR 1310.02(b)(8) will be modified to read: "Hydrochloric acid (including anhydrous hydrogen chloride)."

The comments raised the fact that DEA needs to clarify when a specific form of hydrogen chloride is referred to in the regulations. The appropriate sections of 21 CFR (e.g., 1310.04 and 1310.08) will be modified accordingly to reflect this clarification. The new paragraph (I) in 21 CFR 1310.04(f)(2)(ii) will then be added to read "Anhydrous hydrogen chloride." 21 CFR 1310.04(f)(2)(iv)(A)(1) will read "Anhydrous hydrogen chloride." 21 CFR 1310.08(a) will be amended to read

"Domestic and import transactions of hydrochloric and sulfuric acids but not including anhydrous hydrogen chloride." 21 CFR 1310.08(b) will be amended by inserting after "hydrochloric" the phrase "(including anhydrous hydrogen chloride)".

c. Threshold for Anhydrous Hydrogen Chloride

One comment suggested that the threshold for anhydrous hydrogen chloride be raised to 5 pounds. Many clandestine operations can be successfully carried out with 5 pounds or less of anhydrous hydrogen chloride. While most anhydrous hydrogen chloride containers seized at clandestine laboratories are 65 pounds and less, the DEA has identified small bottles containing 0.5 pounds of anhydrous hydrogen chloride at methamphetamine laboratories. The zero threshold for anhydrous hydrogen chloride has been chosen to prevent the diversion of smaller canisters, as small as 0.5 pounds, for use in illegal drug production.

As stated, the DEA is aware that legitimate chemical distributors understand the growing problem of diversion and act responsibly to prevent their products from being used for illicit purposes. However, some distributors sell products used for the production of illegal substances under the pretense that they are for research purposes only without regard for how the products will actually be used. Raising the threshold to 5 pounds would allow unscrupulous suppliers to sell almost without regard for the regulatory process. DEA determined that clandestine laboratories would be supplied with desired chemical if the threshold were raised to 5 pounds. Therefore, the threshold will be set at 0.0 kilograms.

d. Transactions Involving Residual Amounts of Anhydrous Hydrogen Chloride

One comment stated that undue burden would be placed upon industry if controls of anhydrous hydrogen chloride were to include all containers and physical states. The person stated that regardless of the physical state, all containers would have the gas phase in the container headspace. The headspace refers to the empty space above the solution within a container. When anhydrous hydrogen chloride is dissolved in water to form a solution of hydrochloric acid, a small amount of the hydrogen chloride gas will form in the headspace above the solution. Because of the zero threshold, the comment requests clarification for treatment of

the small amount of gas that naturally forms in any container holding a solution of hydrochloric acid.

DEA would like to clarify that residual anhydrous hydrogen chloride contained in the head space of containers holding a solution of hydrochloric acid will not cause an otherwise non-regulated transaction to be regulated. The chemical being marketed as hydrochloric acid solution is distinctly different than that marketed as anhydrous hydrogen chloride. The natural formation of hydrogen chloride gas above the solution, along with water vapor, does not constitute the formation of anhydrous hydrogen chloride for purposes of this regulation.

The comment also stated that it is not clear from the proposed rule that the domestic regulatory controls would not apply to the inadvertent anhydrous hydrogen chloride present in container headspace of containers of anhydrous hydrogen chloride. The comment is referring to small amounts of anhydrous hydrogen chloride that remain inside a container of anhydrous hydrogen chloride because it is impossible to empty the container completely.

