

presentation, and approximate amount of time requested for the presentation.

The agency requests that persons or groups having similar interests consolidate their presentations and present them through a single representative. Because presentations will be limited to 1 day, the agency may not be able to accommodate all requests for oral presentations. FDA will allocate the time available for the meeting among the persons who properly file requests for oral presentations. If time permits at the conclusion of the meeting, FDA may allow participation from both interested persons attending the meeting who did not submit a written request for an oral presentation and those who requested an opportunity to make a presentation, but, due to the time limitations, were not granted the request.

IV. Requests for Comments

Interested persons may, on or before November 13, 1997, submit written comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

V. Special Accommodations

In order to accommodate the need for space or technical support, persons who are planning on using audiovisual equipment during their oral presentations are urged to provide advance notice of their planned attendance to one of the contact persons identified above. If you need special accommodations due to a disability, please contact one of the contact persons listed above at least 7 days in advance.

VI. Transcripts

Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: September 24, 1997,

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-25937 Filed 9-29-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[DEA-156P]

RIN #1117-aa43

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

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Comprehensive Methamphetamine Control Act of 1996 (MCA) establishes that, effective October 3, 1996, iodine and hydrogen chloride gas are List II chemicals under the Controlled Substances Act (CSA). The inclusion of these chemicals under the CSA requires that each regulated person must keep records and file reports as specified in Title 21 Code Federal Regulations (21 CFR) Part 1310. Since the MCA did not establish thresholds for iodine and hydrogen chloride gas, recordkeeping and reporting requirements became applicable to all domestic transactions of these chemicals. While this notice of proposed rulemaking is proposing a domestic threshold of 0.0 kilograms for hydrogen chloride gas, it proposes to set a domestic threshold of 0.4 kilograms for iodine. This iodine threshold will remove the recordkeeping requirement for many iodine transactions.

This notice of proposed rulemaking also proposes to reinsert the table in 21 CFR 1310.04(f)(2)(iv), listing thresholds for exports, transshipments, and international transactions to designated countries set forth in 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.

DATES: Written comments or objections must be received on or before December 1, 1997.

ADDRESSES: Comments and objections should be submitted in quintuplicate 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: The MCA was signed into law on October 3, 1996, Section 204 of the MCA amends Section 102(35) of the CSA (21 U.S.C. 802(35)) to include iodine and hydrogen chloride gas as List II chemicals. Section 204(b)(1) and (2) of the MCA also states that "iodine shall not be subject to the requirements for listed chemicals provided in section 1018 of the Controlled Substances Import and Export Act (21 U.S.C. 971)." Therefore, the MCA does not impose import/export requirements on iodine. The MCA, however, does not "limit the authority of the Attorney General to impose the requirements for listed chemicals provided in section 1018 of the Controlled Substances Import and Export Act (21 U.S.C. 971)." Although the DEA is not imposing import/export restrictions on iodine at this time, the DEA is currently reviewing available data on iodine to determine if such controls are warranted.

Prior to the MCA, hydrogen chloride gas, also known as anhydrous hydrochloric acid, was already a List II chemical under the CSA (21 CFR 1310.02(b)(8)). Pursuant to 21 CFR 1310.08, all domestic and import transactions of hydrogen chloride gas have been exempt from the regulatory controls under the CSA. In addition, all exports, transshipments and international transactions of hydrogen chloride gas have been exempt from the regulatory controls except those to all South American countries and Panama. Exports to all South American countries and Panama above a threshold of 27 kilograms have been regulated transactions (21 CFR 1310.08(b)). The MCA amends the CSA to impose only domestic controls on iodine and domestic and international controls on hydrogen chloride gas.

The majority of the clandestine laboratories seized in the United States manufacture methamphetamine, a Schedule II controlled substance. Since 1990, more than 2,400 methamphetamine laboratories have been seized in the United States by the DEA. The most frequently used synthesis among clandestine laboratory operators today is the ephedrine/pseudoephedrine reduction method which utilizes hydriodic acid. Hydriodic acid is a List I chemical with a domestic threshold of one liter. With the increased controls on hydriodic acid, clandestine laboratory operators have turned to producing their own hydriodic acid or using iodine directly in the synthesis. Clandestine laboratory

operators, since 1992, have been utilizing iodine either directly in the ephedrine/pseudoephedrine reduction method or have been using iodine to produce hydriodic acid, the traditional reducing agent in the ephedrine/pseudoephedrine reduction method. Hydrogen chloride gas, on the other hand, can be used in the clandestine synthesis of most controlled substances to convert the basic form of a controlled substance to its hydrochloride salt. It is often used in the illicit production of methamphetamine.

