DEA Watched Chemicals (updated: 6/31/07)

This is the latest material available related to chemicals & regulatory law in the United States
Regulated pursuant to Sec. 1300.02(b)(28)(i)(D) & related statutes.

(1) List I chemicals:
(i) Except as provided in paragraph (f)(1)(ii) of this section, the following thresholds have been established for List I chemicals.

Chemical	Threshold by base weight
(A) Anthranilic acid, its esters, and its salts.	30 kilograms.
(B) Benzyl cyanide.....	1 kilogram.
(C) Ergonovine and its salts.....	10 grams.
(D) Ergotamine and its salts.....	20 grams.
(E) N-Acetylanthranilic acid, its esters, and its salts.	40 kilograms.
(F) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	2.5 kilograms.
(G) Phenylacetic acid, its esters, and its salts.	1 kilogram.
(H) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.	2.5 kilograms.
(I) Piperidine and its salts.....	500 grams.
(J) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.	1 kilogram.
(K) 3,4-Methylenedioxyphenyl-2-propanone..	4 kilograms.
(L) Methylamine and its salts.....	1 kilogram.
(M) Ethylamine and its salts.....	1 kilogram.
(N) Propionic anhydride.....	1 gram.
(O) Isosafrole.....	4 kilograms.
(P) Safrole.....	4 kilograms.
(Q) Piperonal.....	4 kilograms.
(R) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers (N-Methylephedrine).	1 kilogram.
(S) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	1 kilogram.

(T) Hydriodic Acid..... 1.7 kilograms (or 1 liter by volume).
(U) Benzaldehyde..... 4 kilograms.
(V) Nitroethane..... 2.5 kilograms.

(ii) Notwithstanding the thresholds established in paragraphs (f)(1)(i) and

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(g) of this section, the following thresholds will apply for the following List I chemicals that are contained in drug products that are regulated pursuant to Sec. 1300.02(b)(28)(i)(D) of this chapter (thresholds for retail distributors and distributors required to report under Sec. 1310.03(c) of this part are for a single transaction; the cumulative threshold provision does not apply. All other distributions are subject to the cumulative threshold provision.):

Chemical Threshold by weight

(A) Ephedrine, its salts, optical isomers, and salts of optical isomers as the sole therapeutically significant medicinal ingredient. No threshold. All transactions regulated.
(B) Ephedrine, its salts, optical isomers, and salts of optical isomers in combination with therapeutically significant amounts of another medicinal ingredient:
(1) Distributions by retail distributors. 24 grams.
(2) Distributions by persons required to report under Sec. 1310.03(c) of this part. 24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(B) (1) and (2) of this section). 1 kilogram.
(4) Imports and Exports..... 1 kilogram
(C) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers

(other than ordinary over-the-counter products):
(1) Distributions by retail 9 grams, and sold in package distributors. sizes of not more than 3 grams of pseudoephedrine base.
(2) Distributions by persons required 9 grams, and sold in package to report under Sec. 1310.03(c) of sizes of not more than 3 this part. grams of pseudoephedrine base.
(3) All other domestic distributions, 1 kilogram.
(other than paragraphs (f)(1)(ii)(C) (1) and (2) of this section).
(4) Imports and Exports..... 1 kilogram.
(D) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers (ordinary over-the-counter products):
(1) Distributions by retail Exempt. distributors.
(2) Distributions by persons required 9 grams, and sold in package to report under Sec. 1310.03(c) of sizes of not more than 3 this part. grams of pseudoephedrine base.
(3) All other domestic distributions 1 kilogram.
(other than paragraphs (f)(1)(ii)(D) (1) and (2) of this section).
(4) Imports and Exports..... 1 kilogram.
(E) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers (other than ordinary over-the-counter products):
(1) Distributions by retail 9 grams, and sold in package distributors. sizes of not more than 3 grams of phenylpropanolamine base.
(2) Distributions by persons required 9 grams, and sold in package to report under Sec. 1310.03(c) of sizes of not more than 3 this part. grams of phenylpropanolamine base.
(3) All other domestic distributions 2.5 kilograms.
(other than paragraphs (f)(1)(ii)(E) (1) and (2) of this section).

(4) Imports and Exports..... 2.5 kilograms.
(F) Phenylpropanolamine, its salts,
optical isomers, and salts of optical
isomers (ordinary over-the-counter
products):
(1) Distributions by retail Exempt.
distributors.
(2) Distributions by persons required 9 grams, and sold in package
to report under Sec. 1310.03(c) of sizes of not more than 3
this part. grams of
phenylpropanolamine base.
(3) All other domestic distributions 2.5 kilograms.
(other than paragraphs (f)(1)(ii)(F)
(1) and (2) of this section).
(4) Imports and Exports..... 2.5 kilograms.
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(2) List II Chemicals:
(i) Imports and Exports

Chemical Threshold by volume Threshold by weight

(A) Acetic anhydride..... 250 gallons..... 1,023 kilograms.
(B) Acetone..... 500 gallons..... 1,500 kilograms.
(C) Benzyl chloride..... N/A..... 4 kilograms.
(D) Ethyl ether..... 500 gallons..... 1,364 kilograms.
(E) Potassium permanganate..... N/A..... 500 kilograms.
(F) 2-Butanone (MEK)..... 500 gallons..... 1,455 kilograms.

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(G) Toluene..... 500 gallons..... 1,591 kilograms.

(ii) Domestic Sales

Chemical Threshold by volume Threshold by weight

(A) Acetic anhydride..... 250 gallons..... 1,023 kilograms.

(B) Acetone..... 50 gallons..... 150 kilograms.
(C) Benzyl chloride..... N/A..... 1 kilogram.
(D) Ethyl ether..... 50 gallons..... 135.8 kilograms.
(E) Potassium permanganate..... N/A..... 55 kilograms.
(F) 2-Butanone (MEK)..... 50 gallons..... 145 kilograms.
(G) Toluene..... 50 gallons..... 159 kilograms.
(H) Iodine..... N/A..... 0.4 kilograms.
(I) Anhydrous Hydrogen chloride..... N/A..... 0.0 kilograms.

(iii) The cumulative threshold is not applicable to domestic sales of Acetone, 2-Butanone (MEK), and Toluene.
(iv) Exports, Transshipments and International Transactions to Designated Countries as Set Forth in Sec. 1310.08(b).

Threshold by
Chemical volume Threshold by weight

(A) Hydrochloric acid..... 50 gallons
(1) Anhydrous Hydrogen ..... 27 kilograms.
chloride.
(B) Sulfuric acid..... 50 gallons

(v) Export and International Transactions to Designated Countries, and Importations for Transshipment or Transfer to Designated Countries

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Threshold by
Chemical volume Threshold by weight

(A) Methyl Isobutyl Ketone 500 gallons..... 1523 kilograms.
(MIBK).
(B) Reserved.

(g) For listed chemicals for which no thresholds have been established, the size of the transaction is not a factor in determining whether the transaction meets the definition of a regulated transaction as set forth in Sec. 1300.02(b)(28) of this chapter. All such transactions, regardless of size, are subject to recordkeeping and

reporting requirements as set forth in this part and notification provisions as set forth in part 1313 of this chapter.
(1) Listed chemicals for which no thresholds have been established:
(i) Ephedrine, its salts, optical isomers and salts of optical isomers
(ii) Red phosphorus
(iii) White phosphorus (Other names: Yellow Phosphorus)
(iv) Hypophosphorous acid and its salts
(v) gamma-Butyrolactone (Other names include: GBL; Dihydro-2(3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone)
(2) [Reserved]
(h) The thresholds and conditions in paragraphs (f) and (g) of this section will apply to transactions involving regulated chemical mixtures. For purposes of determining whether the weight or volume of a chemical mixture meets or exceeds the applicable quantitative threshold, the following rules apply:
(1) For chemical mixtures containing List I chemicals or List II chemicals other than those in paragraph (h)(2) of this section, the threshold is determined by the weight of the listed chemical in the chemical mixture.
(2) For the List II chemicals acetone, ethyl ether, 2-butanone, toluene, and methyl isobutyl ketone, the threshold is determined by the weight of the entire chemical mixture.
(3) If two or more listed chemicals are present in a chemical mixture, and the quantity of any of these chemicals

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equals or exceeds the threshold applicable to that chemical, then the transaction is regulated.

