

Background

What Chemical Controls Have Been Established in the United States?

The Chemical Diversion and Trafficking Act of 1988 (Pub. L. 100-690)(CDTA) was passed by Congress to curtail the diversion of specific chemicals used in the illicit manufacture of controlled substances. The CDTA established recordkeeping and reporting requirements necessary for DEA to identify and track chemical diversion. While the CDTA achieved initial success in curtailing the diversion of chemicals, traffickers soon found and took advantage of certain shortcomings in the law. In the United States (U.S.), traffickers were able to obtain needed supplies by purchasing products that were exempted from regulation under the CDTA. Such products include chemical mixtures.

What Are Chemical Mixtures?

The Chemical Diversion and Trafficking Act of 1988 (CDTA) created a definition of "chemical mixture" (21 U.S.C. 802(40)), and exempted chemical mixtures from regulatory coverage. The Domestic Chemical Diversion Control Act of 1993 (DCDCA), enacted in April of 1994, created a provision dealing with the exemption of chemical mixtures. Chemical mixtures are defined 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."

How Are Ephedrine, N-methylephedrine, N-methylpseudoephedrine, Norpseudoephedrine, Phenylpropanolamine, and Pseudoephedrine Used in Chemical Mixtures and What Are the Regulatory Consequences?

Ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine are List I chemicals. The only chemical mixtures containing these List I chemicals, of which DEA is aware, are dietary and nutritional supplements. Dietary and nutritional supplements are readily available, being commonly sold to the public in drug and grocery stores, health and nutrition stores, and through direct marketing campaigns. These dietary and nutritional supplements contain material from the ephedra plant, or extract from the ephedra plant. If these

dietary and nutritional supplements meet certain criteria under the Federal Food, Drug, and Cosmetic Act (FDCA), they are not recognized as drugs under the FDCA, but are nonetheless considered to be chemical mixtures governed by DEA law and regulations. In contrast, over-the-counter (OTC) and prescription drug products containing these listed chemicals are not considered chemical mixtures and instead are specifically addressed in 21 U.S.C. 802(39)(A)(iv). *Also see 21 CFR 1300.02(b)(28)(i)*. Therefore, this final rulemaking has no impact upon OTC and prescription drug products lawfully marketed under the FDCA.

How Have Chemical Mixtures Been Regulated Until Now?

Prior to the enactment of the DCDCA, the term "regulated transaction" was defined to exclude "any transaction in a chemical mixture" (21 U.S.C. 802(39)(A)(v)). Therefore, transactions involving all chemical mixtures (including dietary supplements) were exempt from recordkeeping, registration and other chemical regulatory control requirements of the CSA.

How Did the DCDCA Affect Regulation of Chemical Mixtures?

With passage of the DCDCA, all chemical mixtures became subject to regulatory requirements for listed chemicals under the law, unless specifically exempted by DEA. These requirements included registration for certain handlers of List I chemicals, recordkeeping, reporting, and security. Thus, all dietary and nutritional supplements containing listed chemicals became subject to DEA regulation. However, pending promulgation of final regulations governing exemption, dietary supplements containing ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine remained exempt from the requirements of the CSA.

What Changes in the Law Did the DCDCA Make With Respect to Chemical Mixtures?

The DCDCA amended the CSA (21 U.S.C. 802(39)(A)(v)) to limit the application of the above stated exemption and provided the Attorney General with the authority to exempt a chemical mixture containing a listed chemical if it is "formulated in such a way that it cannot be easily used in the illicit production of a controlled substance" and "the listed chemical or chemicals contained in the mixture

cannot be readily recovered." Until regulations which delineate criteria and procedures for exempting specific chemical mixtures are finalized, DEA has treated all chemical mixtures as being exempt from the chemical regulatory requirements of the CSA. (Note that OTC and prescription drug products are not considered chemical mixtures and are addressed separately under 21 U.S.C. 802(39)(A)(iv)).

Why Is DEA Concerned About Chemical Mixtures?

Some chemical mixtures can be and have been used by traffickers in the illicit manufacture of controlled substances. This exemption provided traffickers with an unregulated source for obtaining these chemicals. To address these problems, the DCDCA amended the exemption to provide that only those chemical mixtures specified by regulation would be exempt from the definition of "regulated transaction".

What Regulatory Controls Has DEA Previously Proposed for the Control of Chemical Mixtures?

Regulations regarding the exemption of chemical mixtures were initially proposed by DEA on October 13, 1994 (59 FR 51888). In response to industry concerns, the proposed regulations were withdrawn on December 9, 1994 (59 FR 63738). After consulting with the private sector and carefully considering industry and other concerns, new regulations regarding chemical mixtures were proposed on September 16, 1998 (63 FR 49506). The comment period, which was twice extended, closed on April 16, 1999.

There are thousands of chemical mixtures in legitimate commerce, the majority of which are not useful to the illicit laboratory operator. The NPRM proposed criteria for the determination of whether a chemical mixture would be automatically exempt from CSA regulatory controls. Additionally, the NPRM defined an application process by which manufacturers may apply for an exemption for chemical mixtures that do not qualify for automatic exemption.

The DEA proposed that each chemical be assigned a concentration limit that, if found at or below the limit, will cause the mixture to be treated as a nonregulated chemical. This quantitative approach to identifying regulated mixtures is considered necessary due to the complexity of chemical-based commodities and the huge variety of products. These criteria are expected to exempt the vast majority of chemical mixtures containing listed chemicals. The NPRM included the proposed creation of a "Table of