

determinations, such appeal shall be filed with the Commission within 30 days of receipt of actual notice of the determination.

(b) The appeal shall identify the specific action or decision for which a hearing is requested, the date of the action or decision, the interest of the person requesting the hearing in the subject matter of the appeal, and a statement setting forth the basis for objecting to or seeking review of the action or decision. Appeals omitting any of these elements will be considered incomplete and not considered by the Commission.

(c) Any request not filed on or before the applicable deadline established in paragraph (a) of this section hereof will be deemed untimely and such request for a hearing shall be considered denied unless the Commission otherwise authorizes it *nunc pro tunc*. Receipt of requests for hearings, pursuant to this section, whether timely filed or not, shall be submitted by the Executive Director to the commissioners for their information.

(d) Petitioners shall be limited to a single filing that shall set forth all matters and arguments in support thereof, including any ancillary motions or requests for relief. Issues not raised in this single filing shall be considered waived and filings may only be amended or supplemented upon leave of the Executive Director. Where the petitioner is appealing a final determination on a project application and is not the project sponsor, the petitioner shall serve a copy of the appeal upon the project sponsor within five days of its filing.

(e) If granted, hearings shall be held not less than 20 days after notice appears in the **Federal Register**. Hearings may be conducted by one or more members of the Commission, by the Executive Director, or by such other hearing officer as the Commission may designate.

(1) The petitioner may also request a stay of the action or decision giving rise to the appeal pending final disposition of the appeal, which stay may be granted or denied by the Executive Director after consultation with the Commission chair and the member from the affected member State. The decision of the Executive Director on the request for stay shall not be appealable to the Commission under this section and shall remain in full force and effect until the Commission acts on the appeal.

(2) In addition to the contents of the request itself, the Executive Director, in granting or denying the request for stay, will consider the following factors:

(i) Irreparable harm to the petitioner.

(ii) The likelihood that the petitioner will prevail.

(f) The Commission shall grant the hearing request pursuant to this section if it determines that an adequate record with regard to the action or decision is not available, the case involves a determination by the Executive Director or staff which requires further action by the Commission, or that the Commission has found that an administrative review is necessary or desirable. If the Commission denies any request for a hearing, the party seeking such hearing shall be limited to such remedies as may be provided by the compact or other applicable law or court rule.

(g) If a hearing is granted, the Commission shall refer the matter for hearing to be held in accordance with § 808.3, and appoint a hearing officer.

(h) *Intervention*. (1) A request for intervention may be filed with the Commission by persons other than the petitioner within 20 days of the publication of a notice of the granting of such hearing in the **Federal Register**. The request for intervention shall state the interest of the person filing such notice, and the specific grounds of objection to the action or decision or other grounds for appearance. The hearing officer(s) shall determine whether the person requesting intervention has standing in the matter that would justify their admission as an intervener to the proceedings in accordance with Federal case law.

(2) Intervenors shall have the right to be represented by counsel, to present evidence and to examine and cross-examine witnesses.

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Dated: June 15, 2010.

Thomas W. Beauduy,
Deputy Director.

[FR Doc. 2010-15282 Filed 6-24-10; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA-228P]

RIN 1117-AA66

Chemical Mixtures Containing Listed Forms of Phosphorus and Change in Application Process

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The DEA is proposing regulations which establish those chemical mixtures containing red phosphorus, white phosphorus (also known as yellow phosphorus), or hypophosphorous acid and its salts (hereinafter “regulated phosphorus”) that shall automatically qualify for exemption from the Controlled Substances Act (CSA) regulatory controls. DEA is proposing that chemical mixtures containing red phosphorus in a concentration of 80 percent or less and mixtures containing hypophosphorous acid and its salts (hypophosphite salts) in a concentration of 30 percent and less, shall qualify for automatic exemption. DEA is not proposing automatic exemption for chemical mixtures containing white phosphorus. Unless otherwise exempted, all material containing white phosphorus shall become subject to CSA chemical regulatory controls regardless of concentration.

DEA recognizes that concentration criteria alone cannot identify all mixtures that warrant exemption, therefore, an application process has been implemented which allows manufacturers to apply for exemption from CSA regulatory controls for those phosphorus chemical mixtures that do not qualify for automatic exemption. This rulemaking also proposes changes to the application review and notification process.

