

persons who have been convicted of a felony relating to controlled substances or listed chemicals, or have been subject to denial, suspension or revocation of a DEA registration. The registrant must understand that if an employee diverts a listed chemical, the registrant may be subject to a revocation action. The registrant must assess the risks involved in employing such a person and, in the event of employment, institute procedures to limit the potential for diversion of List I chemicals by such an employee.

14. One comment requested that DEA provide comprehensive guidance regarding assessment of security measures as outlined in Section 1309.71(b).

List I chemical handlers vary greatly in size, type of business and volume handled. Under such circumstances, it would not be desirable to establish specific, inflexible security controls and procedures. The factors outlined in Section 1309.71(b) provide a general framework of elements that allow potential registrants flexibility in assessing the potential threat of diversion and to determine measures necessary to prevent diversion. DEA has made and will continue to make available additional suggestions regarding security in separate publications for the chemical industry. In addition, as set forth in Section 1309.71(c), an applicant or registrant may, following development of a proposed system of controls and procedures, submit materials and plans regarding the system to DEA for assessment.

15. One comment opposed the proposal that retailers stock ephedrine drug products that are regulated as List I chemicals behind a counter on the basis that this requirement creates a third class of drugs (Section 1309.71(a)(2)).

DEA is regulating a List I chemical, not a drug. Section 1309.71(a)(2) provides a basic security measure for a List I chemical that is known to have been diverted from both the retail and wholesale levels for the purposes of manufacturing illicit controlled substances. The section does not prohibit any person from purchasing the product or establish any restrictive requirements, such as sale by prescription only, that must be met by the purchaser. The requirement simply provides an additional means of controlling diversion without restricting public access to the product.

Section 1313.12 Requirement of 486 form for Imports

16. One comment questioned the need for advance notice of importation in cases of a return of a previously exported listed chemical and suggested that manufacturers be exempted from this requirement for the return of chemicals which they exported.

DEA previously recognized, under the 1988 Chemical Diversion and Trafficking Act, that exports of listed chemicals might be rejected or otherwise undeliverable, requiring that they be returned to the U.S. exporter. Existing Section 1313.22(e) provides that exports of listed chemicals that are refused, rejected, or otherwise deemed undeliverable may be returned to the U.S. exporter of record without advance notice or a 486 form. That section requires that a written notification be submitted to DEA within a reasonable time following the return.

However, an export that has cleared foreign customs and been accepted by the foreign consignee is not subject to this exception. Any such shipments subsequently returned to the U.S. are imports, subject to all applicable requirements.

17. Two comments questioned the provisions of Section 1313.12(e). One objected that the summary reports of imports required by Section 1313.12(e) are duplicative, since DEA would already have the information available from previously filed 486 forms. The second questioned whether waiver of the advance notice requirement in Section 1313.21(f) would also mean waiver of the quarterly report in Section 1313.21(e), and suggested that DEA publish in Section 1313.21(f) a list of countries with waivers when the final rule is published.

DEA agrees that the wording of this section needed clarification. Section 1313.12(e) proposed minimized reporting procedures for export transactions in circumstances where the Administrator has waived the advance notice requirements as unnecessary for effective chemical diversion control. The comments point out that the proposed section did not specify that a 486 form need not be filed for such transactions. The section has been amended to clarify that a 486 form does not have to be submitted for exports under this section; the regulated person need only file a quarterly summary of such exports. There are presently no waivers established under Section 1313.21(f). This is a new authority granted to the Administrator by the DCDCA. Countries to which this new provision will apply will be determined

after implementation of these regulations.

18. One comment raised concerns regarding the need to file an Import 486 form when foreign customers return containers that have not been completely emptied.

DEA has long recognized the standard industry practice to allow a certain level of 'overage' in the amount of chemicals actually shipped in very large tank car/cargo ship type exports due to the difficulty to full recovery and, therefore, that containers that still contain some of the chemicals may be returned. DEA has not required that a 486 form be filed for the return of containers with such "leavings", when the amount of chemical is within normal or standard residue levels.

Exports

19. One comment noted the provisions of the DCDCA allowing the Administrator to withdraw the waiver of the advance notice requirement for all exports of listed chemical to a specified country. The commenter asked if, in the future, existing waivers might be withdrawn. The comment also questioned whether other countries have agreed to comply with the same rules.

The DCDCA allows DEA to require, by regulation, that all exports of a listed chemical to a specified country be subject to the advance notice requirement, regardless of regular customer status, if it is determined that advance notification of export is necessary for compliance with international agreements regarding chemical controls or is necessary to support chemical control programs in other countries. It is possible that the waiver of the advance notice requirement for exports of a listed chemical to a specified country may be withdrawn. However, DEA would be required to publish a notice in the **Federal Register** regarding the withdrawal of the waiver and provide an opportunity for public comment. With respect to the question of compliance with these rules by other countries, all parties to the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 are required to be able to provide advance notice of exports of List I chemicals, if requested by the importing country.

20. One comment requested clarification of the term "reasonable cause" as used in Section 1313.21(g) and of the responsibilities of exporters to know the laws of the countries to which chemicals are exported.