Regulatory note: Where as a Listed Chemical has a threshold does NOT deem it a non-reportable chemical sale. Any individual, company, or organization that makes any sale of listed chemicals is expected to have available for a period of five (5) years (from Date of Delivery) the sales records of Listed Materials.

A Cumulative Threshold Provision (CTP) is applicable to what may be sold by that provider. What is delineated is the possibility of multiple sales from different providers or sales throughout the life of a company, organization, or individual purchase. Records are to remain available to preclude the intent of the Law from being circumvented.

Suspicious Orders Task Force

PubLaw 104-237 Title V, § 504, Oct 3, 1996

The entire report can be viewed on the Diversion Control internet site: www.deadiversion.usdoj.gov

Choose "Publications," then "program reports"

The law, 21 U.S.C. § 830(b)(1)(A), requires that each regulated person shall report to the Attorney General 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 law. While the CSA requires reporting of suspicious orders, the manner in which industry addresses the requirement determines its effectiveness.

Representatives of government and the chemical industry worked together in 1998 in the Suspicious Orders Task Force to develop voluntary guidelines for recognizing suspicious orders. The Task Force guidelines, entitled "Suspicious Orders Identification Criteria," were endorsed by the Attorney General and widely accepted by industry. The criteria, which are for voluntary use, are specific for each segment of the chemical distribution industry: Importers & Manufacturers; Wholesale Distributors; and Retail Distributors. Task Force guidelines appear in the appendices.

The Task Force recommended that manufacturers of retail over-the-counter drug products containing List I chemicals utilize "ordinary over-the-counter" packaging as defined in the MCA and that products packaged differently be prepared and distributed only for prescription use as defined by the Food, Drug and Cosmetic Act. The industry has widely accepted this recommendation. Industry has distributed the guidelines and incorporated them into employee training programs.

Suspicious Orders Identification Criteria

Each regulated entity is most familiar with its customers and circumstances surrounding the orders it processes. The chemical industry must use its best judgment in identifying suspicious orders. The following criteria are provided in order to assist the industry in identifying suspicious orders.

All Levels / All Chemicals (* indicates that criterion may not apply to all retail settings)

New customer or unfamiliar representative or established customer who begins ordering listed chemicals.*

Customers who don't seem to know industry practice or who fail to provide reasons for an order at variance with accepted legitimate industry practice.

Customer whose communications are not prepared or conducted in a professional business manner.*

Customer who provides evasive responses to any questions or is unable to supply information as to whether chemicals are for domestic use or for export.

Customer who has difficulty pronouncing chemical names.

New customers who don't seem to know Federal or state government regulations.*

Customer whose stated use of listed chemicals is incompatible with destination country's commercial activities or consignee's line of business.*

Customers who want predominantly or only regulated chemicals.

Customers who want multiple regulated or surveillance list (see Appendix G for Special Surveillance List) products, particularly if in contrast to customary use and practice.

Customer who is vague or resists providing information about firm's address, telephone number, and reason for seeking that chemical.*

Customer who provides false or suspicious addresses, telephone numbers or references.

Customer who is vague or will not furnish references for credit purposes.*

Customer who refuses or is reluctant to establish a credit account or provide purchase order information.*

Customer who prefers to pay by cashiers check, postal money order, etc.

Customer who desires to pay cash.*

Customer who wants to pick up the chemicals outside of normal practice in the supplier's experience.

Customer with little or no business background available.*

An established customer who deviates from previous orders or ordering methods.

Customers who want airfreight or express delivery.

Customers who want chemicals shipped to a PO Box or an address other than usual business address. (e.g., residence address)

Customer using a freight forwarder as ultimate consignee.

Customer who requests unusual methods of delivery or routes of shipment.

Customer who provides unusual shipping, labeling, or packaging instructions.

Customer who requests the use of intermediate consignees whose location or business is incompatible with the purported end user's nature of business or location.

Above threshold hydrochloride gas or iodine sales to a non-commercial customer.

Distributor (Non-retail) of Regulated OTC Products

Customers who don't want to tell you what area they will resell into.

Customers who don't want to tell you in what volumes they will resell.

Customers who refuse to tell you who their customers are.

Customers who don't have limits on resales.

Customers who push to buy more than your sales limit.

Customers who repeatedly buy your sales limit at the shortest interval you set.

Customers who don't know customers' limits on individual resales.

Customers who resell to non-traditional outlets for regulated OTC products, e.g., hair salons, head shops, drug paraphernalia stores, liquor stores, record stores, video shops, auto parts stores.

Customers who resell large volumes into the "independent convenience store" market.

Any customer who asks for large bottle sizes, 60 count or higher.

Customers who buy only the largest size available.

Customers that don't sell other pharmaceutical products or appear to sell those other products in token amounts.

Any customer that resells multiple cases that flow through to individual retail outlets.

New customers who want to sell regulated OTC products into California,

Arizona, Nevada, Oregon, Utah, Washington, New Mexico, Texas, Kansas, Missouri, Arkansas.

Any customer who wants to sell to an outlet relocated from California, Missouri, or Kansas to any of the states identified in the prior sentence.

Any customer who wants to export, particularly to Mexico, Canada, or Southeast Asia.

Customers who will not provide you with evidence of registration with DEA.

(Or having applied by the following deadlines: Nov 13, 1995 for single entity ephedrine; July 12, 1997 for ephedrine combination products; Dec 3, 1997 for pseudoephedrine and phenylpropanolamine products.)

Customers who will not provide you with evidence of applicable state registrations/licenses.

Customers who sell mail order and who don't report sales to DEA monthly.

(Note they must also be registered.)

Nominal retail customers who sell above the Federal, "Retail," 9 Gm individual sale limits [Editor's Note: The Task Force's original 24 gram limits were superseded by the 9 gram limit established by the Methamphetamine Anti-Proliferation Act of 2000 on October 17, 2001]

Wholesale Drug Distribution Indicators

Individual pharmacies that intend to export.

Individual pharmacies or chains that won't set a voluntary limit for individual sales at some fraction of the Federal limit to qualify as a retail outlet.

Pharmacies that stock large shelf volumes in stores that have repeated thefts or other sales problems.

Appendix E-2

Factors Which May Suggest a Suspicious Transaction

Retail Level - Regulated Products and/or Combination Purchases

OTC customers who ask for more than the transaction limit in effect.

Customers who are part of a group, each of whom buys the transaction limit.

Customers who buy the transaction limit on the same day and/or repeatedly within a few days.

Customers who buy only the largest size available at the transaction limit.

Customers who buy other methamphetamine processing products at the same time as the regulated products (alcohol, Coleman fuel, acetone, road flares, drain cleaners, iodine, muriatic acid, rock salt, starting fluid (ether), dry gas (alcohol), coffee filters, large amounts of matches, etc.)

Customers who indicate they will resell or export.

Iodine customers who don't have a legitimate reason for the purchase or who don't have an articulate reason for the volume requested.

Customers who purchase iodine crystals or pellets with any other item from the surveillance list.

Customers who want to pay cash when other forms of payment would be customary.