While preparing this rulemaking, DEA became aware that references to section 1018 of the Act (21 U.S.C. 971) were inadvertently omitted from 21 CFR 1310.12(a) and 1310.13(i). Therefore, DEA is proposing that this rulemaking amend these sections by adding this citation. This insertion is a clarification and does not alter the current treatment of exempt chemical mixtures under the CSA.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before August 24, 2010.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-228P” on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152. Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, VA 22152.

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

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by

appointment, please see the **FOR FURTHER INFORMATION** paragraph.

FOR FURTHER INFORMATION CONTACT:

Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152. Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION:

DEA's Legal Authority

DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and Controlled Substances Import and Export Act (21 U.S.C. 801-971), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to end. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical purposes and to deter the diversion of controlled substances to illegal purposes. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity. The CSA as amended also requires DEA to regulate the manufacture, distribution, importation, and exportation of chemicals that may be used to manufacture controlled substances. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances. Those classified as List II chemicals may be used to manufacture controlled substances.

Purpose of This Rule

In this rule, DEA is proposing concentration limits on chemical mixtures containing red phosphorus and/or hypophosphorous acid and its salts. If this rule is finalized as proposed, chemical mixtures containing either of these listed chemicals at or below the concentration limit would be automatically exempt from Controlled Substances Act (CSA) regulatory controls. Mixtures containing these chemicals above the concentration limit would be regulated as List I chemicals. DEA is not proposing automatic exemption for chemical mixtures containing white phosphorus. Unless otherwise exempted, all material containing white phosphorus shall

become subject to CSA chemical regulatory controls regardless of concentration.

DEA's Requirement To Identify Exempt Chemical Mixtures

The Chemical Diversion and Trafficking Act of 1988 (Pub. L. 100-690) (CDTA) created a definition for the term "chemical mixture" (21 U.S.C. 802(40)). The CDTA established 21 U.S.C. 802(39)(A)(vi) to exclude "any transaction in a chemical mixture" from the definition of a "regulated transaction." This exemption was exploited by those that traffic chemicals for illicit purposes in that it provided an unregulated source for obtaining listed chemicals for use in the illicit manufacture of controlled substances.

In April 1994, the Domestic Chemical Diversion Control Act of 1993 (DCDCA) corrected this situation by subjecting such chemical mixtures to CSA regulatory requirements, unless specifically exempted by regulation. These requirements included recordkeeping, reporting, and security for all regulated chemical mixtures with the additional requirement of registration for handlers of List I chemicals including regulated chemical mixtures. The DCDCA also provided the Attorney General with the authority to establish regulations to exempt chemical mixtures from the definition of a "regulated transaction." A chemical mixture can be granted exemption "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" (21 U.S.C. 802(39)(A)(vi)).

DEA has treated all regulated chemical mixtures as non-regulated chemicals until such time that it promulgates a final rule that identifies specific chemical mixtures as exempt. This served to prevent the immediate regulation of all qualified mixtures, which is not necessary. It also allowed DEA to gather information to implement regulations pursuant to 21 U.S.C. 802(39)(A)(vi).

Chemical Mixture Definition

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

combination with any number of non-listed chemicals.

DEA does not consider a chemical mixture to mean the combination of a listed chemical and an inert carrier. An inert carrier can be any chemical that does not modify the function of the listed chemical but is present to aid in the delivery of the listed chemical. Examples include, but are not limited to, dilutions in water, alcohol or the presence of a carrier gas.

In determining which chemical mixtures shall be subject to control, DEA considers the actual and potential clandestine use of such material. 21 U.S.C. 802(39)(A)(vi) states that an exemption can be granted if "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." It should be noted that the requirements described by statute do not allow for exemptions based on such business practices as selling only to known customers, the cost of the mixture, the customer's knowledge of the product's chemical content, packaging, or such related topics.

In 2003, DEA published a Final Rule (68 FR 23195, May 1, 2003) that identified exempt mixtures containing the chemicals ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine. The effective date of this Final Rule was June 2, 2003. In a second Final Rule (69 FR 74957, December 15, 2004; corrected at 70 FR 294, January 4, 2005) DEA finalized regulations which addressed the exemption of chemical mixtures for 27 of the remaining 38 listed chemicals. However, chemical mixtures containing phosphorus were not included. The effective date for that Final Rule was January 14, 2005.

