

number of the retail pharmacy transmitting the prescription;

(2) Keep a record of the date of receipt of the transmitted prescription, the name of the pharmacist filling the prescription, and the date of filling of the prescription;

(3) Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (*i.e.* private, common or contract carrier).

■ 7. Section 1306.24 is amended by redesignating the existing paragraphs (b) and (c) as paragraphs (c) and (d), and by adding a new paragraph (b) to read as follows:

**§ 1306.24 Labeling of substances and filling of prescriptions.**

\* \* \* \* \*

(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the package a label showing the retail pharmacy name and address and a unique identifier, (*i.e.* the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy, in addition to the information required under paragraph (a) of this section.

\* \* \* \* \*

■ 8. Section 1306.26 is amended by adding a new paragraph (g) to read as follows:

**§ 1306.26 Dispensing without prescription.**

\* \* \* \* \*

(g) Central fill pharmacies may not dispense controlled substances to a purchaser at retail pursuant to this section.

■ 9. Section 1306.27 is added to read as follows:

**§ 1306.27 Provision of prescription information between retail pharmacies and central fill pharmacies for initial and refill prescriptions of Schedule III, IV, or V controlled substances.**

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall also apply:

(a) Prescriptions for controlled substances listed in Schedule III, IV or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

(1) Write the word "CENTRAL FILL" on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and the name of the

retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

(2) Ensure that all information required to be on a prescription pursuant to § 1306.05 of this part is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

(3) Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining;

(4) Maintain the original prescription for a period of two years from the date the prescription was last refilled;

(5) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

(1) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and DEA registration number of the retail pharmacy transmitting the prescription;

(2) Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription;

(3) Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (*i.e.* private, common or contract carrier).

Dated: June 17, 2003.

**Laura M. Nagel,**

*Deputy Assistant Administrator, Office of Diversion Control.*

[FR Doc. 03-15912 Filed 6-23-03; 8:45 am]

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Parts 1309 and 1310**

[Docket No. DEA-198F2]

RIN 1117-AA57

**Control of Red Phosphorus, White Phosphorus and Hypophosphorous Acid (and Its Salts) as List I Chemicals; Exclusions and Waivers**

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

**ACTION:** Final rule.

**SUMMARY:** On October 17, 2001, DEA published a Final Rulemaking (66 FR

52670) in which DEA added red phosphorus, white phosphorus (also known as yellow phosphorus) and hypophosphorous acid (and its salts) as List I chemicals. This action was taken because of the use and importance of these chemicals in the illicit manufacture of methamphetamine (a Schedule II controlled substance).

As List I chemicals, handlers of these materials became subject to Controlled Substances Act (CSA) chemical regulatory controls including registration, recordkeeping, reporting, and import/export requirements. DEA had determined that these controls are necessary to prevent the diversion of these chemicals to clandestine drug laboratories.

In order to provide flexibility for legitimate businesses, the October 17, 2001 rule established, on an interim basis, specific exclusions and waivers for chemical handlers engaged in certain activities. DEA has completed its review of comments pertaining to these interim provisions. This rulemaking finalizes these exclusions and waivers related to the handling of the listed chemicals red phosphorus, white phosphorus, and hypophosphorous acid (and its salts).

**EFFECTIVE DATE:** This final rule is effective June 24, 2003.

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

**SUPPLEMENTARY INFORMATION:**

**Background**

On September 25, 2000, DEA published a Notice of Proposed Rulemaking proposing that red phosphorus, white phosphorus, and hypophosphorous acid (and its salts) be made List I chemicals (65 FR 57577). On October 17, 2001, DEA published a Final Rulemaking (66 FR 52670) in which DEA added red phosphorus, white phosphorus (also known as yellow phosphorus) and hypophosphorous acid (and its salts) as List I chemicals. This action was taken because of the use and importance of these chemicals in the illicit manufacture of methamphetamine (a Schedule II controlled substance).

As List I chemicals, handlers of these materials became subject to CSA chemical regulatory controls including registration, recordkeeping, reporting, and import/export requirements. DEA had determined that these controls are necessary to prevent the diversion of these chemicals to clandestine drug laboratories.

In order to provide flexibility for legitimate businesses, the October 17, 2001 rule also established, on an interim basis, specific exclusions and waivers for chemical handlers engaged in certain activities. DEA has completed its review of comments pertaining to these interim provisions. This rulemaking finalizes these exclusions and waivers related to the handling of the listed chemicals red phosphorus, white phosphorus, and hypophosphorous acid (and its salts).