The DEA realizes that a container deemed empty may have residual anhydrous hydrogen chloride present. The purchaser frequently retains these containers until the hydrogen chloride is used and then the container is returned to the distributor. The DEA does not consider transactions involving depleted containers that held anhydrous hydrogen chloride to be regulated transactions just because a residual amount of anhydrous hydrogen chloride is present.

e. Anhydrous Hydrogen Chloride and the Surveillance List

A comment suggested that small quantities of anhydrous hydrogen chloride be included in the DEA Special Surveillance List in lieu of adopting a zero threshold for this chemical. Section 205 of the MCA requires that DEA establish a Special Surveillance List of laboratory supplies. This was established on May 13, 1999 (62 FR 25910). The MCA provides for a civil penalty for distribution of a laboratory supply made with reckless disregard to a person who uses, or attempts to use the laboratory supply in the manufacturing of a controlled substance. The term "laboratory supply" is defined to include listed chemicals. Therefore, listed chemicals are already included on the surveillance list.

The Special Surveillance List is an added means to help prevent the diversion of both listed and other

designated chemicals and equipment that can be used in clandestine synthesis of controlled substances. The surveillance list is not a substitute for regulatory controls on regulated transactions of anhydrous hydrogen chloride, a List II chemical. It does not impose recordkeeping, reporting or registration requirements as do regulations associated with listed chemicals.

f. Synthetic Alternative to Anhydrous Hydrogen Chloride

A comment pointed out that the regulation of anhydrous hydrogen chloride might be a futile attempt at controlling the use of anhydrous hydrogen chloride in the illegal production of controlled substances. Clandestine operators may form their own anhydrous hydrogen chloride by using a method simple enough for such operations.

DEA acknowledges that hydrogen chloride can be manufactured clandestinely. However, commercially produced anhydrous hydrogen chloride is commonly found at seized clandestine laboratories. The control of such chemicals is a valuable tool in denying traffickers a ready supply of anhydrous hydrogen chloride. This is why Congress included such control provisions in the MCA.

g. Impact of This Rule on the Anhydrous Hydrogen Chloride Trade

A comment questioned whether this rulemaking was a significant rule. The person stated that the DEA acknowledged that the industry was large by including the statement "the majority of anhydrous hydrogen chloride transactions involve thousands of pounds" in the proposed rulemaking. This statement refers to the amount of anhydrous hydrogen chloride traded in a single transaction and not the number of persons carrying out such transactions. The major uses of anhydrous hydrogen chloride were determined to be in the cotton industry, the electronic/silicon industry, the pharmaceutical industry and other industries for use in chemical synthesis. All of these industries use large quantities of anhydrous hydrogen chloride for their manufacturing processes.

Distributions of anhydrous hydrogen chloride have been identified as originating from manufacturing sites that produce anhydrous hydrogen chloride as a by-product of a principle manufacturing operation. Manufacturers distribute large quantities of anhydrous hydrogen chloride, sometimes under terms of a contract, to end-users. The

impact of this rulemaking on the trade has been evaluated by considering the added cost of doing business, not the gross annual cost for the entire anhydrous chloride trade. The DEA, as stated, only requires access to records that are part of daily recordkeeping for most companies that trade in this commodity. These records can be those already required by other federal agencies, or by state and local agencies. Normal business records needed by companies for internal recordkeeping are likely to be adequate for the purposes of this rulemaking.

21 CFR 1310.06 states that "* * * normal business records shall be considered adequate if they contain the information listed in paragraph (a) of this section and are readily retrievable from other business records of the regulated person." This acceptance of records that are already maintained by persons in the anhydrous hydrogen chloride trade reduces the impact on the anhydrous hydrogen chloride industry.

3. Conclusion

The DEA has considered the comments submitted in response to the notice of proposed rulemaking (62 FR 51072) to establish the anhydrous hydrogen chloride threshold. Out of seven comments received, only one requested that the threshold be raised. Most comments raised issues of clarification or compliance. The DEA concluded that the threshold for anhydrous hydrogen chloride will be established at 0.0 kilograms for domestic distributions. This threshold is based on anhydrous hydrogen chloride cylinders containing as little as 0.5 pounds of the chemical being recovered at illicit methamphetamine laboratories and legitimate transactions of this chemical being large. Maintaining the zero threshold will help curtail diversion of amounts useful to the clandestine operator. Increasing the threshold will allow for the manufacturing of methamphetamine in quantities normally associated with clandestine operations with traffickers obtaining as little as 0.5 pounds of the chemical.