There may be a legitimate explanation for a purchase that represents one or more of these factors. The list is presented as a guide to instruct retailers and their employees as to which transactions may be suspicious.

Appendix E-3

Suspicious Order Reporting System for Use in Automated Tracking Systems

Terms & Definitions

This voluntary formula is for use by distributors to wholesale and retail levels. The formula calculates the quantity which, if exceeded in one month, constitutes an order which **may** be considered excessive or suspicious and therefore require reporting to DEA.

1) Add purchase quantities for the last 12 months for all customers within same Distribution Center and for customer type (Hospital, Pharmacy or Other) for any List I chemical containing item stocked by the Distribution Center.

2) Add Customer months for every record used in above total. (Months within the last 12 that customer purchases of the item were not zero.)

3) Divide total quantity purchases by the total customer months.

4) Then multiply by the factor below to give the maximum amount that the customer can order per month before showing up on the suspicious order report.

Note: Factor equals 3 for C-II and C-III Controlled Substances Containing List I Chemicals and 8 for C-III-IV-V Controlled Substances and non-Controlled OTC products containing List I chemical items.

5) At the end of each month, a report will be transmitted to DEA (separate reports for List I Chemicals and Schedule II-V Controlled Substances) of all purchases of List I Chemicals and/or C-II-V Controlled Substances and List I containing OTC items by any customer whose purchase quantities exceed the parameters (above) any (2) consecutive months or in three (3) of any moving six (6) month period.

Using a computer to manage and report on high volume transaction business activities with extremely short order cycle times (receipt to delivery) is the only viable, cost effective methodology for the reporting of orders which may be considered excessive or suspicious.

In the following pages will be re-printed in its entirety the ***Chemical Handler's Manual.***

Message from the Administrator

The Drug Enforcement Administration (DEA) is pleased to provide the ***Chemical Handler's Manual*** to assist you in understanding the provisions of the chemical control laws and their implementing regulations. These laws, including the Chemical Diversion and Trafficking Act of 1988, the Domestic Chemical Diversion Control Act of 1993, the Comprehensive Methamphetamine Control Act of 1996, and the Methamphetamine Anti-Proliferation Act (part of the Children's Health Act of 2000) amend the Controlled Substances Act of 1970 (CSA). This manual will answer questions you may have concerning your responsibilities under the Controlled Substances Act and provide you with guidance in complying with its regulations. It is also a resource for industry, law enforcement, regulators, and others interested in chemical control.

Drug abuse damages individuals and families and diminishes the fabric of a community and nation. Drug traffickers, motivated by the desire for profit, are eager to divert chemicals from legitimate commerce to manufacture illicit controlled substances. The chemical control laws and regulations provide a strong and effective deterrence. Your adherence to the law and active support for diversion control make you an important partner in protecting our nation's health and safety.

Sincerely,

Karen P. Tandy
Administrator
Drug Enforcement Administration

Application of Federal and State Law

Nothing in this manual shall be construed as authorizing or permitting any person to commit any act which is prohibited under other federal laws or obligations under international treaties, conventions, or protocols or state laws. The policy statements and other information in this guide are for the purpose of explaining the Controlled Substances Act (CSA) and its implementing regulations and should not be construed as permitting any person to commit any act prohibited by federal or state law.

The chemical control program is relatively new and steadily evolving. Regulated persons should check periodically for new provisions. New and proposed rules can be found in the Federal Register, or online (http://www.access.gpo.gov/nara/index.html), or by calling 1-888-293-6498. Printed copies of the complete regulations implementing the CSA (Title 21, Chapter II, Code of Federal Regulations (21 CFR), Part 1300 to end), may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

The Drug Enforcement Administration

The Drug Enforcement Administration is the federal law enforcement agency charged with the responsibility for combating illicit drug manufacture and distribution, as well as the diversion of licitly produced drugs and chemicals. The DEA was established on July 1, 1973, by Presidential Reorganization Plan No. 2 of 1973. It resulted from the merger of the Bureau of Narcotics and Dangerous Drugs, the Office of Drug Abuse Law Enforcement, the Office of National Narcotics Intelligence, elements of the Bureau of Customs which had drug investigative responsibilities, and those functions of the Office of Science and Technology which were drug enforcement related. The Administration was established to control more effectively narcotic and dangerous drug abuse through enforcement and prevention. In carrying out this mission, the DEA cooperates with other federal agencies, foreign, State, and local governments, private industry, and other organizations.

Origins of the Laws and Regulations

Most illicitly produced drugs result from processes which require chemicals. Drug traffickers depend on access to a variety of chemicals in all parts of the world.

DEA embarked upon a broad chemical control program in 1989 that was based on the Chemical Diversion and Trafficking Act (CDTA) of 1988. At that time, U.S. companies were the main source for 20,000 metric tons of various chemicals used annually to manufacture cocaine in the Andean countries of South America. Among the principal chemicals used by the cocaine manufacturers are acetone, methyl ethyl ketone, ethyl ether, potassium permanganate, hydrochloric acid, methyl isobutyl ketone, and sulfuric acid. The quantity of these chemicals shipped to South America from the United States declined greatly after the CDTA went into effect.

The CDTA was also effective in reducing the supply of illicit methamphetamine. The number of clandestine laboratories seized in the first three years following the law's implementation reversed the trend of the previous three decades and declined by 61

percent. In addition, injuries attributed to illicitly manufactured controlled substances that were reported through the Drug Abuse Warning Network declined by almost 60 percent between 1989 and 1992.

Maintaining this success requires continuous effort to thwart traffickers' never-ending search for new methods of diversion. This is illustrated by more recent changes in the patterns of diversion:

--When the quantity of U.S. chemicals shipped to cocaine manufacturing areas declined, chemical suppliers from other parts of the world emerged as new sources of supply. The U.S. government then undertook an aggressive international campaign to educate and elicit the support of other nations in establishing chemical controls. Today, there is a broad level of international agreement regarding the actions that must be taken to achieve chemical control. Many nations have passed laws to prevent diversion of chemicals.

--As a result of government controls, ephedrine and other chemicals used to manufacture methamphetamine became more difficult to divert. Traffickers then began using over-the-counter capsules and tablets that contained these ingredients. As chemicals rendered into legitimate medicines purportedly for the commercial market, these products were exempted from the CDTA requirements. The Domestic Chemical Diversion Control Act of 1993 (DCDCA) closed this loophole and required DEA registration for all manufacturers, distributors, importers and exporters of List I chemicals. It also established record keeping and reporting requirements for transactions in single-entity ephedrine products.

--When single-entity ephedrine products became regulated, drug traffickers turned to pseudoephedrine. This was addressed by the Comprehensive Methamphetamine Control Act of 1996 (MCA) which expanded regulatory control of lawfully marketed drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine*.

--The Methamphetamine Anti Proliferation Act of 2000 (part of the Children’s Health Act of 2000) addressed continuing diversion from the retail level by constricting the category of retail transactions in pseudoephedrine and phenylpropanolamine drug products by reducing the threshold for such transactions from 24 grams to nine grams of pseudoephedrine or phenylpropanolamine base limited to packages of not more than three grams of base. The Act also increased penalties for chemical diversion and provided for restitution to government for cleanup costs.

Traffickers continue to look for loopholes in the laws and for new methods of illicit manufacture. The government continually monitors the situation. When new patterns of abuse and diversion are identified, the government responds with corrective action, striking a balance which allows the supply of chemicals for legitimate commerce while limiting the availability of chemicals for illicit drug production. DEA recognizes the importance of educating industry on the targets and tactics of the illegal drug trade and

partnering with industry on preventing diversion as the best overall approach to defeating drug traffickers.

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*Due to concerns regarding harmful side effects that phenylpropanolamine (PPA) can have, the Food and Drug Administration has invoked a voluntary ban on over-the counter phenylpropanolamine products.