*What Interim Exclusions and Waivers Did the October 17, 2001 Rule Put Into Effect?*

The October 17, 2001 rule established, on an interim basis, an exclusion from the definition of regulated transaction for domestic transactions involving red phosphorus and white phosphorus which are return shipments of residual quantities (from customer to producer) 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). The rule also established, on an interim basis, a waiver from the registration requirement for such activity. Additionally, this final rule established, on an interim basis, a waiver from the registration requirement for any person whose activities with respect to List I chemicals are limited to the distribution of red phosphorus, white phosphorus, or hypophosphorous acid (and its salts) to: Another location operated by the same firm solely for internal end-use; or an EPA or State licensed waste treatment or disposal firm for the purpose of waste treatment or disposal.

*Why Did the October 17, 2001 Rule Place These Provisions Into Effect on an Interim Basis and Solicit Comments Pertaining to These Provisions?*

DEA became aware of the potential need for these provisions via comments received in response to the September 25, 2000 Notice of Proposed Rulemaking (65 FR 57577) which initially proposed the control of red phosphorus, white phosphorus and hypophosphorous acid as List I chemicals. Since that original NPRM did not propose the exclusion and waivers, the public did not have an opportunity to comment on these issues.

In addition to deciding that exclusion/waivers were warranted, the DEA determined that good cause existed under the Administrative Procedure Act (5 U.S.C. 553 *et seq.*)(APA) to forgo a Notice of Proposed Rulemaking for the exclusion and waivers. The APA states that an agency may forgo a NPRM if it is impracticable, unnecessary, or

contrary to the public interest. To avoid unnecessary or temporary burdens on affected companies during the pendency of proceedings in this matter, DEA included as part of the October 17, 2001 rulemaking, an interim rule with request for comments regarding these issues.

The October 17, 2001 rule, therefore solicited comments only on those portions of the rule pertaining to the exclusion/waiver issues. DEA allowed 60 days for persons to comment on the exclusion and waivers. The rulemaking further indicated that after the close of this comment period, DEA would publish a final rule in the **Federal Register** to inform interested parties if changes were needed or if the exclusion and waivers would be adopted as originally stated.

*What Comments, Submitted in Response to the September 25, 2000 NPRM, Led DEA To Create the Interim Exclusions and Waivers?*

In response to the September 25, 2000 NPRM, two commentors requested clarification regarding the potential applicability of the regulation to end-users that utilize red phosphorus in their production processes. These commentors expressed concerns that an end-user may become subject to regulatory requirements because of distribution of excess material off-site for disposal purposes or because of the transfer of stock from one company location to another.

Under the proposed regulations, distributions of red phosphorus, white phosphorus and/or hypophosphorous acid (and its salts) for the purpose of disposal would be considered regulated transactions subject to all CSA chemical regulatory requirements including registration, recordkeeping and reporting. Additionally, the transfer of stock from one company location to another would require the registration of each location.

The CSA, pursuant to 21 U.S.C. 822(d), provides that the Attorney General may, by regulation, waive the requirement of registration of certain manufacturers, distributors or dispensers, if consistent with the public health and safety. Therefore, in order to reduce any burden on end-users of these chemicals, DEA agreed to waive the registration requirement for any person whose activities with respect to List I chemicals are limited to the distribution of red phosphorus, white phosphorus, or hypophosphorous acid (and its salts) to: Another location operated by the same firm solely for internal end-use; or an EPA or State licensed waste treatment or disposal firm for the purpose of waste treatment or disposal.

This waiver of registration as it pertains to distributions for waste treatment or disposal applies only to the registration requirement, and all other CSA chemical regulatory controls such as recordkeeping and reporting will still apply.

Additionally, in response to the September 25, 2000 NPRM, two producers of elemental phosphorus requested that large transactions be exempted when shipped in reusable containers with capacities of 2500 or 2800 gallons. These commentors stated that these bulk containers are exclusively rail cars or large intermodal tank containers specially designed to enable safe transport. After unloading, the bulk containers are shipped back to the producers (filled with water for safety reasons due to the remaining phosphorus in the container) for reuse. Therefore, the commentors expressed concerns that their other sites and customers would possibly be subject to recordkeeping and registration requirements due to the return shipments. The commentors further stated that "safeguards already include recordkeeping, incident reporting, tamper-detection, sealed valves, and use of bulk reusable containers". The commentors believe that "registering and tracking these types of shipments back and forth with DEA would provide no additional benefit and would impose an undue burden on DEA, our operations and our customers."