Uses of Chemical Mixtures Containing Regulated Phosphorus

Chemical mixtures that contain red phosphorus are used in the manufacture of plastics, flame retardants, pyrotechnics, striker plates (*e.g.*, for safety matches and flares), incendiary shells, smoke bombs, and tracer bullets. Chemical mixtures containing hypophosphorous acid salts (*e.g.*, hypophosphite salts) function as catalysts, stabilizers, and growth inhibitors. They are used in plastics, films, paints, paper products, and fibers, with applications that include automotive parts, furniture, wiring,

containers, and housings for appliances and power tools. DEA has not identified any chemical mixtures containing white phosphorus.

Information Gathered by DEA Concerning Chemical Mixtures Containing Regulated Phosphorus

On January 31, 2003, DEA published in the **Federal Register** an Advance Notice of Proposed Rulemaking (ANPRM) (68 FR 4968) to solicit input from industry regarding chemical mixtures containing regulated phosphorus. The ANPRM invited interested persons to supply information on formulations that contain regulated phosphorus. DEA received three responses to this request, all from industrial firms. In addition, DEA obtained information on types of formulations containing regulated phosphorus and their uses separate from the ANPRM.

All three commenters informed DEA of commercial applications for their chemical mixtures containing regulated phosphorus, which are discussed below. The commenters also informed DEA of concentration ranges for red phosphorus and salts of hypophosphorous acid (*e.g.* hypophosphite salts). DEA has not identified any chemical mixtures containing hypophosphorous acid or white phosphorus either through industry comments or as a result of DEA research.

Comments to the ANPRM

One commenter stated that its red phosphorus is stabilized against chemical reactions prior to its use by industry. To achieve this, the red phosphorus is blended with other chemicals to become part of a matrix that protects it from chemical reactions. The amount of red phosphorus formulated in these types of chemical mixtures is not more than 50 percent. The comment claimed that such red phosphorus cannot be used for the illicit production of methamphetamine.

Another commenter reported that red phosphorus is formulated with dust suppressing agents. These chemical mixtures have applications as raw material used in different industrial sectors, including in the manufacturing of flame retardants, pyrotechnics, matches, and pesticides. The concentration of red phosphorus in these raw materials/chemical mixtures is generally above 90 percent.

Two commenters informed DEA that sodium hypophosphite, a regulated salt of hypophosphorous acid, is used in low concentrations as a stabilizer or as a catalyst. Chemical mixtures for these applications are formulated within a

range of less than one percent to no greater than 20 percent in sodium hypophosphite. Both commenters claimed that these formulations are not useful to traffickers.

Diversification of Chemical Mixtures Containing Regulated Phosphorus

Regulated phosphorus plays an important role in the chemical reaction to produce methamphetamine, a schedule II controlled substance for which the public health consequences of the manufacture, trafficking, and abuse are well known and documented. DEA has documented that the predominant method for the illicit manufacture of methamphetamine utilizes phosphorus.

DEA has identified chemical mixtures containing red phosphorus at domestic illicit methamphetamine manufacturing sites. Traffickers sometimes utilize the striker plates of safety matchbooks or boxes, or road flares as a source of red phosphorus. The coating on the striker plate contains from 25 to 60 percent red phosphorus. An estimated 20 to 400 striker plates are needed to obtain one gram of red phosphorus. One gram of red phosphorus could yield approximately 1.5 grams of methamphetamine hydrochloride, which is the end product of clandestine manufacturing. DEA conducted a review of data collected by the El Paso Intelligence Center (EPIC), which collects data on clandestine laboratory seizures by federal and state authorities. In 2004, EPIC reported 4,454 methamphetamine laboratories that utilized red phosphorus; 458 of these obtained the red phosphorus from matchbook striker plates, which is approximately ten percent of the total.

EPIC does not report the potential amount of methamphetamine produced from red phosphorus extracted from striker plates. However, only the smallest illicit laboratories (in terms of production capability) are known to use extracted red phosphorus, and these individuals manufacture predominantly for personal use. Although ten percent of the laboratories use extracted red phosphorus, the total amount of methamphetamine produced by these laboratories is relatively small. Large scale methamphetamine laboratories which have been identified by DEA have historically utilized bulk red phosphorus and not red phosphorus extracted from striker plates.

Proposed Concentration Limits for Exempt Chemical Mixtures Containing Regulated Phosphorus

DEA is proposing to establish concentration limits for chemical

mixtures containing phosphorus. If finalized as proposed, all chemical mixtures that have a concentration at or below the established concentration limit shall be automatically exempt from CSA chemical regulatory controls. Those chemical mixtures having a concentration above the concentration limit shall be List I regulated chemicals and subject to the chemical regulatory requirements of the CSA.