Principal Provisions of the Chemical Diversion Control Laws and Regulations

The chemical control laws and the implementing regulations seek to strike a balance between allowing the chemical handler to pursue legitimate business while limiting the availability of chemicals for illicit drug production. The Chemical Diversion and Trafficking Act of 1988 (CDTA), the Domestic Chemical Diversion Control Act of 1993 (DCDCA), the Comprehensive Methamphetamine Control Act of 1996 (MCA), and the Methamphetamine Anti-Proliferation Act of 2000 (MAPA, part of the Children's Health Act of 2000) are the legislative acts which are the foundation of the government's program to prevent chemical diversion.

The laws and regulations require regulated persons (manufacturers, distributors, importers, and exporters of listed chemicals) to implement measures which prevent diversion by:

•obtaining proof of identity from their customers (21 U.S.C. § 830 (a)(3) and 21 CFR §1310.07)

•maintaining retrievable receipt and distribution records (21 U.S.C. § 830 (a) and 21 CFR Part 1310), and

•reporting to the Drug Enforcement Administration (DEA) any suspicious orders[1] (21 U.S.C. § 830 (b)(1) and 21 CFR §1310.05 (a)(1)).

Manufacturers who distribute or export, distributors, importers, and exporters of List I chemicals are also required to:

•register with DEA (21 U.S.C. § 822 (a)(1) and 21 CFR §1309.21), and

•provide controls and procedures to guard against theft and diversion.

(21 U.S.C. § 823 (h) and 21 CFR §1309.71-73).

Regulated persons (importers, exporters, brokers and traders in international transactions and transshippers) are required to notify DEA at least 15 days prior to the date of the transaction

(21 U.S.C. § 971 (a) and 21 CFR Part 1313). The notification may be provided to DEA on or before the date of importation or exportation under certain conditions. The conditions are specified in the sections titled "Waiver of 15-Day Advance Notification Requirement" and "Criteria for Waiver of Advance Notification Requirement."

Some manufacturers of List I and List II chemicals are required to report annual production data (21 U.S.C. § 830 (b)(2) and 21 CFR §1310.05 (d)).

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1 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 law.

Inspection Authority

21 U.S.C. § 822 (f) and 21 CFR § 1316.03

DEA has the authority to enter and conduct an inspection of places, including factories, warehouses, or other establishments and conveyances, where persons registered under the CSA, or exempted from registration under the CSA, or regulated persons may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of controlled substances or listed chemicals or where records relating to those activities are maintained. Inspectors are authorized to:

• enter controlled premises and conduct administrative inspections for the purpose of inspecting, copying, and verifying the correctness of records, reports, or other required documents;

• inspect within reasonable limits and to a reasonable manner equipment, finished and unfinished controlled substances, listed chemicals, and related materials and containers;

• make a physical inventory of all controlled substances and listed chemicals on-hand at the premises

• collect samples of controlled substances or listed chemicals.

Suspension of Shipments

21 U.S.C. § 971 (c) and 21 CFR § 1313.41

DEA has the authority to suspend shipments of a listed chemical for import or export which are not destined for legitimate medical, scientific, or commercial use. DEA may suspend any importation or exportation of a listed chemical based on evidence that the chemical may be diverted for use in the clandestine manufacture of a controlled substance. When a shipment is suspended, the Administration will issue a suspension notice to the regulated person explaining the circumstances of the suspension.

The regulated person to whom the suspension order applies may request an administrative hearing under the Administrative Procedure Act (5 U.S.C. §551 - 559) to determine the issues involving the suspension of shipment (see 21 CFR §1313.51-1313.57). A request for a hearing must be made within 30 days after receipt of shipment suspension notice.

Active Voluntary Compliance

The CDTA, the DCDCA, the MCA and MAPA imposed reporting requirements on the chemical industry. However, the involvement of private industry and the public should not be limited to the laws enacted by Congress. The vast majority of industry recognizes and supports the idea that the responsibilities of the chemical industry extend beyond the letter of the law to actively supporting efforts to stop the flood of clandestinely produced drugs which plague our nation. Industry's voluntary support constitutes a powerful resource for protecting the health and safety of our nation. We urge each firm to be vigilant and to become a partner with DEA in combating the diversion of chemicals to illegal drug production.

Awareness of Diversion Patterns

Manufacturers and distributors of listed chemicals can prevent diversion by being aware of diversion patterns, avoiding suspect transactions, and reporting suspicious activities to authorities.

DEA and state/local authorities throughout the United States have noted a continuous and dramatic trend toward the use of pseudoephedrine and ephedrine combination over-the-counter drug products in the clandestine manufacture of methamphetamine.

Many illicit distributors and retailers of pseudoephedrine and combination ephedrine products purchase these List I chemicals from more than one source. Suppliers should be aware of such practices. Some retailers purchase combination ephedrine products as substitute products for pseudoephedrine and vice versa when these products are not substitutes for each other except for the manufacture of illicit methamphetamine.

Other suspect practices include the following:

• Ordering single entity pseudoephedrine and combination ephedrine products in amounts that can not be marketed for legitimate use.

• Ordering pseudoephedrine on a constant basis throughout the year (legitimate retailers order more during cold and flu season).

• Ordering single entity pseudoephedrine products instead of an array of combination pseudoephedrine and other over-the-counter products.

• Selling pseudoephedrine and combination ephedrine products to numerous distributors or retailers concentrated in one metropolitan area.

• Selling brands that have not been on the market for more than several years or that have little or no advertising.

• Selling single entity pseudoephedrine and combination ephedrine packaged in large quantities, particularly when such products are not in blister packs and are marketed for so called off label uses such as weight loss and alertness aids.

• Selling single entity pseudoephedrine and combination ephedrine products to retail establishments that traditionally do little or no marketing of these products and where consumers normally do not purchase over-the-counter medications.

Chemical handlers can find additional guidance on the DEA diversion control web site at www.DEAdiversion.usdoj.gov>Federal Register Notices>registrant actions.

Definitions

Complete definitions appear in 21 CFR Part 1300 and 21 U.S.C. § 802.

Broker and Trader (in an international transaction)

A *broker and trader* is any individual, corporation, corporate division, partnership, association, or other legal entity which assists in arranging an international transaction in a listed chemical by

• negotiating contracts;

• serving as an agent or intermediary; or

•fulfilling a formal obligation to complete the transaction by bringing together a buyer and seller, a buyer and transporter, or a seller and transporter, or by receiving any form of compensation for so doing.

Chemical Exporter

A *chemical exporter* is a regulated person who has the power and responsibility for controlling the sending of a listed chemical out of the United States.

Chemical Importer

A *chemical importer* is a regulated person who has the power and responsibility for controlling the bringing in or introduction of a listed chemical into the United States.

Chemical Mixture

A *chemical mixture* is a combination of two or more chemical substances, at least one of which is not a listed chemical. Concentration limits have been established (21 CFR 1310.12(c)) for chemical mixtures containing ephedrine, n-methylephedrine, n-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine. (These mixtures are often found as dietary or nutritional supplements.) Mixtures equal to or below the concentration limits are not regulated materials.

Established Business Relationship with a Foreign Customer

An *established business relationship with a foreign customer* means that the regulated person has exported a listed chemical at least once within the past six months, or twice within the past twelve months to a foreign manufacturer, distributor, or end user of the chemical that has an established business in the foreign country with a fixed street address. A person or business which functions as a broker or intermediary is not a customer for purposes of this definition. The term also means that the regulated person has provided DEA with specified information in accordance with the waiver of 15-day advance notice requirements. DEA can disqualify the foreign customer for waiver of the advance notification requirement. Written explanation of the reasons will be provided. The regulated person is entitled to a hearing within 45 days after the written request.

