DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–137F2]

RIN 1117–AA31

Exemption of Chemical Mixtures

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule with request for comment.

SUMMARY: On September 16, 1998, the Drug Enforcement Administration (DEA) published a Notice of Proposed Rulemaking (NPRM) (63 FR 49506) that proposed new regulations concerning chemical mixtures that contain any of the 34 listed chemicals subject to DEA control at that time. The NPRM was the initial step toward implementation of Controlled Substances Act (CSA) provisions that require that only those chemical mixtures identified by regulation be exempt from applicable regulatory controls. This Final Rule will implement regulations that define those chemical mixtures that qualify for automatic exemption for 27 of the 34 listed chemicals addressed in the NPRM.

Under separate rulemaking (68 FR 23195) DEA has finalized regulations pertaining to six of the listed chemicals addressed in the initial NPRM. That rulemaking specifies those chemical mixtures qualifying for automatic exemption based upon specific exemption categories and concentration limits. That rulemaking also finalized an application process for chemical mixtures that do not qualify for automatic exemption.

This Final Rulemaking will add a new provision not previously raised in the NPRM. This newly introduced provision will exempt from the recordkeeping and reporting requirements both domestic and import transactions in mixtures containing the List II chemicals acetone, ethyl ether, 2-butanone, and toluene. Because this exemption was not discussed in the NPRM published on September 16, 1998, DEA is implementing this exemption on an interim basis and requests public comment with respect to only this exemption.

DATES: This Final Rule is effective January 14, 2005. Persons seeking registration must apply on or before February 14, 2005, in order to continue their business pending final action by DEA on their application. DEA is seeking comments on new Section 1310.08(l) only. Written comments must be postmarked, and electronic comments must be sent, on or before January 14, 2005.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–137F2'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCD. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/CCD, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. 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.

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SUPPLEMENTARY INFORMATION:

I. Background

Historical Legal Status of Chemical Mixtures

The Chemical Diversion and Trafficking Act of 1988 (Pub. L. 100–690) (CDTA) created the definition of ''chemical mixture'' (21 U.S.C. 802(40)), and exempted chemical mixtures from regulatory control. The CDTA established 21 U.S.C. 802(39)(A)(v) to exclude ''any transaction in a chemical mixture'' from the definition of a ''regulated transaction.'' The exemption of all chemical mixtures, however, provided traffickers with an unregulated source for obtaining listed chemicals for use in the illicit manufacture of controlled substances.

To remedy this situation, the Domestic Chemical Diversion Control Act of 1993 (DCDCA), enacted in April 1994, subjected chemical mixtures containing listed chemicals to CSA regulatory requirements, unless specifically exempted by regulation. The DCDCA, therefore, subjected all regulated chemical mixtures to recordkeeping, reporting, and security requirements of the CSA. Additionally, the DCDCA added a registration requirement for handlers of regulated List I chemical mixtures.

The DCDCA, however, also amended 21 U.S.C. 802(39)(A)(v) to provide the Attorney General with the authority to establish regulations exempting chemical mixtures from the definition of a ''regulated transaction'' ''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)(v)). This authority has been delegated to the Administrator of DEA by 28 CFR 0.100 and redelegated to the Deputy Administrator under 28 CFR 0.104 (Subpart R) Appendix Sec. 12.

Prior to publication of a final rulemaking, chemical mixtures containing listed chemicals have been treated as exempt from CSA regulatory control. This final rulemaking specifies criteria used to determine whether chemical mixtures qualify for automatic exemption from CSA chemical regulatory controls. Those chemical mixtures that do not meet the exemption criteria shall be treated as regulated chemicals and therefore subject to CSA chemical regulatory controls.

Since DEA recognizes that concentration or category criteria alone cannot identify all mixtures that warrant exemption, an application process has been implemented in 21 CFR 1310.13. This process, finalized in a Final Rule published in the **Federal Register** at 68 FR 23195 (May 1, 2003), allows manufacturers to apply for exemption from CSA regulatory controls, for those chemical mixtures that do not qualify for automatic exemption.

Chemical Mixture Definition

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 along with any number of non-listed chemicals. A combination of only listed chemicals is, therefore, not a chemical mixture pursuant to CSA definition. As such, the regulatory controls pertaining

to each individual listed chemical are applicable.

DEA does not consider a chemical mixture to mean the combination of a listed chemical in an inert carrier. An inert carrier can be any chemical that does not interfere with the listed chemical's function but is present to aid in the delivery of the listed chemical so it can be used in some chemical process. Examples include, but are not limited to, solutions of listed chemicals such as methylamine in water or hydrogen chloride dissolved in water or alcohol. Sassafras oil, an essential oil mostly consisting of safrole, is not regarded as a chemical mixture containing safrole. It is regulated as the List I chemical safrole. These examples have always been treated as listed chemicals and are not new to this rulemaking. Persons who question if their formulations are chemical mixtures should contact DEA for guidance.