DEA is not aware of any chemical mixtures containing white phosphorus. It is believed that few chemical mixtures in this chemical exist because it is too reactive and unstable when mixed with other chemicals. Since DEA has not identified any white phosphorus mixtures, DEA is not proposing a concentration limit for white phosphorus and therefore, any chemical mixture containing white phosphorus would be subject to CSA regulatory control.

Hypophosphorous acid is marketed in aqueous solutions of 50 percent and can be readily used in the illicit manufacture of methamphetamine. Such aqueous solutions of hypophosphorous acid, however, are not considered chemical mixtures and are therefore currently subject to DEA chemical regulations, regardless of concentration. (As stated earlier, DEA does not consider a chemical mixture to mean the combination of a listed chemical and an inert carrier. An inert carrier can be any chemical that does not modify the function of the listed chemical but is present to aid in the delivery of the listed chemical. Examples include, but are not limited to, dilutions in water, alcohol or the presence of a carrier gas.) No chemical mixtures containing hypophosphorous acid have been identified by DEA.

Traffickers use hypophosphite salts and hypophosphorous acid similarly. DEA has identified several chemical mixtures containing hypophosphite salts in combination with other chemicals for use as mold and mildew inhibitors. Additionally, DEA has identified at least one industrial product where sodium hypophosphite is in a chemical mixture in combination with resins. The concentration of hypophosphite salts within these chemical mixtures does not exceed 20 percent.

The above chemical mixtures have limited potential for use in a clandestine laboratory because of the (a) low concentrations of the hypophosphite salts, and (b) interference from other chemicals in the mixtures. Therefore, DEA is proposing that a 30 percent concentration limit for

hypophosphorous acid and its salts (hypophosphite salts) be established.

It is important to clarify, again, that DEA does not consider a chemical mixture to mean the combination of a listed chemical and an inert carrier. Therefore, solutions of hypophosphorous acid or hypophosphite salt in water, alcohol, or another inert carrier, are not considered chemical mixtures and are therefore currently subject to DEA chemical regulatory controls regardless of concentration.

As discussed above, only the smallest clandestine methamphetamine laboratories use chemical mixtures obtained from matchbook striker plates as a source of red phosphorus. Although concerned about this type of diversion, DEA determined that the regulation of matchbook striker plates is impractical and will create undue administrative burdens for both law enforcement and the regulated sector.

DEA is proposing an 80 percent concentration limit for red phosphorus. DEA has determined that chemical mixtures containing over 80 percent red phosphorus are useful in large-scale methamphetamine production and therefore should not be automatically exempt from regulatory controls.

A chemical mixture having a regulated form of phosphorus at or below the concentration limit can still be a regulated chemical mixture if another listed chemical is present above its concentration limit. The exemption of chemical mixtures from regulatory controls does not remove criminal liability for persons who knowingly sell or possess any products containing regulated phosphorus for use in violation of the CSA.

Exemption by Application Process

DEA recognizes that the concentration limits proposed in this rule may not identify all phosphorus mixtures that should receive exemption status. DEA has implemented an application process to exempt additional mixtures (21 CFR 1310.13). This application process was finalized in the Final Rule (68 FR 23195) published May 1, 2003. Under the application process, manufacturers may submit an application for exemption for those mixtures that do not qualify for automatic exemption. Exemption status can be granted if DEA determines that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and the listed chemical cannot be readily recovered (i.e., it meets the conditions in 21 U.S.C. 802(39)(A)(vi)). An application may be for a single or a multiple number of

formulations. All chemical mixtures which are granted exemption via the application process will be listed in 21 CFR 1310.13(i).

This rulemaking is also proposing changes to the existing application process. 21 CFR 1310.13(e) provides that within 30 days after the receipt of an application for an exemption, the Administrator will notify the applicant of acceptance or rejection of the application. This paragraph is proposed to be modified in order to clarify that this acceptance or rejection only pertains to the acceptance or rejection of the application "for filing" and does not pertain to the granting or denial of the application based upon the merits of the application. Furthermore, DEA is proposing that this paragraph be modified by removing the 30-day timeframe for notification, and instead, specify that such notification be "in writing" and "within a reasonable period of time".