Established Record as an Importer

Established record as an importer means that the regulated person has imported a listed chemical at least once within the past six months, or twice within the past 12 months from a foreign supplier. The term also means that the regulated person has provided DEA with the following information, in accordance with the waiver of the 15-day advance notice requirements:

(a) the name, DEA registration number (where applicable), street address, telephone number, telex number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and

(b) the frequency and number of transactions occurring during the preceding 12-month period.

DEA can disqualify the importer for waiver of the advance notification requirement. Written explanation of the reasons will be provided. The regulated person is entitled to a hearing within 45 days after the written request.

International Transaction

International transaction is a transaction arranged by a broker or trader located in the United States involving the shipment of a listed chemical across an international border (other than a U. S. border).

Listed Chemical

Listed chemical is any List I chemical or List II chemical. A listing appears in Appendix A.

List I Chemical

List I chemical is a chemical that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the CSA and is designated a List I chemical by the DEA Administrator or Congress. Chemicals in List I generally are precursors and have been determined by DEA to require a greater level of control than other listed chemicals. Anthranilic acid, ergotamine, piperidine, and drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine are examples of List I chemicals.

List II Chemical

List II chemical is a chemical, other than a List I chemical, that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the CSA and is designated a List II chemical by the DEA Administrator or Congress. Chemicals in List II are generally reagents and solvents.

Readily Retrievable

Readily retrievable means that certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner made visually identifiable apart from other items appearing on the record.

Registrant

Registrant is a person who distributes, imports, exports, or manufactures for distribution or export any List I chemical and who has been granted a Certificate of Registration by the Administrator of DEA to manufacture for distribution, distribute, import or export List I chemicals. Also included are certain controlled substances registrants who handle List I chemicals.

Regulated Person

A *regulated person* is any individual, corporation, partnership, association or other legal entity who manufactures, distributes, imports, or exports a listed chemical, or a tableting machine or encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or encapsulating machine.

Regulated Transaction

21 U.S.C. §802 (39) and 21 CFR § 1300.02 (b)(28)

A *regulated transaction* is a distribution, receipt, sale, importation, exportation, or international transaction involving shipment of a threshold amount of a listed chemical (including a cumulative threshold amount for multiple transactions), a tableting machine or an encapsulating machine. Distributors of listed chemicals who conduct regulated transactions are subject to pertinent regulatory requirements of reporting, recordkeeping and customer identification.

The following transactions are not regulated:

• normal distribution between agents or employees of a single regulated person, and delivery to a common or contract carrier or to or by a warehouseman for storage, unless the carriage or storage is in connection with the distribution, importation or exportation of a listed chemical to a third party.

• any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act **unless**

--the drug contains ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, or salts of optical isomers; or

--the Administrator has determined that the drug or group of drugs is being diverted; and

--the quantity of listed chemical equals or exceeds the threshold established for that chemical.

•sales by retail distributors of ordinary over-the-counter pseudoephedrine or phenylpropanolamine products, directly to walk-in customers or in face-to-face transactions, in below-threshold quantities in a single transaction to an individual for legitimate medical use. Ordinary over-the-counter pseudoephedrine or phenylpropanolamine products are non-liquids sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base and packaged in blister packs, each blister containing not more than two dosage units or where the use of blister packs is technically infeasible, packaged in unit dose packets or pouches and for liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or phenylpropanolamine base.

•sales by retail distributors of other than ordinary over-the-counter pseudoephedrine or phenylpropanolamine drug products of nine grams or less of base in a single transaction, sold in package sizes of not more than three grams of pseudoephedrine base or three grams of phenylpropanolamine base (21 USC 802(39)(A)(iv)(II))

•any transaction in a chemical mixture that the Attorney General has by regulation designated as exempt 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. Chemical handlers should check the Federal Register for the issuance of a final rule on chemical mixtures and subsequent changes.

• transactions in chemical mixtures containing ephedrine, n-methylephedrine, n-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine that are equal to or below concentration limits specified in 21 CFR 1310.12(c)) (see Appendix B)

• harvested plant material that contains ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and/or pseudoephedrine, that is in its natural state or has been processed in a way that preserves the natural constituents in the ratios that are found in the plant's natural state.

• Additionally, the following transactions have been determined by DEA to be excluded from the definition of regulated transaction (21CFR 1310.08):

(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:

Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, French Guiana, Guyana, Panama, Paraguay, Peru, Suriname, Uruguay, Venezuela

(c) domestic transactions of methyl isobutyl ketone (MIBK)

(d) import transactions of methyl isobutyl ketone (MIBK) destined for the United States

(e) export transactions, international transactions, and import transactions for transshipment or transfer of methyl isobutyl ketone (MIBK) destined for Canada or any country outside of the Western Hemisphere

(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

(j) domestic return shipments of reusable containers from customer to producer containing residual red phosphorus or white phosphorus in isotainers and rail cars with capacities greater than or equal to 2500 gallons (in a single container)

(k) domestic, import, and export distributions of gamma-butyrolactone weighing 4,000 kilograms (net weight) or more in a single container

Retail Distributor

(relates only to drug products containing ephedrine, pseudoephedrine and phenylpropanolamine) 21 CFR §1300.02(29) A *retail distributor* is a grocery store, general merchandise store, drug store, or other merchandise store, or other entity or person whose activities as a distributor relating to drug products containing pseudoephedrine, phenylpropanolamine or ephedrine are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. Sale for personal use means the distribution of below-threshold quantities in a single transaction to an individual *for legitimate medical use.*

The MCA defines retailer as an entity or person whose activities as a distributor of legal drug products containing listed chemicals are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. Distributors who do not meet the retail definition are subject to the requirements for wholesale distributors.

Registration

21 U.S.C. § 822, 823, 21 CFR Part 1309

Who Must Register

Every person (unless specifically exempted below) who engages or proposes to engage in any of the following activities is required to register annually with DEA:

•manufacturing a List I chemical for distribution

•distribution of a List I chemical

•importation of a List I chemical

•exportation of a List I chemical

Separate Registration for Independent Activities

21 CFR §1309.22

The following groups of activities are independent of each other and each requires a separate registration:

1. Retail distributing of drug products that contain List I chemicals. Sales of chemicals such as hydriodic acid or methylamine are non-retail distributions.

2. Non-retail distributing of List I chemicals;

3. Importing List I chemicals (note that importers are authorized to distribute those List I chemicals which they have imported); and

4. Exporting List I chemicals.

Separate Registration for Separate Locations

21 CFR § 1309.23

A separate registration is required for each principal place of business where a List I chemical is manufactured for distribution, distributed, imported, or exported.

Exemptions from Registration Requirement

21 CFR § 1309.24

Exempt from registration are:

• a manufacturer of a List I chemical who uses the chemical solely for internal consumption without subsequent distribution or exportation.

• a person who imports or exports a drug product containing a List I chemical if that person is registered with DEA to engage in the same activity with a controlled substance. Security, record keeping and reporting requirements apply.

• a person who distributes a drug product containing a List I chemical, if that person is registered with DEA to manufacture, distribute, or dispense controlled substances. Activities with drug products containing List I chemicals should remain consistent with controlled substances activities; e.g., a retail pharmacy registrant should engage in retail sales rather than wholesale distributions of regulated drug products. Security, record keeping and reporting requirements apply. Distribution of List I chemicals requires a separate registration.

• retail distributors of ordinary over-the-counter pseudoephedrine, phenylpropanolamine and ephedrine combination drug products. Retail distributors whose activities as distributors of over-the-counter drug products and combination ephedrine drug products are limited exclusively to sales for personal use, either directly to walk-in customers or in face-to-face transactions by direct sales. Sale for personal use is the sale of below-threshold quantities in a single transaction to an individual for legitimate medical use.