Part III Category Exemption

a. Comments Requesting Category Exemption

The DEA received comments requesting exemption for two categories of transactions involving anhydrous hydrogen chloride. These are transactions involving: (1) Refrigerated liquid; and (2) anhydrous hydrogen chloride distributed by pipeline. The DEA agrees that anhydrous hydrogen

chloride distributed by these methods is unlikely to be susceptible to diversion. The exemption for these categories was not proposed in the Notice of Proposed Rulemaking. Authority to remove a category of transaction from the definition of "regulated transaction" is given in 21 U.S.C. 802(39)(A)(iii), which permits exclusion of "any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Attorney General as excluded from this definition as unnecessary for enforcement of this subchapter or subchapter II of this chapter."

b. Refrigerated Liquid; Large Quantity Distributions of Anhydrous Hydrogen Chloride

The DEA collected additional information from the affected industry. DEA learned that rail and truck carriers ship refrigerated liquid only in large containers. The average payload of a rail car is approximately 135,000 pounds. The capacity for tank trucks is approximately 12,000 to 30,000 pounds. These shipments are in single containers holding the specified weights. Specialized equipment and engineering skills are needed to off-load this commodity. Distributors are aware of their customers and are involved in tracking shipments. The DEA believes that anhydrous hydrogen chloride in this form and in these quantities is not likely to be diverted.

DEA has not identified any shipment of refrigerated anhydrous hydrogen chloride less than the tank truck size of approximately 12,000 pounds. Therefore, domestic distributions of anhydrous hydrogen chloride in single container shipments of 12,000 pounds (net weight) or more will be excluded from the definition of regulated transaction. Transactions that involve multiple containers, each containing less than 12,000 pounds of the chemical are regulated transactions even if the aggregate weight is over 12,000 pounds.

Why Not Just Provide an Exemption for All Transactions in "Anhydrous Hydrogen Chloride, Refrigerated Liquid"?

The refrigerated liquid is not clearly defined or distinguished from the gaseous form except by the weight of the anhydrous hydrogen chloride contained in a single vessel. Distributors use both cooling and pressure to liquefy the gas in order to increase the amount of anhydrous hydrogen chloride that the container can hold. However, the containers that transport the liquefied hydrogen chloride are not refrigerated. The method of distributing the

refrigerated form is only clearly distinguished by the size of the vessel used to transport the commodity. DEA is concerned that unscrupulous persons may attempt to deceive law enforcement personnel by distributing smaller quantities mislabeled as refrigerated liquid. Therefore, the DEA concluded that a category be defined by the net weight of anhydrous hydrogen chloride that a single container holds. Defining the category by using the net weight of anhydrous hydrogen chloride in a single container eliminates the possibility of misinterpreting whether or not a distribution is a regulated transaction.

c. Pipeline Transfers

The DEA also received comments that included reasons to eliminate pipeline transactions of anhydrous hydrogen chloride as regulated transactions. Pipeline transactions involve pumping the chemical through a closed system, directly to the customer from the distributor's site. Pipelines are located underground or in piperacks and are maintained at high pressure. Diversion from a pipeline is unlikely because of the location, construction and the obvious danger associated with the unauthorized tapping of this source. Pipeline distributions may involve thousands of pounds of anhydrous hydrogen chloride transferred on a given day.

The DEA concluded, in light of these comments, that these transactions have an insignificant risk of diversion. Therefore, domestic pipeline transactions will be the second category of transaction in anhydrous hydrogen chloride regarded as a non-regulated transaction.

d. Exclusion of Categories; Interim Rule With Request for Comments

This Final Rule will establish, on an interim basis, that domestic transactions of (1) anhydrous hydrogen chloride weighing 12,000 pounds (net weight) or more in a single container or (2) anhydrous hydrogen chloride by pipeline are excluded from the definition of regulated transactions. These exemptions will take effect on the day that this Final Rule is published in the **Federal Register**.