Thresholds and Excluded Transactions for Regulated Phosphorus Chemical Mixtures

Regulated phosphorus compounds do not have a threshold as described in 21 CFR 1310.04(g)(1). Thus, all transactions in regulated phosphorus, including its regulated chemical mixtures, are regulated transactions. Certain transactions, described in 21 CFR 1310.08, are excluded from the definition of a regulated transaction. These are domestic and international return shipments of reusable containers from customer to producer containing residual quantities of red phosphorus or white phosphorus in rail cars and intermodal tank containers which conform to International Standards Organization specifications (with capacities greater than or equal to 2,500 gallons in a single container). This exclusion also applies to regulated chemical mixtures containing red phosphorus or white phosphorus.

Requirements That Apply to Regulated List I Chemical Mixtures

Persons interested in handling List I chemicals, including regulated chemical mixtures containing List I chemicals, must comply with the following:

Registration. Any person who manufactures, distributes, imports, or exports a List I chemical, or proposes to engage in the manufacture, distribution, importation, or exportation of a List I chemical, must obtain a registration pursuant to the CSA (21 U.S.C. 823, 957). Regulations describing registration for List I chemical handlers are set forth in 21 CFR part 1309.

Separate registration is required for manufacturing, distribution, importing, and exporting. Different locations operated by a single entity require separate registration if any location is involved with the manufacture, distribution, import, or export of a List I chemical. Any person manufacturing, distributing, importing, or exporting a regulated List I chemical mixture is subject to the registration requirement under the CSA. DEA recognizes, however, that it is not possible for persons who manufacture, distribute, import, or export regulated phosphorus compounds, to immediately complete and submit an application for registration and for DEA to issue registrations immediately for those activities. Therefore, to allow continued legitimate commerce in the compounds, DEA is proposing to establish in 21 CFR 1310.09 a temporary exemption from the registration requirement for persons desiring to manufacture, distribute, import, or export regulated phosphorus compounds, provided that DEA receives a properly completed application for registration on or before 30 days after DEA publishes a Final Rule finalizing these requirements in the **Federal Register**. The temporary exemption for such persons will remain in effect until DEA takes final action on their application for registration.

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

DEA notes that warehouses are exempt from the requirement of registration and may lawfully possess List I chemicals, if the possession of those chemicals is in the usual course of business (21 U.S.C. 822(c)(2), 21 U.S.C. 957(b)(1)(B)). For purposes of this exemption, the warehouse must receive the List I chemical from a DEA registrant and shall only distribute the List I chemical back to the DEA registrant and registered location from which it was received. All other activities conducted by a warehouse do not fall under this exemption; a warehouse that distributes List I chemicals to persons other than the registrant and registered location from which they were obtained is conducting distribution activities and is required to

register as such (21 U.S.C. 802(39)(A)(ii)).

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

Each regulated bulk manufacturer of a regulated mixture shall submit manufacturing, inventory and use data on an annual basis (21 CFR 1310.05(d)). Bulk manufacturers producing the mixture solely for internal consumption, e.g., formulating a non-regulated mixture, are not required to submit this information. Existing standard industry reports containing the required information are acceptable, provided the information is readily retrievable from the report.

Title 21 CFR 1310.05 requires that each regulated person shall report to DEA any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the CSA. Regulated persons are also required to report to DEA any proposed regulated transaction with a person whose description or other identifying information has been furnished to the regulated person. Finally, regulated persons are required to report any unusual or excessive loss or disappearance of a listed chemical.

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

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

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

inspections of these controlled premises as provided in 21 CFR 1316 subpart A.

The goal of this rulemaking is to deny traffickers access to regulated phosphorus compounds while minimizing the burden on legitimate industry. Persons who obtain a regulated chemical, but do not distribute the chemical, are end users. End users are not subject to CSA chemical regulatory control provisions such as registration or recordkeeping requirements. Some examples of end users are those who chemically react phosphorus compounds and change them into non-listed chemicals, formulate phosphorus compounds into exempt chemical mixtures or consume them in industrial processes.

Technical Revision to 21 CFR 1310.12(a) and 1310.13(i)

While preparing this rulemaking, DEA became aware that references to section 1018 of the Act (21 U.S.C. 971) were inadvertently omitted from 21 CFR 1310.12(a) and 1310.13(i). Therefore, DEA is proposing that this rulemaking amend these sections by adding this citation. This insertion is a clarification and does not alter the current treatment of exempt chemical mixtures under the CSA.