Any distributions of single-entity ephedrine are subject to the registration requirement.

Applying for Registration

An application for registration (DEA Form 510), and information regarding current fees and renewal of registration may be obtained by contacting your nearest DEA office, by downloading for printing from the diversion control website, www.DEAdiversion.usdoj.gov>On-line Forms and Applications or by writing to:

U.S. Department of Justice
DEA, Chemical Registration/ODRR
P.O. Box 2427
Arlington, VA 22202-2427

Security

21 U.S.C. § 823 (h) and 21 CFR § 1309.71

Registrants are required to provide effective controls and procedures to guard against theft and diversion of List I chemicals. Historically, distributors have focused on knowledge of the customer and close attention to sales as a means to control diversion. Registrants recently have experienced significant thefts of drug products and bulk material. These chemicals are highly sought on the illicit market. It is important for legitimate handlers to provide extra safeguards for chemicals in their possession. Specific attention should be paid to the following areas:

• A List I chemical should be sealed in a container that will reveal any attempts at tampering. If a chemical cannot be stored in such a sealed container, access to the chemical should be controlled through physical means (i.e., locked in a secure place) or through human or electronic monitoring.

• In a retail setting open to the public, single-entity ephedrine products must be stocked behind a counter where only employees have access.

• The registrant should exercise caution in considering the employment of persons who have been convicted of a felony offense relating to controlled substances or listed chemicals. The registrant should assess the risks involved in employing such persons, including the potential for revocation of registration.

• An employee who has knowledge of diversion by a fellow employee has an obligation to report such information to the employer or a responsible representative of the employer. A failure to report such information will be considered in determining future access to areas with List I chemicals. It is the employer's responsibility to inform employees of this policy.

• Some of the factors that registrants should take into account when planning for security include:

1. the quantity of List I chemicals handled,
2. the location of the premises,
3. the type of building construction and the general characteristics of the building,
4. electronic detection and alarm systems,
5. the extent of unsupervised public access to the facility
6. the adequacy of supervision over employees who have access to List I chemicals,
7. procedures for handling guests, maintenance personnel and non-employee service personnel, and
9. adequacy of systems for monitoring receipt, distribution and disposition of List I chemicals.

Any registrant or applicant desiring to determine whether a proposed system of security controls and procedures is adequate for listed chemicals may submit materials and plans regarding the proposed security controls and procedures either to the local Diversion Group Supervisor or to DEA, Chemical Control Section/ODI, PO Box 2427, Arlington, VA 22202-2427.

"Know Your Customer" Policy

It is fundamental for sound operations that handlers take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently, identify those transactions conducted by their customers that are suspicious in nature. Regulated persons are encouraged to thoroughly review the chapter in this manual entitled "Awareness of Diversion Patterns" and the Appendices, particularly E-1, E-2, and E-3.

Some states have restrictions on distribution practices that are more stringent than the federal rules. The extent of compliance with state law is taken into consideration when civil, administrative, or criminal actions are under consideration.

It is required that any regulated person verify that a customer for List I products possesses a valid DEA registration or is exempted from that requirement.

The granting of a DEA registration signals only a proper application, the establishment of the required records system, and the required security system at the time of the on-site inspection by DEA. The registration is not a confirmation of proper ongoing business practices and does not relieve the chemical handler of the responsibility to evaluate such transaction.

Proof of Identity

21 U.S.C. § 830 (a) (3) and 21 CFR § 1310.07

The CSA requires that a regulated person engaging in a regulated transaction must identify the other party to the transaction. The regulated person must verify the existence and apparent validity of a business entity ordering a listed chemical, tableting or encapsulating machine and must maintain customer files. If the regulated person is unable to establish the identity or legitimacy of a customer, sound practice requires the handler to postpone opening an account with this customer until such information is satisfactorily established. Regulated persons should maintain customer files which may be reviewed for adequacy by DEA during on-site visits.

For domestic transactions, this may be accomplished at the time the order is placed by having the other party present documents to verify their identity and registration

status if a registrant. Verification of documents may be accomplished through the following sources: telephone directory, local credit bureau, local Chamber of Commerce, or the local Better Business Bureau. DEA registration may be verified by DEA. When transacting business with a new representative of a firm, the regulated person must verify the agency status of the representative.

For cash sales or sales to individuals, the proof of identity must consist of at least the signature of the purchaser, a driver's license and one other form of identification. It is recommended that the second form of identification should corroborate the first and should be valid in its own right. If an individual presents an identification card issued by an appropriate state authority in lieu of a driver's license, such identification is acceptable provided that it contains the individual's name, address, a unique identification number, and the individual's photograph. A record, preferably a photocopy, should be kept of proof of identity information.

For new customers that are not individuals or cash customers, the regulated person must establish the identity of the authorized purchasing agent(s) and have on file that person's signature, electronic password or other identification. Once the authorized identity has been established the agent list may be updated annually rather than on each order.

For electronic orders, the identity of the purchaser shall consist of a computer password, identification number or some other means of identification consistent with electronic orders.

For an export transaction, proof of identity is to be accompanied by a good faith inquiry to verify the existence and validity of the foreign business entity. This can be done by verifying the business telephone listing through international telephone information, checking the firm's listing in international or foreign national chemical or commerce directories or trade publications, confirmation through foreign subsidiaries of the U.S. regulated person, or verification through the commercial attaché of the embassy of the country of destination. Official documents provided by the purchaser may confirm the existence and apparent validity of the business entity.

Any exports to individuals or exports paid in cash are suspect and should be handled as such. For such exports, the regulated person must obtain from the purchaser or independently seek to confirm clear documentation which proves the person is properly identified such as through foreign identity documents, driver's license, passport information and photograph, etc. Any regulated person who fails to adequately prove the identity of the other party to the transaction may be subject to the specific penalties provided for violations of law related to regulated transactions in listed chemicals.

Record Keeping Requirements

21 U.S.C. § 830 and 21 CFR Part 1310

Persons Required to Keep Records

Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine must keep a readily retrievable record of the transaction. Distribution records are required if the cumulative amount for multiple transactions to a person within a calendar month exceeds the threshold. Thresholds can be found in Appendix B and Appendix C.

Contents of Regulated Transaction Records

21 CFR § 1310.06

Each record for a domestic transaction must contain the following information:

1. The name, address, and if required, the DEA registration number of each party to the regulated transaction.

2. The date of the transaction.

3. The name, quantity, and form of packaging of the listed chemical, or description of the tableting machine or encapsulating machine (including make, model and serial number).

4. The method of transfer (company truck, picked up by the customer, etc.).

5. The type of identification used by the purchaser and any unique number of that identification.

Location and Availability of Records

21 CFR § 1310.04

A record of a regulated transaction is required to be kept at the business location where the transaction occurred. As an alternative, the record can be maintained at a single, central location which has been provided in writing and sent to the Special Agent in Charge of the local DEA Division Office by registered or certified mail (return receipt requested). A regulated person with more than one place of business where a record is required to be kept must devise a record keeping system that detects purchases which are made at multiple locations to circumvent the cumulative threshold requirements.

Maintenance of Records

21 CFR § 1310.04

A record must be kept for two years from the date of transaction.

Reports to the Drug Enforcement Administration

21 U.S.C. § 830 and 21 CFR Part 1310

Types of Required Reports

In addition to periodic written reports required of bulk manufacturers and certain mail order distributors, there are four events that require prompt oral reporting to DEA.