Federal Register Publications Pertaining to Chemical Mixture Exemption

Regulations regarding the exemption of chemical mixtures were initially proposed by DEA on October 13, 1994 as part of its proposed regulations to implement the DCDCA (59 FR 51888). In response to industry concerns, the proposed regulations were withdrawn on December 9, 1994 (59 FR 63738).

DEA proposed new regulations regarding the exemption of chemical mixtures by publishing a new NPRM entitled ''Exemption of Chemical Mixtures'' on September 16, 1998 (63 FR 49506). DEA proposed the following three-tiered approach to identify which chemical mixtures qualify for automatic exemption: (1) It contains a listed chemical at or below an established concentration limit; or (2) it falls within a specifically defined category; or (3) the manufacturer of the mixture applies for and is granted a specific exemption for the product.

1. Concentration Limits

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 non-regulated chemical. This quantitative approach is considered necessary in order to simplify the method of identifying regulated chemical mixtures. Identifying regulated chemical mixtures by narrative is impractical due to the variety of chemical products. These concentration limits are expected to exempt the vast majority of chemical mixtures containing listed chemicals.

2. Exemption Categories

DEA also proposed the creation of three specific categories of automatic exemption. They are (1) waste materials regulated by the Environmental Protection Agency (EPA); (2) fully formulated paints and coatings; and (3) harvested plant material. A chemical mixture that falls into one of these three categories is exempt regardless of the amount of listed chemical it contains.

Waste materials were proposed as an exempt category provided there is documentation on EPA Form 8700–22 (Uniform Hazardous Waste Manifest) and the materials are being distributed to another person solely for the purpose of disposal by incineration. These mixtures include only those that are covered by EPA regulations and have a ''cradle to grave'' paper trail. Further, the exemption applies only to the extent that the Form 8700–22 is available for inspection and copying by DEA.

Completely formulated paints and coatings were proposed for exemption because they contain ingredients, such as pigments, and other components, which render them unsuitable to traffickers. Proposed for inclusion in this category were paints, clear coats, topcoats, primers, varnishes, sealers, adhesives, lacquers, stains, shellacs, inks, and temporary protective coatings.

The final proposed exempt category is harvested plant material. Harvested plant material that contains listed chemicals, while meeting the definition of a chemical mixture, was proposed for exemption if the plant material is not concentrated or changed from its natural state. This provision was finalized in a **Federal Register** Notice (68 FR 23195) published May 1, 2003. Harvested plant material refers to the plant itself and not material growing on a plant, such as Ergot, a source for the List I chemicals ergonovine and ergotamine.

3. Exemption by Application Process

As stated above, DEA recognizes that the concentration limit and category exemption criteria cannot identify all mixtures that should receive exemption status. DEA has implemented an application process to exempt additional mixtures (21 CFR 1310.13). This application process was also finalized in the Federal Register Notice (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)(v)). An application may be for a single or a multiple number of formulations.

Actions Being Taken in This Final Rule

a. Exemption Based on Concentration Limits for Each Listed Chemical

While the September 16, 1998 NPRM (63 FR 49506) pertained to the regulation of chemical mixtures which contain any of 34 listed chemicals subject to DEA control, this rulemaking finalizes only those portions of the NPRM pertaining to the 27 chemicals given in The Table of Concentration Limits provided in this rulemaking (hereafter referred to as ''The Table''). Six of the 34 listed chemicals—ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine—were addressed in a separate rulemaking (68 FR 23195, May 1, 2003). Concentration limits for the List I chemical iodine, which were proposed to be established as part of the September 16, 1998 rulemaking, will be addressed in a separate rulemaking.

A concentration limit is established for each listed chemical provided in The Table. If the concentration of the listed chemical is at or below the limit, then the mixture will be automatically exempted and treated as a non-regulated chemical mixture. The Table also gives conditions for calculating the concentration limit.

The concentration limits are being finalized as proposed, except those for the chemicals benzaldehyde, anthranilic acid, and phenylacetic acid. The concentration limits for these three chemicals are being increased from the limits which were proposed.

One comment, which DEA received in response to the NPRM, informed DEA that there are a significant number of chemical mixtures in anthranilic acid and phenylacetic acid that could be regulated at the proposed concentration limit of 20 percent. Since DEA determined that these chemical mixtures do not pose a significant risk of being diverted, the DEA is increasing the concentration limit to 50 and 40 percent for anthranilic acid and phenylacetic acid, respectively. The comment also suggested increasing the concentration limit for benzaldehyde from 35 percent to 85 percent. However, the DEA determined that chemical mixtures containing greater than 50 percent benzaldehyde are at risk of diversion. Therefore, in order to

minimize the risk of diversion and provide the maximum amount of regulatory relief, the concentration limit for benzaldehyde is being finalized at 50 percent (for a discussion see Part II Comment Section 11. Exempt Formulations Used as Flavor and Fragrances).

b. Exemption by Category

Two categories that were originally proposed as exempt categories of chemical mixtures are distributions to waste disposal facilities and completely formulated paints and coatings. These categories may contain chemical mixtures that have listed chemical(s) above the established concentration limits. However, DEA believes that chemical mixtures in these categories are not likely to be diverted.