As DEA discussed in its December 15, 2004, Final Rule (specifically 69 FR 74963, comment 10) all chemical mixtures not exempt from CSA regulatory controls are subject to all aspects of those controls, including importation and exportation requirements. Thus, chemical mixtures that are exempt under 21 CFR 1310.12 and 1310.13 are also exempt from the requirements of Section 1018 of the Act (21 U.S.C. 971). The requirements of 21 U.S.C. 971 apply to "each regulated person, who imports or exports a listed chemical." Since a person distributing an exempt chemical mixture is not a "regulated person" as defined by 21 U.S.C. 802(38), that person is exempt from the requirements of 21 U.S.C. 971.

DEA notes that this is a technical correction only. All exempt chemical mixtures have been treated as such for import and export purposes, and all regulated mixtures have been treated as regulated transactions for import and export purposes. DEA is merely including a reference which was inadvertently omitted from this regulatory language.

Regulatory Certifications

Regulatory Flexibility and Small Business Concerns

The Deputy Administrator hereby certifies that this rulemaking has been

drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612). In the ANPRM, DEA sought information from manufacturers about the impact of setting concentration limits for chemical mixtures containing phosphorus. Only three companies, none small businesses, provided information. Some of the mixtures sold by one of the commenters would be subject to this proposed rule, but DEA could not determine whether any of the products that may be produced with those phosphorus mixtures would also be covered. DEA is, therefore, seeking comments on whether any of the products contain phosphorus would exceed the proposed concentration limits. DEA notes, however, that the cost of compliance with the rule is low and is unlikely to impose a significant cost on any manufacturing, distributing, importing, or exporting firm. The recordkeeping requirements can be met with standard business records; most firms maintain adequate security to meet DEA's regulations. The primary cost of compliance is the registration fee. For manufacturers, the registration fee is \$2,293 annually; for distributors, importers, and exporters, the fee is \$1,147 annually. These fees are substantially less than one percent of annual sales for manufacturers, distributors, importers, and exporters. Data from the 2002 Economic Census indicate that small chemical manufacturers generally have sales well above \$1 million; most small chemical distributors have sales above \$250,000.

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, Section 1(b), Principles of Regulation. It has been determined that this rule is a “significant regulatory action” under Executive Order 12866, Section 3(f), Regulatory Planning and Review, and accordingly this rule has been reviewed by the Office of Management and Budget. The information DEA received in response to the ANPRM indicates that few phosphorus mixtures will be subject to the regulation. Those mixtures appear to be produced by current DEA registrants on whom the rule will impose no new requirements. DEA is seeking comments on whether any firms purchasing covered mixtures are producing products that would themselves be subject to the rule.

As stated earlier in this rulemaking the vast majority of the chemical mixtures that will become subject to this proposed rulemaking have large industrial uses. Regulated chemical mixtures are not items having common

household uses. Although concerned about the diversion of matchbook striker plates, DEA determined that the regulation of matchbook striker plates is impractical and will create undue administrative burdens for both law enforcement and the regulated sector.

Benefits. Phosphorus is a chemical important in the clandestine manufacture of methamphetamine and amphetamine. This rule seeks to eliminate the use of certain chemical mixtures whose high concentrations of phosphorus make them valued by traffickers seeking this chemical for their clandestine laboratory operations.

Methamphetamine remains the primary drug produced in illicit laboratories within the U.S. Data from the El Paso Intelligence Center's (EPIC) Clandestine Laboratory Database indicates that there were more than 17,170 methamphetamine laboratory incidents in calendar year 2004; in 2005, as State laws began to limit sales of over-the-counter medications containing primary ingredients used in the illicit manufacture of methamphetamine (ephedrine, pseudoephedrine, and phenylpropanolamine), the number of incidents declined to 12,139. In 2006, with both State and Federal controls coming into effect, the number of incidents fell significantly to 7,347, but that is still about 20 clandestine laboratory incidents a day.

According to the Substance Abuse and Mental Health Services Administration (SAMHSA), Drug Abuse Warning Network, in 2003, the latest year for which data are available (since SAMHSA is currently amending 2004, 2005, and 2006 data), amphetamine and methamphetamine emergency department (ED) visits rose from 25,200 in 1995 to 38,960 in 2002 and 42,500 in 2003. If the cost of the ED visit is \$500, which is probably low in many areas, the total cost for 42,500 visits would have been \$21.25 million for 2003.