Certain provisions of the CSA and its regulations are applicable only to regulated transactions involving listed chemicals. For purposes of defining a regulated transaction (21 U.S.C. 802(39)), the CSA provides that the Attorney General may impose 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 multiple transactions by an individual within a calendar month are considered regulated transactions. If the transaction is considered a regulated transaction, then they are recordkeeping and reporting requirements as specified in 21 CFR 1310.

The DEA examined several types of information in proposing a domestic threshold for iodine: legitimate use in industry, including the quantities normally required for such uses; quantities purchased by clandestine laboratory operators; quantities seized at clandestine laboratory sites; and its use in the production of methamphetamine. The number of clandestine laboratories using iodine in the synthesis of methamphetamine has increased drastically in the past five years. In 1992, the DEA documented that 18 of the 228 (approximately 6 percent) methamphetamine clandestine laboratories seized by DEA used iodine. During 1996, at least 290 methamphetamine clandestine laboratories seized by DEA used iodine. The majority of these clandestine laboratories are producing small quantities (i.e., less than one-half kilogram) of methamphetamine. Seizures of iodine at the clandestine laboratory sites ranged from approximately 10 grams to 3,000 kilograms. The DEA cannot determine the source of all of the iodine seized at clandestine laboratory sites due to clandestine laboratory 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 sought information from legitimate handlers of iodine (i.e., manufacturers, end-users, distributors, and veterinary, feed and farm supply stores/companies) to determine the uses of iodine and the quantities typically found in legitimate transactions. Of particular interest to DEA was the sale of relatively small quantities of iodine for cauterization of a hoof wound and for the treatment of thrush. The DEA sought information from over 300 veterinary suppliers and feed and farm supply stores to determine if the stores sold iodine. Of the 300 stores and suppliers which provided information, only nine sold iodine. Several suppliers and end-users stated that a two-ounce bottle of iodine would last a rancher or a farrier several months and that, typically, an individual would purchase at the most 3–2 ounce bottles (approximately 0.2 kilograms) at a time.

Based on this information, the DEA is proposing a domestic threshold of 0.4 kg for iodine. This 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.

The proposed domestic threshold of hydrogen chloride gas is based upon several items: its legitimate use in industry; quantities used by legitimate industry; and quantities of hydrogen chloride gas seized at clandestine laboratories.

Hydrogen chloride gas is sold in cylinders. Traditionally, cylinders of hydrogen chloride gas have been seen mostly at methamphetamine clandestine laboratory sites in the western part of the United States. Most of the cylinders seized at the clandestine laboratory sites contain approximately 60 pounds of hydrogen chloride gas. Small cylinders which contain 0.5 pounds of hydrogen chloride gas have also been seen at some laboratory sites.

The DEA gathered information on the legitimate uses of hydrogen chloride gas in the United States. The major uses of hydrogen chloride gas were determined to be in the cotton industry, the electronic/silicon industry, the pharmaceutical industry and other industries for use in chemical syntheses. All of these industries use large quantities of hydrogen chloride gas for their manufacturing processes. Generally, thousands of pounds are involved in single transactions with the exception of smaller quantities (i.e., single or multiple cylinders) being used

by research, analytical or synthetic laboratories. There are also safety issues regarding the handling of hydrogen chloride gas. Since the majority of hydrogen chloride gas transactions involve thousands of pounds and to ensure the most effective controls on the diversion of hydrogen chloride gas, the DEA proposes a domestic threshold of 0 kg for hydrogen chloride gas. A threshold of 0 kg means that all sales of hydrogen chloride gas would be regulated.

Before the MCA was passed, hydrogen chloride gas, also known as anhydrous hydrochloric acid, was already a List II chemical under the CSA (21 CFR 1310.02(b)(8)). All domestic and import transactions, and exports, transshipments and international transactions, except those to all South American countries and Panama, have been exempt from regulatory controls under the CSA. Exports, transshipments and international transactions of hydrogen chloride gas to all South American countries and Panama above a threshold of 27 kilograms have been regulated transactions pursuant to 21 CFR 1310.08(b). These transactions became regulated due to the DEA having evidence that hydrogen chloride gas was being diverted from illicit channels to illicit channels for cocaine hydrochloride production in these countries. With the passage of the MCA, both domestic and international controls apply to hydrogen chloride gas.

The DEA is also including in this proposed **Federal Register** notice the reinsertion of the table in 21 CFR 1310.04(f)(2)(iv), listing thresholds for exports, transshipments, and international transactions to designated countries set forth in 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.