Based on comments to the NPRM, DEA modified these categories from those originally proposed. The proposed category that includes transportation of chemical waste has been modified to include chemical mixtures intended for recycling. Added are distributions to waste recycling facilities that have a ''paper trail'' as required by the United States Environmental Protection Agency.

The category of paints and coatings is modified to make it clear that inks are included in the category. Inks were intended to be included, however, a comment pointed out that the inclusion of inks could be overlooked under the proposed wording. A comment raised concern over distributions of multiple-component paint systems, which are not included in this category because they are not completely formulated. The DEA agrees that multiple-component paint systems are not likely to be diverted in domestic and import transactions. DEA is introducing an interim rule that addresses this concern and provides regulatory relief for chemical mixtures that are not at risk of diversion (see below).

c. Introduction of A New Category of List II Chemical Mixtures as an Interim Rule

Based on comments and DEA's analysis of the potential for diversion, this Final Rule also adds a new exemption category. Comments informed DEA of a significant number of distributions that may not be exempt under the proposed regulations. DEA determined that certain solvent based mixtures involving silicon-based products, paint-related materials, and other solvent-based chemical mixtures containing acetone, ethyl ether, 2-butanone, and toluene are not likely to be diverted domestically. These solvent chemicals are mostly a concern because they are used in cocaine and heroin processing, which occurs outside the United States. These chemical mixtures pose a risk of diversion for international transactions for which the requirement of 21 U.S.C. 802(39)(A)(v) is not met.

Therefore, DEA is creating a new exemption category for these mixtures. Domestic and import transactions in chemical mixtures that are regulated solely due to the presence of the List II solvent chemicals acetone, ethyl ether, 2-butanone, or toluene are removed from the definition of a regulated transaction by adding a new paragraph to 21 CFR 1310.08. Methyl isobutyl ketone, also a List II solvent chemical, is not included because domestic and import transactions in that chemical have already been excluded from the definition of a regulated transaction at 21 CFR 1310.08.

DEA is exempting domestic and import transactions in these chemical mixtures under 21 CFR 1310.08 pursuant to 21 U.S.C. 802(39) (A) (iii) because regulation of such transactions has been determined to be unnecessary for the enforcement of the CSA. DEA determined that there is not a significant risk of domestic diversion for these chemical mixtures. However, exports of these chemical mixtures could have significant potential for diversion. Therefore, these chemical mixtures, unless otherwise exempt, are subject to the export requirements of the CSA. Mixtures containing these List II chemicals will not qualify for automatic exemption if the mixture also contains another listed chemical above its concentration limit.

This new exemption (for domestic and import transactions in chemical mixtures containing the List II chemicals acetone, ethyl ether, 2-butanone, and toluene) was not discussed in the original NPRM. Therefore, this exemption will be implemented on an interim basis with opportunity for public comment. DEA is soliciting comments only on this portion of this final rule. After close of this comment period, DEA will publish a Final Rule in the **Federal Register** to inform interested persons if changes are needed or if this regulation will be adopted as written.

Other Actions Taken in This Rulemaking

In addition, other modifications to the original proposed regulations are being made. All references to the American Society for Testing Materials have been removed and the manufacturers are being allowed to determine the unit of measurement in calculating the concentration limit for liquid chemicals. These modifications were suggested in the comments and DEA agrees that they should be implemented.

Chemical Mixture Issues Not Being Addressed in the Rulemaking

a. Iodine

DEA received comments that chemical mixtures containing seven percent iodine are being diverted for the illicit manufacture of methamphetamine. Methamphetamine is an addictive Schedule II controlled substance and is the primary controlled substance clandestinely produced in the United States. It is regarded by DEA as a major threat to public health and safety.

DEA proposed a 20 percent concentration limit for iodine. This proposed amount is consistent with the proposed concentration limit for other listed chemicals that are used as reagents, as is iodine. Prior to the publication of the NPRM and while DEA was formulating the proposed regulations, seven percent iodine chemical mixtures were not a concern to law enforcement. Although DEA theorized that seven percent iodine solutions have the potential to be diverted, DEA lacked sufficient evidence to show that these chemical mixtures were being diverted prior to establishing the proposed concentration limit.