DEA agreed that return shipments of residual quantities should not be impacted by this regulation. DEA also recognized the difficulty in quantifying the residual amounts of red and white phosphorus contained in these rail cars and intermodal tank containers which conform to International Standards Organization specifications (with capacities greater than or equal to 2500 gallons in a single container). The CSA authorizes DEA, pursuant to 21 U.S.C. 802(39)(A)(iii), to remove certain transactions in listed chemicals from the definition of regulated transaction. Therefore DEA issued an interim rule excluding from the definition of regulated transaction (21 CFR 1310.08(j)), domestic transactions involving red phosphorus and white phosphorus which are return shipments of residual quantities (from customer to producer) in rail cars and intermodal tank containers which conform to International Standards Organization specifications (with capacities greater than or equal to 2500 gallons in a single container). As such, these return shipment transactions will not require recordkeeping. Additionally, DEA issued an interim rule waiving the

registration requirement pursuant to 21 CFR 1309.24(g) for any person whose distribution of red phosphorus or white phosphorus is limited to residual quantities of chemical returned to the producer in reusable rail cars and intermodal tank containers which conform to International Standards Organization specifications (with capacities greater than or equal to 2500 gallons in a single container).

The October 17, 2001 rulemaking made it clear that the exclusion and waiver pertain only to these return shipments. Manufacturers shall still be subject to registration, recordkeeping, reporting and other CSA chemical regulatory requirements pertaining to the production and distribution of listed chemicals to their customers. The customers will not be subject to registration or recordkeeping requirements for the return of residual quantities in reusable containers to the producer. However, should these customers re-distribute any of the received material (other than the return of reusable containers to the producer), they shall be subject to all CSA chemical regulatory requirements.

*What Comments Pertaining to the Interim Exclusion and Waivers Were Received in Response to the October 17, 2001 Rule? What Final Action Is DEA Taking Regarding the Exclusion and Waivers?*

Two comments were received in response to the exclusion from the definition of regulated transaction of domestic transactions involving red phosphorus and white phosphorus which are return shipments of residual quantities (from customer to producer) in rail cars and intermodal tank containers which conform to International Standards Organization specifications (with capacities greater than or equal to 2500 gallons in a single container). These two comments requested that the exclusion and waiver from registration be expanded to include domestic and international shipments.

DEA does not believe that such international shipments pose a more substantial risk of diversion than domestic transactions. Therefore, in response to these comments, DEA is expanding the exclusion and waiver in 21 CFR 1309.24(g) and 21 CFR 1310.08(j) to include domestic and international transactions involving red phosphorus and white phosphorus which are return shipments of residual quantities (from customer to producer) in rail cars and intermodal tank containers which conform to International Standards Organization

specifications (with capacities greater than or equal to 2500 gallons in a single container). The registration requirement for persons engaged in such activity will also be waived.

The proposed regulatory language in 21 CFR 1309.24(g) and 21 CFR 1310.08(j) utilized the term "isotainer." It is DEA's understanding that an isotainer is an intermodal tank container which conforms to International Standards Organization specifications. Therefore DEA has chosen to modify 21 CFR 1309.24(g) and 21 CFR 1310.08(j) to clarify that the provisions pertain to "intermodal tank containers which conform to International Standards Organization specifications." This change does not modify the intended meaning of these paragraphs.

Each of these two comments also requested clarification regarding the term "residual quantities." In response to these comments, DEA understands that when a customer purchases rail cars and intermodal tank containers of red phosphorus and white phosphorus, it is not possible to remove 100 percent of the material during the unloading operation. Therefore, these "emptied" containers, in fact, contain residual quantities of phosphorus. The term "residual quantities" refers to those quantities of phosphorus routinely remaining in "emptied" rail cars and intermodal tank containers under normal industry unloading procedures and consistent with normal industry practice.

One commentator wanted to ensure that DEA understands that return shipments of "emptied" rail cars and intermodal tank containers holding "residual quantities" of phosphorus, also contain widely varying amounts of water and/or nitrogen which are added to these rail cars and intermodal tank containers as a safety precaution since the phosphorus is spontaneously combustible when exposed to air. In response to this comment, DEA acknowledges that it understands that this is normal industry practice.

One commentator also stated that the phrase "whose distribution of red and white phosphorus is limited solely to residual quantities of chemicals returned to the producer" could be misinterpreted to mean that the waiver does not apply if the person meets all the conditions but also is involved in other types of distributions which qualify for a waiver of registration (*i.e.* disposal or intra-company transfers).

As clarification, DEA wishes to make it clear that if the registration requirement has been waived for each and every activity in which a person is engaged, then that person is not

required to register. 21 CFR 1309.24(f) waives the registration requirement for any person whose activities with respect to List I chemicals are limited to the distribution of red phosphorus, white phosphorus, or hypophosphorous acid (and its salts) to: Another location operated by the same firm solely for internal end-use; or an EPA or State licensed waste treatment or disposal firm for the purpose of waste treatment or disposal. 21 CFR 1309.24(g) waives the registration requirement for any person whose distribution of red phosphorus or white phosphorus is limited solely to residual quantities of chemical returned to the producer, in reusable 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). In providing these waivers, DEA intended to waive the registration requirement for persons engaged in any of these waived activities, as long as they do not engage in other regulated activities which require registration. 21 CFR 1309.24(i) clarifies that "If any person exempted under paragraph (b), (c), (d), (e), (f) or (g) of this section also engages in the distribution, importation or exportation of a List I chemical, other than as described in such paragraph, the person shall obtain a registration for such activities, as required by Section 1309.21 of this part."