The Deputy Assistant Administrator of DEA's Office of Diversion Control hereby certifies that this proposed rulemaking will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. Controls on iodine apply to iodine crystals. These controls do not pertain to common household products such as iodine tinctures of iodide salts. The proposed iodine rulemaking applies only to those companies manufacturing and distributing iodine in larger volumes. Recordkeeping requirements will not impact researchers or other end-users. Further, this proposed rule is not a significant regulatory action

pursuant to the criteria of Executive Order 12866, since the 0.4 kg iodine threshold does not affect small businesses and since there is not a large industry for hydrogen chloride gas. Therefore, this proposed rule has not been reviewed by the Office of Management and Budget.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1310

Drug traffic control, Reporting and recordkeeping requirements.

For reasons set out above, 21 CFR part 1310 is proposed to be 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 proposed to be 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 Hydrogen chloride gas)

* * * * *

(11) Iodine

* * * * *

3. Section 1310.04 is proposed to be 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) Hydro-gen chlo-ride gas.	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) Hydro-chloric acid.	50 gallons ...	N/A.
(1) Hydro-gen chlo-ride gas.	N/A	27 kilograms.
(B) Sulfuric acid.	50 gallons ...	N/A.

* * * * *

4. Section 1310.08 is proposed to be amended by adding new paragraphs (f) and (g) to read as follows:

§ 1310.08 Excluded transactions

* * * * *

(f) Import and export transactions of iodine.

(g) Import transactions of hydrogen chloride gas.

Dated: July 21, 1997.

John H. King,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 97-25362 Filed 9-29-97; 8:45 am]

BILLING CODE 4410-09-M

LEGAL SERVICES CORPORATION

45 CFR Part 1643

Restriction on Assisted Suicide, Euthanasia, and Mercy Killing

AGENCY: Legal Services Corporation.

ACTION: Proposed rule.

SUMMARY: This rule is intended to implement a new statutory restriction that amends the Legal Services Corporation Act ("LSC" or "Corporation") and is applicable to recipients of grants from the Legal Services Corporation. The restriction prohibits the use of LSC funds by recipients for legal or other assistance that would cause, assist in, advocate for, or fund assisted suicide, euthanasia, or mercy killing.

DATES: Comments should be received on or before October 30, 1997.

ADDRESSES: Comments should be submitted to the Office of the General Counsel, Legal Services Corporation, 750 First St. NE., 11th Floor, Washington, DC 20002-4250.

FOR FURTHER INFORMATION CONTACT: Office of the General Counsel, (202) 336-8817.

SUPPLEMENTARY INFORMATION: The Assisted Suicide Funding Restriction Act of 1997 ("Assisted Suicide Act" or "Act"), Pub. L. 105-12, was enacted and became effective on April 30, 1997. Several provisions of the Assisted

Suicide Act expressly apply to the Legal Services Corporation, one of which amends Section 1007(b) of the LSC Act, 42 U.S.C. 2996f(b)(11). This rule is intended to implement this legislation as it applies to the Corporation and its recipients.

Background and Summary of Law

The stated purpose of the Assisted Suicide Act is to maintain current Federal policy that Federal funds not be used to support, assist in, or advocate for assisted suicide, euthanasia or mercy killing. H. Rep. No. 46, 105th Cong., 1st Sess. at 3 (April 8, 1997). Although assisted suicide, euthanasia and mercy killing are illegal in almost all states, Congress was concerned that pending litigation might change the status quo and wanted to make it clear by legislation that, regardless of a change in State law, Federal policy would remain the same. H. Rep. at 3-4. Subsequent to the passage of the Act, the Supreme Court upheld as constitutional laws in the States of New York and Washington which prohibit assisted suicide and euthanasia. See *Vacco v. Quill*, 117 S. Ct. 2293 (1997); *Washington v. Glucksberg*, 117 S. Ct. 2302 (1997). The State of Oregon, on the other hand, adopted an initiative in 1996 that legalized physician-assisted suicide for competent, terminally ill adults. H. Rep. at 4. Court challenges have kept the law from going into effect and a new initiative to repeal the law will be on the ballot this November. See Associated Press, September 15, 1997 (1997 WL 2549490); *Lee v. Oregon*, 107 F.3d 1382 (9th Cir. Feb. 27, 1997); Petition for Certiorari Filed, 65 USLW 3783 (May 16, 1997) (No. 96-1824).

The Assisted Suicide Act applies to numerous Federally funded health care programs and facilities, such as Medicare, Medicaid, CHAMPUS and the veterans' and military health care systems. It also applies to certain legal aid and advocacy programs, including the Legal Services Corporation.

Section 9 of the Assisted Suicide Act amends Section 1007(b) of the LSC Act to provide that "No funds made available by the Corporation under this title, either by grant or contract, may be used * * * to provide legal assistance in a manner inconsistent with the Assisted Suicide Funding Restriction Act of 1997." Section 5 of the Assisted Suicide Act sets out the restrictions as they apply to LSC funds by generally prohibiting the use of appropriated funds for legal or other assistance for the purpose of (1) securing or funding any