In addition to information obtained from law enforcement, public sources, and communication with the regulated community, DEA relies on comments to the NPRM to help establish regulations. DEA was informed that seven percent iodine chemical mixtures are being used in the illicit manufacture of methamphetamine. The proposed concentration limit of 20 percent is high relative to the concentration of iodine contained in mixtures used by traffickers. The approach of the proposed rule dictates that the concentration limit be lowered to assure that chemical mixtures desirable to traffickers are not automatically exempt. Persons who may not have commented on the 20 percent concentration limit may have comments on this relatively lower concentration limit. In order to ensure that the public has adequate opportunity for comment, the DEA is addressing issues relating to the regulation of iodine chemical mixtures in a separate NPRM.

b. Ephedrine Alkaloids

In a separate final rule (68 FR 23195, May 1, 2003), DEA finalized those portions of the NPRM pertaining to the

six List I chemicals ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine. Like the approach taken in this rulemaking, that Final Rule established a concentration limit for each of the above List I chemicals. The exempt category of harvested plant material was also finalized in that rulemaking.

c. Gamma-butyrolactone (GBL) and Phosphorus-Related Compounds

This rulemaking does not address the List I chemicals gamma-butyrolactone (GBL), red phosphorus, white phosphorus, or hypophosphorous acid and its salts. When the NPRM ''Exemption of Chemical Mixtures'' was published, they were not listed chemicals. Therefore, regulations to exempt their chemical mixtures were not proposed. DEA will address provisions concerning GBL and the above phosphorus chemicals in separate **Federal Register** publications.

To that end, on July 19, 2002, DEA published an Advance Notice of Proposed Rulemaking soliciting comments from the regulated industry regarding chemical mixtures containing GBL (67 FR 47493; corrected at 67 FR 53842, August 19, 2002; corrected at 67 FR 56776, September 5, 2002). DEA also published an Advance Notice of Proposed Rulemaking soliciting industry comment regarding chemical mixtures containing listed forms of phosphorus (68 FR 4968, January 31, 2003). Based on comments received from these publications, DEA will develop regulations concerning chemical mixtures containing GBL and the phosphorus chemicals.

II. Comments Received Regarding the Proposed Regulations

DEA received fourteen comments in response to the NPRM which was published September 16, 1998 (63 FR 49506). Five comments were from industry related membership organizations, three from law enforcement organizations, and the remaining from commercial interests.

Comment Summary

In general, the comments supported efforts by DEA to regulate chemical mixtures that have potential use to drug traffickers. Some comments requested that DEA exempt an additional category or increase some concentration limits. Comments also suggested that mixtures be exempted based on the type of distribution. Other comments requested clarification or suggested ways to ease compliance.

Specific Comments

1. *Reference to the American Society for Testing Materials (ASTM):* ASTM is a not-for-profit organization that develops test methods, and other criteria, with application to 130 areas. Reference to ASTM was made in the NPRM section that proposed the exemption of paints/coatings. That section stated that a paint/coating would be exempt if, among other things, it met the ASTM specifications for the product. This statement was included to help authenticate the product. Authenticity is desired by DEA to prevent this category from being used by traffickers as a loophole. However, DEA was informed that such a requirement is not practical.

Although the manufacturer can use some test methods to insure quality control, the methods are not definitive in qualifying a product. Not all paints/coatings are necessarily subject to these test methods in order to be marketed as an authentic product.

DEA was also informed that ASTM standards are not written to cover all applications. Some products can have unique applications where ASTM standards are not applicable. Therefore, in response to the comments, DEA is removing all references to the ASTM requirement. This action does not alter the basic definition of ''completely formulated,'' which determines whether such products are automatically exempt.

2. *Request to exempt small container transactions:* Three persons suggested that DEA exempt chemical mixtures based on container size. One comment requested that DEA consider a minimum container volume limit to which the rule does not apply. The commenter questioned whether the rule applies to a 1-ml vial or a 3-ounce tube. A second comment suggested that mixtures of List II solvents in containers of five gallons or less be exempt from regulation. A third comment suggested that transactions in 55-gallon size containers and less should be exempt.

DEA has considered the request to exempt transactions of regulated chemicals based on container size. DEA determined that traffickers have and could divert regulated chemicals if packaged in small containers. Therefore, an exemption based on container size will not be added.

DEA regulates transactions of chemicals that are desirable to traffickers, in part, by establishing thresholds. Thresholds are established so that records do not have to be maintained for certain transactions, *i.e.*, those below the threshold to a single customer within a calendar month. The thresholds for export of the List II solvent chemicals acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene are considered large enough that distributions in small container sizes are not likely to be above the established threshold.

The threshold is meant to allow smaller volume distributions without the imposition of regulatory controls. However, the threshold can be easily reached using gallon size containers, including five and 55-gallon containers. DEA determined that adopting this suggestion would result in unlimited non-regulated export of chemicals desired by traffickers, especially those chemicals desired by cocaine traffickers.

3. *Request to adopt a single concentration limit for List II chemicals:* Three comments requested that List II chemicals be assigned a single concentration limit of 35 percent. They believed this would allow for better compliance and management of inventory by simplifying the process.

DEA proposed that the List II solvent chemicals, which have the same basic application, be assigned the same concentration limit. The chemicals acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene all function as solvents. These chemicals have been identified to be responsible for the greatest number of List II chemical mixtures, some of which may be regulated. This group of chemicals already has been assigned a single concentration limit of 35 percent. Thus, the argument to ease compliance with a uniform concentration limit is addressed by the single value for these chemicals having the same basic application.