Oral Reports

21 CFR § 1310.05

There are four types of transactions specified in the CSA which require a regulated person to make oral notification to the Special Agent in Charge, or a designee, of the local DEA Division Office whenever possible. The oral report must be made as soon as possible, and as far in advance of the conclusion of the regulated transaction, as possible. A written report of a transaction listed in paragraphs 1, 3, and 4 below is required to be sent to that office within 15 days after the regulated person becomes aware of the circumstances of the event. The four circumstances are:

1. 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 law.

2. Any proposed regulated transaction with a person whose description or other identifying characteristic has been previously furnished by DEA to the regulated person. Such a transaction may not be completed unless the transaction is approved by DEA.

3. Any unusual or excessive loss or disappearance of a listed chemical that is under the control of the regulated person. The regulated person responsible for reporting a loss in transit is the supplier.

4. Any regulated transaction involving a tableting or encapsulating machine.

Recognizing Suspicious Orders

21 U.S.C. § 830 (b) (1) (A)

The law, 21 U.S.C. § 830 (b)(1)(A), requires that each regulated person shall report to the Attorney General 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 law. While reporting suspicious orders to DEA is required by law, the manner in which industry addresses the requirement determines its effectiveness.

In 1998 representatives of the chemical industry, including those whose products contain pseudoephedrine, phenylpropanolamine and other chemicals sought by drug traffickers, met in the Suspicious Orders Task Force with representatives of federal, state and local law enforcement and prosecutors. The Suspicious Orders Task Force considered issues relating to the diversion of these products. Industry representatives helped develop guidelines and expressed a willingness to distribute them through industry publications. They also agreed to incorporate the guidelines into existing employee training programs. One set of guidelines is the "Suspicious Orders Identification Criteria" for recognizing potential diversion at all levels of the distribution chain. Another set of guidelines is for use in automated tracking systems. See Appendix E for suspicious order identification criteria.

When a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicions. In addition to making the required reports, the transaction should not be completed until the customer is able to eliminate the suspicions. The distributor may have to forego some transactions. When DEA reviews distributor decisions, minor events are not cause for government action. At the same time a regulated person who fails to implement a system to prevent diversion will be closely scrutinized and if warranted, may be subject to civil, administrative, or criminal penalties.

The Task Force concluded that the term "suspicious order" had different meanings at different levels of the manufacturing and distribution chain. Accordingly, the recommendations of the Task Force and the definition of "suspicious" are specific for each group: Importers & Manufacturers; Wholesale Distributors; and Retail Distributors. Task Force findings appear in the appendices.

Bulk Manufacturers' Reports

Regulated bulk manufacturers of listed chemicals are required to submit manufacturing, inventory, and use data on an annual basis to DEA, Drug and Chemical Evaluation Section, Washington, D.C. 20537. Reports are due by March 15 of the year immediately following the calendar year in which the inventory took place. Details of reporting requirements appear in 21 CFR §1310.05(d) and §1310.06(h).

Reports of Mail Order Distributions

21 U.S.C. § 830 (b) (3) (A)

Each regulated person who engages in a transaction with a non-regulated party (a consumer or end-user who does not re-distribute) which involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals) via postal service, private carrier or commercial carrier, is required to submit a monthly report of all such transactions regardless of the size of the transaction.

The reports must include the name of the purchaser; the quantity and form of the ephedrine, pseudoephedrine, or phenylpropanolamine purchased; the date of each transaction; the address to which the product was sent; and such other items of information which DEA may by regulation require. Reports should be sent to the Chemical Control Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537. Regulated persons should check with DEA for the latest requirements.

The following distributions of drug products to non-regulated persons are exempted from the mail order reporting requirements:

1. Distributions of sample packages of drug products when those packages contain not more than two solid dosage units or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.

2. Distributions by retail distributors that may not include face-to-face transactions, to the extent that such distributions are consistent with the activities of a retail distributor.

3. Distributions to a resident of a long term care facility, or to a long term care facility for dispensing to or use by a resident of that facility.

4. Distributions in accordance with a valid prescription.

5. Exports which have been reported to DEA under the transshipment reporting requirements (21 CFR 1313.31), or the international transaction reporting requirements (21 CFR 1313.32), or for which advance notification reporting requirements are waived (21 CFR 1313.21).

DEA may revoke exemptions for regulated persons whose distributions are found to violate the regulations.

Imports, Exports, and International Transactions

Import/Export Declaration - DEA Form 486

21 U.S.C. § 971 and 21 CFR § 1313.12, 21, 32, 34

An Import/Export Declaration, DEA Form 486, must be completed by each regulated person for each regulated import, export, or international transaction. For the first shipment to a new customer, this form must be received by DEA at least 15 days prior to the import, export, or

international transaction of the listed chemical. The exceptions to the 15-day rule are explained in the following paragraphs. Failure to complete the DEA Form 486 entirely and accurately may result in the shipment being suspended.

General Waiver of Advance Notification Requirement

21 U.S.C. § 971 (e) (2), (3) and 21 CFR § 1313.12 (c) (2), (e), (f) and § 1313.21 (c) (2), (e), (f)

DEA may determine in some circumstances that effective diversion control does not require advance notification for a regulated import of a listed chemical or a regulated export to a specific country. In those circumstances, DEA may issue a regulation waiving the notification requirement and no Form 486 is required. The regulated person, however, must submit summary quarterly reports. The requirement has been waived for imports of acetone, 2-butanone, and toluene.

Waiver of 15-day Advance Notification Requirement for Regular Customers or Regular Importers

21 CFR § 1313.15, 24

The 15-day advance notification requirement for regulated imports and exports of a listed chemical by regular customers or suppliers may be waived in the circumstances listed below.

It is important to note that although the 15-day advance notification may be waived, the DEA Form 486 must be received by DEA, Chemical Control Section, on or before the date of importation or exportation. Form 486 should be mailed to: Drug Enforcement Administration, Chemical Control Section, P.O. Box 28346, Washington, D.C. 20038, or transmitted by facsimile to (202) 307-4702.

Criteria for Waiver of Advance Notification Requirement

For importers, the 15-day advance notification requirement may be waived for any regulated person with an established record as an importer. To have an established record as an importer, the regulated person must have imported a listed chemical[1] at least once within the past six months, or twice within the past 12 months from a foreign supplier. The term also means that the regulated person has provided DEA with the following information:

1. the name, DEA registration number (where applicable), street address, telephone number, telex number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and
2. the frequency and number of transactions occurring during the preceding 12-month period.

For exporters, the 15-day advance notification requirement may be waived for any regulated person who has an established business relationship with a foreign customer. An established business relationship with a foreign customer means that the regulated person has exported a listed chemical[2] at least once within the past six months, or twice within the past 12

months to a foreign manufacturer, distributor, or end user of the chemical that has an established business in the foreign country with a fixed street address. The term also means that the regulated person has provided DEA with the following information:

1. the name and street address of the chemical exporter and of each regular customer,
2. the telephone number, telex number, contact person, and where available, the facsimile number for the chemical exporter and for each regular customer,
3. the nature of the regular customer's business (i.e. importer, exporter, distributor, manufacturer, etc.) and if known, the use to which the listed chemical or chemicals will be applied,
4. the duration of the business relationship,
5. the frequency and number of transactions occurring during the preceding 12-month period,
6. the amounts and the listed chemical or chemicals involved in regulated transactions between the chemical exporter and the regular customer,
7. the method of delivery, and
8. other information that the chemical exporter considers relevant for determining whether a customer is a regular customer.

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1 A regular importer of any of these chemicals - acetone, methyl ethyl ketone, or toluene - is qualified as a regular importer of all three chemicals, unless DEA notifies an importer to the contrary.

2 A regular customer of any one of these three chemicals - acetone, methyl ethyl ketone, or toluene - is qualified as a regular customer of all three chemicals, unless DEA notifies an exporter to the contrary.