To exempt these categories, two new paragraphs (h) and (i) in Title 21 CFR Section 1310.08 will be added to read; (h) Domestic distribution of anhydrous hydrogen chloride weighing 12,000 pounds (net weight) or more in a single container; and (i) Domestic distribution of anhydrous hydrogen chloride by pipeline. The DEA is soliciting comments only on this portion of this Final Rule. The DEA will allow 30 days

for persons to comment on these category exemptions.

After the close of this comment period pertaining to the exempted categories, DEA will publish a notice in the **Federal Register** to inform interested persons if changes are needed or if these categories will be adopted as stated.

e. Exemption Authority

The CSA authorizes DEA, pursuant to 21 U.S.C. 802(39)(A)(iii), to remove certain transactions in listed chemicals from the definition of regulated transaction. DEA has determined that transactions in anhydrous hydrogen chloride in the form of refrigerated liquid and transactions involving the direct transfer of anhydrous hydrogen chloride by pipeline are unlikely sources for diversion and should be removed from the definition of regulated transaction. DEA became aware of these types of transactions by the comments received in response to the **Federal Register** proposal to establish thresholds for iodine and anhydrous hydrogen chloride (62 FR 51072). Since that proposal did not propose that these categories of transactions in anhydrous hydrogen chloride would be exempt, the general public did not have the opportunity to comment on the exclusion of these transactions from the definition of regulated transaction.

The DEA has determined that good cause exists under the Administrative Procedure Act (5 U.S.C. 553 *et seq.*) (APA) to forego a notice of proposed rulemaking for the exclusion of these transactions from the definition of regulated transaction. The AP states that an agency may forego a notice of proposed rule making if it is impracticable, unnecessary, or contrary to the public interest.

Although all transactions involving anhydrous hydrogen chloride are considered regulated until and unless DEA establishes a threshold, establishing a zero threshold for this substance may cause affected parties to implement a permanent system of recordkeeping and reporting for all transactions. This would involve some companies who otherwise may not engage in regulated transactions if the exemptions are finalized. If a proposal is published in the **Federal Register** to exclude these transactions from the definition of regulated transactions, each affected entity may find it necessary to establish these procedures on a permanent basis even though the requirement may only be temporary. To avoid unnecessary burdens on affected companies during the pendency of proceedings in this matter, the DEA will

include as part of this rulemaking an interim rule, with request for comments, that removes these two types of transactions from the definition of regulated transactions.

The DEA is also including in this final rulemaking the reinsertion of the table in 21 CFR 1310.40(f)(2)(iv), listing thresholds for exports, transshipments, and international transactions to designated countries set forth in 21 CFR 1310.08(b). The DEA's final rule regarding implementation of the Domestic Chemical Diversion Control Act of 1993, published on June 22, 1995 (60 FR 32447), inadvertently omitted the table from the section. A DEA chemical code number for iodine, 6699, will also be included in this rule.

This regulation has been drafted and reviewed in accordance with Executive Order 12866, Section 1(b), Principles of Regulation. The DEA has determined that this rule is not a "significant regulatory action" under Executive Order 12866, Section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by the Office of Management and Budget.

The Deputy Administrator in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities for the following reasons: The DEA sought information from legitimate handlers of iodine to determine the uses of iodine and the quantities typically sold in legitimate transactions. The DEA sought information from over 300 veterinary suppliers and feed and farm supply stores to determine how iodine is typically sold. The DEA learned that walk-in customers would purchase, at the most, three 2-ounce bottles (less than 0.2 kilograms). Suppliers and end-users claim that a 2-ounce bottle lasts several months. Iodine has very limited application for walk-in customers. Setting the iodine threshold at 0.4 kilograms will not have a significant effect on small businesses. The iodine portion of this Final Rule applies only to those companies manufacturing and distributing iodine in larger volumes. Recordkeeping requirements will not impact researchers or other end-users.