The chemicals acetic anhydride and benzyl chloride can be considered precursors while hydrochloric acid, iodine, and sulfuric acid function as reagents. Except for iodine, which is being addressed in a separate NPRM, these are assigned the single concentration limit of 20 percent. Potassium permanganate, also a reagent, is assigned the concentration limit of 15 percent. The limit is lower for this chemical because DEA has not identified any legitimately produced chemical mixture containing potassium permanganate greater than 15 percent.

After careful consideration, DEA decided not to change the concentration limit for all List II chemicals to 35 percent. Concerns regarding compliance are mostly addressed because the concentration limits are the same for List II chemicals that have similar functions. In addition, other comments

have raised the issue of iodine and hydrochloric acid as having application to the manufacture of illicit substances at a lower concentration than the proposed concentration limit.

4. *Request to allow companies to choose the unit of measure to calculate the percent concentration:* Two comments suggested that each manufacturer should be allowed to determine the unit of measurement to use when calculating the percent concentration. There appears to be no commercial standard practice that predisposes that a chemical is measured by weight or by volume when formulating a mixture. These persons are concerned about the possible administrative impact of forcing manufacturers to convert existing and extensive records and chemical record systems.

The amount of chemical present in a mixture can vary depending on the unit used to measure the chemical when formulating. Chemicals can be measured in units of weight or volume. The numerical values of weight and volume for chemicals are not usually equal. Therefore, a mixture reporting the concentrations of a chemical can actually contain different amounts of the chemical, depending on whether the concentration is based on weight or volume.

The comments informed DEA that some manufacturers might already have procedures in place to calculate the concentration. They state that converting from one unit to another is burdensome. DEA has considered this and decided that manufacturers should determine the unit of measure when formulating liquid mixtures. Therefore, a formulation containing liquid chemicals may have a concentration based on the volume or the weight of the chemicals contained.

DEA determined that accurate measurement of solids and gases by the unit of volume is not practical. Therefore, solids and gases should be calculated by unit of weight. The ''Table of Concentration Limits'' is being amended to reflect this modification.

5. *Request for clarification of issues relating to internal transfer and research and development:* Two persons requested clarification on issues of internal transfers and research and development. A third person asked whether research and development activities are exempt from this rule.

Chemical mixtures that do not qualify for automatic exemption are regarded and treated like listed chemicals. The term ''regulated transaction'' as defined in 21 U.S.C. 802(39), excludes ''a domestic lawful distribution in the usual course of business between agents or employees of a single regulated person.'' Therefore, such internal transfers are not regarded as regulated transactions. However, one must understand what a regulated person is to understand what transactions are regulated.

The definition of a ''regulated person'' is given in 21 U.S.C. 802(38) and means a person who manufactures, distributes, imports, or exports a listed chemical. The term ''distribute'' and ''distributor'' are defined in 21 U.S.C. 802(11). By definition, a distribution occurs when a listed chemical is delivered while a distributor is the person who makes the delivery.

21 U.S.C. 822(e) requires that each site which handles a List I chemical must have a separate registration. Each registered location is regarded as a ''regulated person.'' A distribution of List I chemicals between separate locations, even if owned by the same person, fulfills the definition in 21 U.S.C. 802(11). Therefore, above threshold distributions of List I chemicals between separately registered sites are regulated transactions as defined in 21 U.S.C. 802(39).

However, different locations that do not require separate registration are regarded as a single ''regulated person'' if owned by a single business. Because separate site registration for handling List II chemicals is not required, distributions of List II chemicals between sites owned by a single person are not regulated transactions.

The CSA does not include provisions that exempt the distribution of listed chemicals if associated with research and development. If a regulated mixture is distributed at or above threshold quantities, even for the purpose of research and development, the transaction is regulated.

6. *Request for publication of Chemical Abstract Service numbers for listed chemicals:* Two persons requested that Chemical Abstract Service (CAS) numbers be published for listed chemicals in the ''Table of Concentration Limits.'' The commenter stated that CAS numbers are used worldwide by industry and should be listed to simplify the identification of listed chemicals.

Although the CAS numbers are used throughout industry and specific to a chemical, DEA believes that publishing these numbers in the Code of Federal Regulations (CFR) may not be beneficial. CAS numbers are specific to a given chemical. If a chemical can exist in the form of a salt, for example, there is a separate CAS number for each form of the salt. Several listed chemicals include their salts, esters, optical isomers, and salts of optical isomers. All of these variations have individual CAS numbers. DEA believes it is not practical to list all such numbers, as the list will be extensive and possibly non-inclusive. Listing only the CAS numbers for the specifically named listed chemicals may mislead some to believe the list is all-inclusive. Therefore, DEA has decided not to publish CAS numbers in the CFR.

7. *Request for category exemption of multiple-component paint systems:* DEA proposed the exemption of paints/coatings only if the product is ''completely formulated.'' ''Completely formulated'' is defined in the proposed rule as ''only those formulations that contain all the components of the paint/coating for use in the final application without the need to add any additional substance except possibly a thinner.''