Disqualification of Waiver

21 U.S.C. § 971 (c) and 21 CFR § 1313.15 (c), § 1313.24 (e)

If there are grounds to believe that the chemical being imported or exported may be diverted to the clandestine manufacture of a controlled substance, DEA may disqualify the importer or exporter from the "regular customer" or "regular importer" status and thereby terminate the waiver of the advance notification requirement. A written notice

explaining the reasons for such disqualification will be provided. The regulated person is entitled to a hearing within 45 days after written request.

Exports in Violation of Foreign Laws

21 CFR § 1313.25

It is incumbent upon the exporter, broker or trader to assure that each chemical export from the United States complies with the laws and regulations of the destination country. Exporters may contact DEA Office of Diversion Control, Chemical Control Section, for information on a specific country. If a shipment is found to be in violation of the laws of the foreign country, the exporter is subject to a penalty of up to 10 years imprisonment under 21 U.S.C. 960(d), and 18 U.S.C. 3571(3) provides for a $250,000 fine for an individual, and a $500,000 fine for an organization for each violation.

Execution of the Import/Export Declaration – DEA Form 486

21 CFR § 1313.12-14, 21-23, 32

The Import/Export Declaration, DEA Form 486, is a three-part form that may be acquired from the nearest DEA office or may be downloaded for printing from the diversion control website, www.DEAdiversion.usdoj.gov>On-Line Forms and Applications.

A DEA Form 486 must be completed by each regulated person for each regulated import, export, or international transaction. Form 486 is distributed as follows:

1. Copy 1 is to be retained by the importer, exporter, or broker/trader as an official record of the import, export, or international transaction;

2. Copy 2 serves as the notification copy. To assure that the completed copy 2 of the DEA Form 486 is received as soon as possible by DEA, it should be mailed to: Drug Enforcement Administration, P.O. Box 27284, Chemical Control Section, Washington, D.C. 20038.

3. Copy 3 is presented to the U.S. Customs Service:

a. For **imports**, with the customs entry form.

b. For **exports**, at the port of exit along with the Department of Commerce Shipper's Export Declaration for each export of a listed chemical.

c. For **international transactions involving a broker or trader**, copy 3 is retained by the broker or trader as the official record of the international transaction. Declaration forms must be retained for two years.

If the 15-day advance notice has been waived for an import or export, it must be so indicated on the DEA Form 486 by checking the appropriate block (1c.) If a waiver has been granted, the DEA Form 486 must be received in Headquarters on or before the date of the import or export.

If a waiver has not been granted, the DEA Form 486 must be received by DEA at least 15 days prior to the date of import, export, or other international transaction.

The completed copy may be sent to DEA via electronic facsimile if desired. The DEA import/export facsimile number is (202) 307-4702.

Transshipment through the United States

21 CFR § 1313.31

A chemical imported for transshipment or transit through the United States for immediate exportation is subject to notification requirements if the quantity equals or exceeds the threshold amount. DEA must be notified at least 15 days prior to the proposed transshipment date. The notification must be in the form of a notice or letter (not a DEA Form 486) providing pertinent details of the transshipment and must be received by DEA at least 15 days prior to the proposed transshipment date. The notification either may be mailed to the Drug Enforcement Administration, PO Box 27284, Washington, D.C. 20038, or may be sent via electronic facsimile to (202) 307-4702. The following details must be included:

1. The date the notice was executed;

2. The complete name and description of the listed chemical as it appears on the label or container;

3. The name of the chemical as it appears in 21 CFR §1310.02 and as listed in this manual;

4. The number of containers and the size or weight of each container for each listed chemical;

5. The net weight of each listed chemical given in kilograms;

6. The gross weight of the shipment given in kilograms;

7. The name, address, telephone number, business of foreign exporter, telex number, and, where available, the facsimile number;

8. The foreign port of exportation;

9. The approximate date of exportation;

10. The complete identification of the exporting carrier;

11. The name, address, business, telephone number, telex number, and, where available, the facsimile number of the importer, transferor, or transshipper;

12. The U.S. port of entry;

13. The approximate date of entry;

14. The name, address, telephone number, telex number, business of the consignee and, where available, the facsimile number of the consignee at the foreign port of entry;

15. The shipping route from the U.S. port of exportation to foreign port of entry at final destination;

16. The approximate date of receipt by the consignee at the foreign port of entry; and

17. The signature of the importer, transferor, transshipper, or agent, accompanied by the agent's title.

Returned Export

21 CFR § 1313.22 (e)

When an export of a listed chemical is refused, rejected or otherwise deemed undeliverable, it may be returned to the U.S. chemical exporter of record. A brief written notification (not a DEA Form 486) must be sent to DEA within a reasonable period of time outlining the circumstances. This explanation must be sent to the following address: Drug Enforcement Administration, Chemical Control Section, P.O. Box 27284, Washington, D.C. 20038. This does not apply to a shipment that has cleared foreign customs, been delivered and accepted by the foreign consignee. The application of this provision requires that rejection of the chemical by the consignee occur within reasonable proximity to the delivery (i.e., the "acceptance" of the chemical would be indicated by such events as full payment for the chemical and its introduction into inventory). A return to a third party in the United States will be regarded as an import.

Special Policy Regarding Exports of Certain Chemicals to Colombia

In March, 1996, the United States Government (U.S.G.) took steps to decertify Colombia's status as a nation actively cooperating with the United States on drug control. DEA has historically experienced great difficulty in determining the legitimacy and final destination of exports of chemicals from the United States to Colombian companies. Additionally, DEA is unable to rely on the Colombian government to insure that listed chemicals imported from the United States and other sources are not diverted to illicit drug manufacture. Following the U.S.G.'s decertification, DEA revoked regular customer status for all U.S. exports of the following cocaine essential chemicals to Colombia: acetone, potassium permanganate, MEK, MIBK, toluene, and ethyl ether. Despite the fact that since then Colombia has become conditionally certified, DEA continues to employ a heightened standard of review to scrutinize proposed exports and transshipments to Colombia because of the high probability that these chemicals may be diverted to the clandestine manufacture of cocaine. Details can be found in the Federal Register Notice dated March 28, 1996, pages 13759-13760 which establishes and explains this policy (Appendix F).

Suspension of Shipments

21 U.S.C. § 971 (c) and 21 CFR § 1313.41

The Administrator may suspend any importation or exportation of a listed chemical based on evidence that the chemical may be diverted to the clandestine manufacture of a controlled substance. DEA will provide written notice to the regulated person explaining the legal and factual

basis of the suspension. The regulated person may request an administrative hearing to determine the issues involving the suspension. A request for a hearing must be made within 30 days after receipt of the suspension notice.

Confidentiality

DEA collects confidential business information (CBI) from required reports and may collect CBI in the course of investigations. With respect to the chemical program, the release of CBI that is protected from disclosure under Exemption 4 of the Freedom of Information Act (FOIA), 5 U.S.C. § 552(b)(4) is governed by Section 830(c) of the CSA (21 U.S.C. § 830 (c)) and the Department of Justice procedures set forth in 28 CFR §16.7. The CSA (21 U.S.C. § 830) provides that information that is protected from disclosure under Exemption 4 may only be released in circumstances related to the enforcement of controlled substance or chemical laws, customs laws, or for compliance with U.S. obligations under treaty or international agreements. The Department of Justice procedures establish that if a FOIA request is received for release of information that is protected under Exemption 4, the submitter of the protected information must be

notified of such a request, given an opportunity to object to the disclosure, and allowed to provide justification as to why the information should not be disclosed.

In addition to the statutory and regulatory requirements, DEA has established internal guidelines governing the handling of CBI, including provisions that the material be maintained in locked containers, that access to the information be on a need-to-know basis, and that any disclosure under Section 830 be made only pursuant to a non-disclosure agreement by the receiving party.