This regulation will not have a significant economic impact upon a substantial number of small entities that trade in anhydrous hydrogen chloride. Trade in anhydrous hydrogen chloride is mostly in very large quantities. Generally, thousands of pounds are involved in single industrial transactions. Smaller quantities *i.e.*,

single or multiple cylinders) are being used by research, analytical or synthetic laboratories. The majority of anhydrous hydrogen chloride is traded in thousands of pound quantities. The DEA has included in this Final Rule the exclusion from the definition of "regulated transaction" transactions involving anhydrous hydrogen chloride in bulk quantities of 12,000 pounds (net weight) or more. The DEA is soliciting comments on that part of this Final Rule.

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in

accordance with Executive Order 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1210

Drug traffic control, Reporting and recordkeeping requirements.

For reasons set out above, 21 CFR Part 1310 is amended as follows:

PART 1310—[AMENDED]

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

Authority: 21 U.S.C. 802, 830, 871(b).

2. Section 1310.02 is amended by revising paragraph (b)(8) and adding paragraph (b)(11) to read as follows:

§ 1310.02 Substances covered.

* * * * *
 (b) List II chemicals:
 * * * * *

- (8) Hydrochloric acid (including anhydrous hydrogen chloride) 6545
- * * * * *
- (11) Iodine 6699

3. Section 1310.04 is amended by adding new paragraphs (f)(2)(ii) (H) and (I), and revising (f)(2)(iv) to read as follows:

§ 1310.04 Maintenance of records.

* * * * *
 (f) * * *
 (2) * * *
 (i) * * *
 (ii) Domestic Sales

Chemical	Threshold by volume	Threshold by weight
(H) Iodine	N/A	0.4 kilograms.
(I) Anhydrous Hydrogen chloride	N/A	0.0 kilograms.

(iii) * * * (iv) Exports, Transshipments and International Transactions to Designated Countries as Set Forth in § 1310.08(b).

Chemical	Threshold by volume	Threshold by weight
(A) Hydrochloric acid	50 gallons	
(1) Anhydrous Hydrogen chloride		27 kilograms.
(B) Sulfuric acid	50 gallons	

* * * * *
 4. Section 1310.08 is amended by revising paragraphs (a) and (b) introductory text and by adding new paragraphs (f), (g), (h) and (i) to read as follows:

§ 1310.08 Excluded transactions.

- * * * * *
- (a) Domestic and import transactions of hydrochloric and sulfuric acids but not including anhydrous hydrogen chloride.
- (b) Exports, transshipments, and international transactions of hydrochloric (including anhydrous hydrogen chloride) and sulfuric acids, except for exports, transshipments and international transactions to the following countries:
 * * * * *
- (f) Import and export transactions of iodine.
- (g) Import transactions of anhydrous hydrogen chloride.
- (h) Domestic distribution of anhydrous hydrogen chloride weighing

12,000 pounds (net weight) or more in a single container.
 (i) Domestic distribution of anhydrous hydrogen chloride by pipeline.

Dated: May 18, 2000.
Donnie R. Marshall,
Deputy Administrator.
 [FR Doc. 00-19289 Filed 8-1-00; 8:45 am]
BILLING CODE 4410-09-M

DEPARTMENT OF TRANSPORTATION

Coast Guard
33 CFR Part 100
[CGD05-00-027]
RIN 2115-AE46

Special Local Regulations for Marine Events; Thunder on the Narrows Hydroplane Races, Prospect Bay, Kent Island Narrows, Maryland

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is adopting temporary special local regulations during the "Thunder on the Narrows" hydroplane races to be held on the waters of Prospect Bay near Kent Island Narrows, Maryland. These special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in portions of Prospect Bay during the event.

DATES: This rule is effective from 10:30 a.m., August 5, 2000 until 6:30 p.m., August 6, 2000.

ADDRESSES: You may mail comments and related material to Commander (Aoax), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704-5004, or deliver them to the same address between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays. Comments and materials received from the public as well as