DEA proposed the exemption of completely formulated paints/coatings because these products are complex, high density mixtures having several components, including pigments, binders, curing agents, and other chemicals in a single system. The numerous additives that make up a substantial bulk of the formulation deter the use of these mixtures in an illicit operation. In addition, completely formulated paints cure upon exposure to air or heat, rendering them unusable by traffickers.

One comment argued that some paints actually consist of multiple components. Multiple-component paint systems consist of one or more separate formulations of hardeners, activators, catalysts, polymeric material, pigments, accelerators, solvents, or other components. A single component may contain one or more of these ingredients mixed, suspended, emulsified, dissolved, or somehow formulated into a chemical mixture containing a List II chemical(s). The List II chemicals are typically solvent chemicals in these formulations. The components are kept separate because once mixed, the paint begins to cure. Therefore, they are mixed just prior to application. The comment claimed that the use of any one of these component mixtures in an illicit operation is as difficult as using a completely formulated paint.

DEA was informed that multiple-component paint systems are a predominant technology used in the automobile refinishing market. There are approximately 60,000 such body shops in the United States; each one engages in a large number of domestic transactions each year. The mixtures they utilize may contain one or more of the List II solvent chemicals acetone,

ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene.

DEA has not found significant examples of diversion of these chemical mixtures domestically or through imports. However, traffickers in other countries have used related formulations. Therefore, DEA will exempt domestic and import distributions of mixtures in the List II solvent chemicals acetone, ethyl ether, 2-butanone, and toluene from the definition of ''regulated transaction.'' Such an exemption for domestic and import distributions of methyl isobutyl ketone already exists under 21 CFR 1310.08.

This exemption will not apply if the mixture contains a List I chemical or a List II chemical (other than acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, or toluene) above its established concentration limit. This category exempts chemical mixtures used by different industries, not only those associated with paints and coatings. Therefore, it will be included separately from the category of fully formulated paints and coatings.

This new exemption (for domestic and import transactions in chemical mixtures containing the List II chemicals acetone, ethyl ether, 2-butanone, and toluene) was not discussed in the original NPRM. Therefore, this exemption will be implemented on an interim basis with opportunity for public comment. DEA is soliciting comments only on this portion of this final rule. Comments should be submitted on or before January 14, 2005. After close of this comment period, DEA will publish a notice in the **Federal Register** to inform interested persons if changes are needed or if this regulation will be adopted as written.

Although DEA is establishing this exemption on an interim basis, an alternative means to exempt multiple-component paint systems was supplied in this comment. It sets a concentration limit for both the solid component and for the listed chemical(s). The commenter suggested that a chemical mixture be exempt if it contains at least 10 percent by weight of solids, including resins, polymers, or film formers, and less than 65 percent cumulative weight of List II solvents.

Although the above suggestion addresses those concerned about multiple-component paint systems, it may only partially address similar concerns of other sectors. Also, a dual-exemption criterion that considers both the concentration of solids and the listed chemical may be confusing and difficult for both industry and law enforcement to implement. Therefore, DEA decided to create a new category, as explained above, to exempt a broader range of mixtures. The new exempt category is easily interpreted and is not limited to a single sector but all industries that may use these solvents in chemical mixtures.

A second comment suggested the inclusion of multiple-component paint systems in the category of exempt paints and coatings. The comment included suggested wording that is similar to the language proposed by DEA except that it includes, in addition to completely formulated paints, two-part systems. It is anticipated that perceived burdens incurred by regulating distributions of multiple-component paint systems will be addressed via the creation of the interim exemption of domestic and import transactions of the List II solvents discussed above.

8. *Silicone products as exempt mixtures:* One comment suggested that exempt mixtures should include silicone related products. These silicone products are manufactured for downstream customers who produce end products and could contain List II solvent chemicals. To exempt these products, the commenter suggested that the mixture meet three criteria: the mixture is produced and distributed (1) through sophisticated, well-established channels; (2) in accordance with recognized commercial specifications; and (3) for controlled end-use applications.

The comment did not elaborate on how to define these criteria or how to identify if a product is produced in compliance with these criteria. DEA concluded that these suggestions regarding the exemption of silicone products are overly subjective and open to interpretation.

In attempting to identify silicone products, DEA learned that silicone products cannot be clearly distinguished by the chemical content alone. Representative formulations submitted by this industry show concentrations of up to 99 percent listed chemical. The example formulations contain silicone material from less than 1 percent to 75 percent while some contain no silicone or other solid material. These silicone related chemical mixtures are similar to the multiple component paint systems discussed above in relation to their risk of diversion. DEA has determined that regulation of domestic and import transactions are not at significant risk of diversion.

DEA is establishing provisions, on an interim basis, to exempt all domestic and import transactions in the List II chemicals of concern to this industry (see above). Some export transactions in these mixtures are exempt via the established concentration limit. Therefore, DEA decided that there is no need to take additional action to exempt this category because most transactions in these mixtures are addressed in the interim portion of this rulemaking. Because the exemption is on an interim basis, this interest, as well as others, will have the opportunity to inform DEA whether this approach is suitable.