The surge in methamphetamine abuse and the manufacture of the drug in clandestine laboratories have caused serious law enforcement and environmental problems, particularly in rural communities. Rural areas are frequently the site of clandestine laboratories because the manufacturing process produces distinctive odors and can be identified if there are close neighbors. Besides causing crime as clandestine laboratory operators steal ingredients to make methamphetamine and steal to support their addiction, the clandestine laboratories often leave serious pollution behind. A laboratory can produce 6 to 10 pounds of hazardous waste for every pound of

methamphetamine produced. As DEA noted in its Interim Final Rule implementing the retail sales requirements of the Combat Methamphetamine Epidemic Act of 2005 (CMEA) (Title VII of Pub. L. 109–172), clean-up costs in Fiscal Year 2006 were more than \$12 million (71 FR 56008, September 26, 2006).

The Federal and State cleanups are generally limited to removing chemicals that could be reused; they do not address water and soil pollution that remains. Owners of the property are responsible for completing the cleanup of contaminated water and soil, but if the owner cannot pay the cost, either the local governments must bear the burden or the contamination remains.

This rule is intended to continue the trend of reducing the number of clandestine laboratories. This trend will reduce the cost to State and local governments as well as the hazard to law enforcement officers and others from exposure to the toxic chemicals left behind.

Executive Order 12988

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

Executive Order 13132

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

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or

on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Paperwork Reduction Act

This rule proposes that chemical mixtures containing 80 percent and less of red phosphorus or 30 percent and less of hypophosphorous acid or its salts are automatically exempt from CSA regulatory controls pertaining to chemicals and that no automatic exemption be established for chemical mixtures containing white phosphorus. Under this proposed method of automatic exemption, persons who handle these exempt chemical mixtures will not be subject to CSA regulatory controls, including the requirement to register with DEA, the requirement to report manufacturing activities to DEA annually, and the requirement to file importation and exportation advance notification and return declaration information with DEA. For persons handling regulated chemical mixtures, DEA anticipates granting some of these mixtures exempt status by the application process (21 CFR 1310.13).

At this time, DEA lacks specific information regarding the potential impact of this regulation on the regulated industry. DEA does not believe that the impact will be significant, and has been unable to identify any chemical mixtures that are certain to be affected by this regulation. DEA also anticipates that some chemical mixtures would be granted exemptions based on the application process.

DEA does not have reliable estimates regarding the number of persons who would be required to register as a result of the control of chemical mixtures containing regulated forms of phosphorus. Nor does DEA have accurate estimates regarding manufacturing, import and export activities involving chemicals mixtures addressed in this rulemaking. Responses to the previous Advance Notice of Proposed Rulemaking did not address this issue. Therefore, DEA is specifically

seeking information regarding the number of persons affected, and the potential number of importation and exportation transactions that would be affected by this regulation. Therefore, DEA will revise three existing information collections related to the handling of chemical mixtures containing listed forms of phosphorus once it receives further information:

- “Application for Registration under Domestic Chemical Diversion Control Act of 1993 and Renewal Application for Registration under Domestic Chemical Diversion Control Act of 1993” [OMB information collection 1117–0031]
- “Annual Reporting Requirement for Manufacturers of Listed Chemicals” [OMB information collection 1117–0029]
- “Import/Export Declaration for List I and List II Chemicals” [OMB information collection 1117–0023]

List of Subjects in 21 CFR Part 1310

Drug traffic control, List I and List II chemicals, reporting requirements.
For the reasons set out above, 21 CFR Part 1310 is proposed to be amended as follows:

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

1. The authority citation for part 1310 continues to read as follows:
Authority: 21 U.S.C. 802, 827(h), 830, 871(b), 890.
2. Section 1310.09 is amended by revising paragraph (k) to read as follows:

§ 1310.09 Temporary Exemption From Registration.
* * * * *
(k) Each person required by Sections 302 and 1007 of the Act (21 U.S.C. 822 and 957) to obtain a registration to manufacture, distribute, import, or export regulated chemical mixtures which contain red phosphorus, white phosphorus, hypophosphorous acid (and its salts), pursuant to Sections 1310.12 and 1310.13, is temporarily

exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption on or before July 26, 2010. The exemption will remain in effect for each person who has made such application until the Administrator has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect. Any person who manufactures, distributes, imports, or exports a chemical mixture whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for these persons, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has not been approved. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

3. Section 1310.12 is amended by revising paragraph (a) and by amending the Table of Concentration Limits in paragraph (c) by adding entries for “hypophosphorous acid and its salts”, “red phosphorus”, and “white phosphorus” in alphabetical order to read as follows:

§ 1310.12 Exempt Chemical Mixtures.
(a) The chemical mixtures meeting the criteria in paragraphs (c) or (d) of this Section are exempted by the Administrator from application of Sections 302, 303, 310, 1007, 1008, and 1018 of the Act (21 U.S.C. 822, 823, 830, 957, 958, and 971) to the extent described in paragraphs (b) and (c) of this Section.
* * * * *
(c) * * *

TABLE OF CONCENTRATION LIMITS

List I chemicals	DEA chemical code number	Concentration (percent)	Special conditions
* Hypophosphorous acid and its salts.	* 6797	* 30% by weight if a solid, weight or volume if a liquid.	* The weight is determined by measuring the mass of hypophosphorous acid and its salts in the mixture; the concentration limit is calculated by summing the concentrations of all forms of hypophosphorous acid and its salts in the mixture. The Administration does not consider a chemical mixture to mean the combination of a listed chemical and an inert carrier. Therefore, any solution consisting of hypophosphorous acid (and its salts), dispersed in water, alcohol, or another inert carrier, is not considered a chemical mixture and is therefore subject to chemical regulatory controls at all concentrations.

TABLE OF CONCENTRATION LIMITS—Continued

List I chemicals	DEA chemical code number	Concentration (percent)	Special conditions
* Red Phosphorus	* 6795	* 80% by weight.	* *
* White phosphorus ...	* 6796	* Not exempt at any concentration.	* Chemical mixtures containing any amount of white phosphorus are not exempt due to concentration, unless otherwise exempted.
* List II chemicals.	* *	* *	* *
* *	* *	* *	* *

* * * * *

4. Section 1310.13 is amended by revising paragraph (e) and paragraph (i) introductory text to read as follows:

§ 1310.13 Exemption of chemical mixtures; application.

* * * * *

(e) Within a reasonable period of time after the receipt of an application for an exemption under this section, the Administrator will notify the applicant in writing of the acceptance or rejection of the application for filing. If the application is not accepted for filing, an explanation will be provided. The Administrator is not required to accept an application if any information required pursuant to paragraph (c) of this section or requested pursuant to paragraph (d) of this section is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of paragraphs (c) and (d) of this section. If the exemption is subsequently granted, the applicant shall again be notified in writing and the Administrator shall issue, and publish in the **Federal Register**, an order on the application. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or conclusions of law upon which the order is based, the Administrator may suspend the effectiveness of the order until he has reconsidered the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as deemed appropriate.

* * * * *

(i) The following chemical mixtures, in the form and quantity listed in the application submitted (indicated as the "date") are designated as exempt chemical mixtures for the purposes set

forth in this section and are exempted by the Administrator from application of Sections 302, 303, 310, 1007, 1008, and 1018 of the Act (21 U.S.C. 822, 823, 830, 957, 958, and 971):

* * * * *

Dated: June 16, 2010.

Michele M. Leonhart,
Acting Administrator.

[FR Doc. 2010-15160 Filed 6-24-10; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2010-0441]

RIN 1625-AA09

Drawbridge Operation Regulation; Arkansas Waterway, Pine Bluff, AR

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes that operating procedures on the Rob Roy Drawbridge across the Arkansas Waterway at mile 67.4 at Pine Bluff, AR be revised in the Code of Federal Regulations to reflect that vessel operators contact the remote drawbridge operator via microphone keying on VHF-FM Channel 12 when requesting a draw opening. This keying activates an indicator on the remote drawbridge operator's console and sends an acknowledgement tone back to the vessel and the remote drawbridge operator then establishes normal verbal radio communications. This protocol is used to isolate and differentiate these radio communications from the railroad communications that the remote drawbridge operator receives, thus ensuring that vessel calls receive immediate attention.

DATES: Comments and related material must reach the Coast Guard on or before August 24, 2010.

ADDRESSES: You may submit comments identified by docket number USCG-2010-0441 using any one of the following methods:

(1) *Federal eRulemaking Portal:*
<http://www.regulations.gov>.

(2) *Fax:* 202-493-2251.

(3) *Mail:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC, 20590-0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail Mr. Eric Washburn, Bridge Administrator, Eighth Coast Guard District, Bridge Branch; telephone 314-269-2378, e-mail Eric.Washburn@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change to <http://www.regulations.gov> and will include