

chemicals as impurities in non-regulated products, it is DEA's understanding that the impurities are present only in trace amounts. It is not DEA's intent that the distribution of non-regulated chemicals that contain trace amounts of List I chemicals as unintentional by-products of the manufacturing process be subject to the registration requirement.

7. One comment suggested that if the Food and Drug Administration (FDA) removes ephedrine from over-the-counter status, the primary reason for, and economic foundation of, the registration program would be removed through the elimination of the need to register and collect fees from the estimated 10,000 retail distributors that handle ephedrine drug products that are regulated as List I chemicals. The comment urged that if such a circumstance occurs, DEA should withdraw the registration requirement.

The DCDCA requires registration of any person who distributes, imports or exports any List I chemical and was not intended solely to control the distribution of regulated ephedrine drug products. DEA's chemical control program, including registration, applies to all List I chemicals. The potential elimination of the need to register retail distributors of ephedrine drug products would not change the purpose of the program. Secondly, the FDA action is only speculative at this time, and its subsequent impact, if passed, is even more uncertain. However, OMB Circular A-25 requires the review of all fees every two years. Under this review, any major change in the registration population would require reassessment of the fees for other registrants. Any change to the fees would be subject to notice and comment.

8. One comment characterized the registration of sites that manufacture List I chemicals as unnecessary, since it duplicates existing site reporting requirements under other Federal laws. A second comment questioned the need for a pre-registrant investigation and fee for high volume manufacturers.

The DCDCA requires persons who distribute, import or export a List I chemical to obtain a registration and requires that DEA determine if such registration would be in the public interest pursuant to the criteria set forth in Section 823(h) of the Act. The pre-registrant investigation must be conducted to determine whether the criteria regarding the public interest are met. The required fee is assessed to cover the costs of that investigation.

9. One comment requested clarification of the exemption from chemical registration found in Section

1309.25, for companies that are registered with DEA to handle controlled substances.

A controlled substance registrant that distributes, imports or exports a List I chemical, other than a regulated drug product that may be marketed or distributed under the Food, Drug, and Cosmetic Act (FDCA), must obtain a chemical registration for such activities. The exemption in Section 1309.25 applies only to controlled substance registrants who engage in similar activities with a regulated drug product that may be marketed or distributed under the FDCA. The exemption is directed at the approximately 65,000 pharmacies and others who are already registered with DEA under the CSA, so as to avoid a duplicative registration requirement on these registrants. In response to this comment and to help clarify the provisions of the exemption, Section 1309.25 has been amended to specify that the exemption applies only to activities involving drug products that may be marketed or distributed under the Food, Drug and Cosmetic Act, that are regulated as List I chemicals pursuant to Section 1310.01(f)(1)(iv).

10. One comment expressed concerns that the regulations will require persons who handle exempt chemical mixtures containing List I chemicals to register.

The proposed Section 1310.13, which was withdrawn for re-publication at a later date, established that the chemical mixtures exempted by the Administrator would not be subject to the registration, recordkeeping, reporting, and import/export provisions of the Act. It is DEA's intention that the same provision will be included in the new chemical mixture exemption regulations. In the interim, chemical mixtures will be exempt until the exemption regulations are promulgated. However, creation of a chemical mixture for the purpose of evading the requirements of the CSA is a violation of CSA (21 U.S.C. 843(a)(8)), subject to a penalty of imprisonment for not more than four years, a fine of \$30,000, or both.

#### Brokers and Traders

11. Three comments found the definition of "broker" and "trader" in Sections 1310.01(k) and 1313.02(m) to be overly broad. Specifically, subparagraph (3) of each section may be read as covering any action, whether deliberate or inadvertent, that results in an international transaction taking place, i.e., a chemical distributor provides a foreign customer with a list of possible sources for a chemical that the distributor does not carry, thus "bringing together a buyer and a seller."

DEA agrees that the definition is not intended to cover such circumstances. DEA has amended the wording of subparagraph (3) of the definition to read "Fulfilling a formal obligation to effect 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."

12. One comment requested clarification of whether import brokers and freight forwarders would be considered brokers or traders.

Brokers and traders are defined as U.S. based persons who assist in arranging international transactions in listed chemicals; the definition does not apply to domestic transactions, including imports into or exports from the United States. Further, brokers and traders, as defined, do not take possession of listed chemicals. Under the circumstances, U.S. based import brokers and freight forwarders would not be considered brokers or traders, as defined, while acting in the normal course of their business. However, it must be understood that imports, exports and distributions of listed chemicals are subject to other provisions of the CDTA and DCDCA and a regulated person is responsible for those transactions.

#### Security Provisions

13. Two comments questioned the appropriateness of the proposed Section 1309.72, which concerns employment of persons who have been convicted of a felony relating to controlled substances or listed chemicals or have been subject to a denial, suspension or revocation of a DEA registration. One comment raised the issue of whether the requirements violate occupational safety and health, privacy, and non-discrimination laws. The other pointed out that in the absence of the stringent security and storage requirements applied to controlled substances, a far greater number of personnel would have access to List I chemicals, such as ephedrine, thus increasing the burden required to satisfy the requirements of this section.

DEA agrees that the lack of restrictions regarding possession of List I chemicals makes it difficult to employ comprehensive screen practices for all potential employees as proposed in Section 1309.72. However, registrants must employ safeguards to prevent List I chemicals from being diverted from their businesses into the illicit traffic. DEA is, therefore, withdrawing the proposal prohibiting such employment, and in its place establishing that registrants must exercise caution in their employment practices regarding