9. *Mixtures intended for recycling:* One comment stated that the exemption category that includes distributions of waste products to incinerators does not include distributions to recycling centers. The comment suggested including distributions to authorized waste recyclers and reprocessors under the category of exempt waste material. DEA agrees with this comment.

Waste materials were proposed as an exempt category provided there is documentation on U.S. Environmental Protection Agency (EPA) Form 8700–22 (Uniform Hazardous Waste Manifest) and the waste materials are being distributed to another person solely for the purpose of disposal by incineration. These mixtures include only those that are covered by EPA regulations and have a ''cradle to grave'' paper trail. Further, the exemption applies only to the extent that the Form 8700–22 is available for inspection and copying by DEA.

The comment cites Department of Transportation (DOT) regulation 49 CFR 172.205 to show that records are required for waste-recovery shipments. Examination of this section shows that DOT requires the same EPA Form 8700–22 that was proposed as a requirement for exemption of waste product. Therefore, the same ''paper trail'' is in place for distributions sent to incinerators or to recyclers. DEA agrees that distributions to recycling facilities should be included in the category that exempts distributions to incinerators. DEA is amending the language of Section 1310.12(d)(2) to expand the category to include distribution to recyclers as requested in the comment.

DEA proposed the exemption of distributions of waste material provided a ''paper trail,'' which is required by another agency, already exists. Exemption, if to a recycler or incinerator, is contingent on the existence of a hazardous waste manifest (EPA form 8700–22). It will be the generator's responsibility to maintain records if EPA does not already require a hazardous waste manifest.

Although a distribution to a recycling facility may not be a regulated

transaction, recovering a listed chemical from a chemical mixture in a recycling process satisfies the term ''manufacture'' as defined at 21 U.S.C. 802(15). However, this is not new to this rulemaking. Any person who performs a manufacturing operation, including the recovery of a listed chemical from a chemical mixture, has been bound to applicable regulations since their inception.

The comment also expressed concerns over distributions that are not required to have an EPA Form 8700–22 and, therefore, are not automatically exempt under this category. DEA decided not to categorically exempt all distributions for waste recycling or incineration. Such a category would include any combination of listed and non-listed chemical. DEA decided that such an exemption category could result in diversion of chemicals desirable to traffickers. Such distributions shall be regulated unless the transactions meet other exemption criteria.

10. *Clarification as to whether chemical mixtures are included in 21 CFR Part 1313:* One comment requested that DEA clarify whether the requirements governing the importation, exportation, transshipment and in-transit shipment of listed chemicals pursuant to 21 CFR Part 1313 apply to regulated chemical mixtures.

The commenter asserted that Part 1313 includes reference to ''listed chemicals'' but does not specifically include chemical mixtures. Therefore, the commenter concluded, mixtures of List II chemicals do not appear to be subject to import/export notification requirements.

DEA disagrees. A chemical mixture, if not exempt by regulation or the application process, is regarded and treated as a listed chemical pursuant to all provisions of the CSA. This includes provisions of 21 CFR Part 1313.

The term ''regulated transaction'' means ''a distribution, receipt, sale, importation or exportation of, or an international transaction involving shipment of, a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount, including a cumulative threshold amount for multiple transactions * * * of a listed chemical * * *'' (21 U.S.C. 802(39)). The term excludes ''any transaction in a chemical mixture which the Attorney General has by regulation designated as exempt * * * 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)(v)). The term ''chemical mixture'' is defined in 21 U.S.C. 802(40) as a combination of two or more chemicals, at least one of which is not a List I or List II chemical.

This rulemaking is finalizing regulations that identify those chemical mixtures that the Attorney General designates as exempt. Outside of those exemptions, distributions in chemical mixtures, including importation, exportation, transshipment, and in-transit shipment, are subject to the regulatory controls of the CSA that pertain to listed chemicals. This rulemaking establishes that chemical mixtures containing listed chemicals are treated as listed chemicals unless exempted by regulation.

11. *Request for exemption of formulations used as flavors and fragrances:* One commenter, representing both the Flavor and Extract Manufacturers Association of the United States and the Fragrance Materials Association of the United States (hereafter referred to as the flavor and fragrance industries), gave arguments as to why their mixtures should be exempt from regulatory controls. The commenter suggested that the flavor and fragrance industries be exempt by category. As an alternative, the commenter suggested that the concentration limits for benzaldehyde, anthranilic acid, and phenylacetic acid be increased.

The commenter stated that an industry exemption should be provided because of the manner in which the flavor and fragrance industry operates. The commenter stated that while manufacturers work closely with customers to develop the necessary flavoring or fragrance, routinely their formulations are unknown to the customer. The commenter asserted that traffickers would not know what to order because the trafficker would not know the mixture's composition. Additionally, the commenter stated that these mixtures are expensive because of developmental costs and therefore, they would not be a practical source of precursor chemicals. The commenter also stated that these mixtures are not sold to the public but only to manufacturers of foods and toiletries. In addition, the commenter claimed that the mixtures are complex formulations that make the extraction of listed chemicals, or direct use of the mixture impractical.