One commentator also requested that DEA omit the term "residual quantities" completely and therefore provide an exclusion/waiver in the case that "a partial shipment be returned from the customer back to the producer." DEA wishes to be clear on this point. The exclusion and waiver are not intended to exempt any partial shipments from customer back to producer. The undocumented transfer of such material poses a diversion risk. These transactions shall therefore be subject to all chemical regulatory control provisions of the CSA.

DEA did not receive any comments relating specifically to the interim waiver from the registration requirement (as specified in 21 CFR 1309.24(f)) for any person whose activities with respect to List I chemicals are limited to the distribution of red phosphorus, white phosphorus, or hypophosphorous acid (and its salts) to: Another location operated by the same firm solely for internal end-use; or an EPA or State licensed waste treatment or disposal firm for the purpose of waste treatment or disposal. Since no comments regarding this waiver were received, this waiver is being adopted as originally

stated in the October 17, 2001 rulemaking.

DEA is therefore finalizing 21 CFR 1309.24(f) to provide that "The requirement of registration is waived for any person whose activities with respect to List I chemicals are limited to the distribution of red phosphorus, white phosphorus, or hypophosphorous acid (and its salts) to: Another location operated by the same firm solely for internal end-use; or an EPA or State licensed waste treatment or disposal firm for the purpose of waste treatment or disposal".

#### Certifications

##### *Regulatory Flexibility Act*

The Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed it, and by approving it certifies that this rulemaking will not have a significant economic impact on a substantial number of small entities. This final rule finalizes an interim exclusion from the definition of regulated transaction for return shipments of residual quantities of red phosphorus and white phosphorus in rail cars and intermodal tank containers, as well as three waivers of the requirement of registration for certain persons handling the List I chemicals red phosphorus, white phosphorus, and hypophosphorous acid (and its salts). Finalization of the interim exclusion and waivers reduces the regulatory burden for those persons.

##### *Administrative Procedure Act*

Under the Administrative Procedure Act (5 U.S.C. 553(d)(1)), an agency may make a rulemaking effective before the required 30 days if the rule "grants or recognizes an exemption or relieves a restriction." DEA finds good cause to make this rule effective immediately upon publication. This rule provides an exclusion from the definition of regulated transaction and waives the requirement of registration for certain persons, thereby reducing the regulatory burden for those persons.

##### *Executive Order 12866*

The Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). DEA has determined that this is not a significant rulemaking action. Therefore, this action has not been reviewed by the Office of Management and Budget.

##### *Executive Order 12988—Civil Justice Reform*

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

##### *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 \$100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

##### *Small Business Regulatory Enforcement Fairness Act of 1996*

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

#### List of Subjects

##### *21 CFR Part 1309*

Administrative practice and procedure, Drug traffic control, List I and List II chemicals, Reporting and recordkeeping requirements.

##### *21 CFR Part 1310*

Drug traffic control, Reporting and recordkeeping requirements.

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

#### **PART 1309—[AMENDED]**

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

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

■ 2. In §1309.24, paragraph (g) is revised to read as follows:

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

\* \* \* \* \*

(g) The requirement of registration is waived for any person whose distribution of red phosphorus or white phosphorus is limited solely to residual quantities of chemical returned to the producer, in reusable 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).

\* \* \* \* \*

#### **PART 1310—[AMENDED]**

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

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

■ 2. Section 1310.08 is amended by revising paragraph (j) to read as follows:

#### **§ 1310.08 Excluded transactions.**

\* \* \* \* \*

(j) 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).

Dated: May 28, 2003.

**William B. Simpkins,**

*Acting Administrator.*

[FR Doc. 03-15788 Filed 6-23-03; 8:45 am]

**BILLING CODE 4410-09-P**

## **DEPARTMENT OF THE TREASURY**

### **Internal Revenue Service**

#### **26 CFR Part 1**

**[TD 9062]**

**RIN 1545-BB83**

#### **Assumption of Partner Liabilities**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Temporary regulations.

**SUMMARY:** This document contains temporary regulations regarding a partnership's assumption of a partner's liabilities in a transaction occurring after October 18, 1999, and before June 24, 2003. These temporary regulations affect partners and partnerships and clarify the tax treatment of an assumption by a partnership of a partner's liability. The text of these