DEA agrees that legitimately traded, expensive, and chemically complex chemical mixtures, which are marketed under strict self-imposed practices, are at a lower risk of diversion. However, these conditions may not be universal to all that trade in these commodities. Therefore, DEA has decided that exempting these industries would create a loophole for traffickers to divert List I chemicals. Under a blanket exemption for these industries, any person could distribute any listed chemical they use without restriction.

The comment requested that, as an alternative to a category exemption, the concentration limits for benzaldehyde, anthranilic acid, and phenylacetic acid be set to 85, 50, and 40 percent, respectively. The concentration limits for these chemicals were proposed at 35 percent for benzaldehyde and 20 percent for anthranilic acid and phenylacetic acid. The concentration limit for benzaldehyde was proposed higher than the 20 percent proposed for most other precursor chemicals because benzaldehyde was known to be used by food flavoring manufacturers in higher concentrations than the other chemicals.

DEA weighed the degree of regulatory relief, as indicated in the comment, against the risk of diversion for the chemicals of concern to these industries. Based on the comments and an examination of sample formulations, DEA concluded that some, but not all, of the conditions requested in the comment could be put into regulation without significantly increasing the risk of diversion.

i. Concentration Limits for Anthranilic Acid and Phenylacetic Acid

The commenter indicated that these industries' formulations contain no more than 50 and 40 percent of anthranilic acid and phenylacetic acid, respectively, and that these formulations are not at risk of diversion. This was the only comment concerned with these List I chemicals. DEA has not identified these chemicals as being important in the formulation of other chemical mixtures. Formulations that use these chemicals are complex and not likely to be diverted. Considering these facts, DEA has decided to increase the concentration limits for benzaldehyde and anthranilic acid to 50 percent and phenylacetic acid to 40 percent.

ii. Increasing the Concentration Limit for Benzaldehyde

The commenter also requested that the concentration limit be increased to 85 percent for benzaldehyde. Benzaldehyde is used in clandestine operations to make the Schedule II controlled substances amphetamine, phenyl-2-propanone, and methamphetamine. It was once the chemical of choice in the synthesis of

methamphetamine. Currently, over 95 percent of the clandestine laboratories seized in the United States are methamphetamine laboratories. Although the precursor favored in the clandestine synthesis of methamphetamine has changed, the demand for methamphetamine and increased controls of the current precursor of choice is likely to contribute to increased diversion of benzaldehyde if it is not carefully regulated.

DEA considered increasing the concentration limit for benzaldehyde from the proposed 35 percent to the suggested 85 percent. However, benzaldehyde may be found in simpler formulations than those alluded to in the comment, either within the represented industries or other sectors. Increasing the concentration limit will impact all sectors of the chemical industry, including those conducting commerce with the public. Increasing the concentration limit to 85 percent could result in unrestricted trade in exempt mixtures useful to traffickers. DEA determined that traffickers would seek simpler formulations containing benzaldehyde at the suggested concentration limit if there are no regulatory controls governing their distribution. DEA regards an 85 percent concentration limit in benzaldehyde to be significantly high; such mixtures are at risk of diversion.

DEA re-examined the concentration limit for benzaldehyde in light of the comment from the flavor and fragrance industries and decided that increasing the concentration limit to 50 percent will not significantly increase the risk of diversion. The comment stated that the types of formulations containing benzaldehyde are as complex as those containing anthranilic acid and phenylacetic acid. DEA has not identified benzaldehyde chemical mixtures as being used prominently outside the flavor and fragrance industry. A 50 percent concentration limit is consistent with objectives of this regulation.

DEA recognizes that benzaldehyde is important to the food flavoring industry and sometimes found in formulations at a higher concentration than other List I chemicals. However, DEA decided that an 85 percent concentration limit is too high, especially in light of the fact that it is a chemical used in the illicit manufacture of methamphetamine, the primary illicit controlled substance manufactured in the United States.

The comment also expressed concerns regarding the exemption application process (Section 1310.13) and claimed that the application process is an impractical means to exempt these formulations because hundreds or thousands of new formulations are produced monthly and formulations are altered continuously. In addition, the industry resists revealing their formulations as required in the application, because they are closely guarded trade secrets.

There should be no concern over the need to reapply for each change in formulation or revealing details about a formulation. The application process is written to alleviate the need to reapply every time a formulation changes. A group of mixtures may be exempted within a single application. Formulations having identical function and containing the same listed chemical(s) can be part of the same group. However, not all formulations are required to have the same non-listed chemicals to be included in a group. This approach will eliminate the need for persons to reapply every time a formulation changes.

DEA will allow for partial disclosure in the application process of a complex chemical formulation. DEA has learned that formulations used by the food and flavoring industries sometimes contain several chemicals at a concentration of less than one-percent. DEA will accept an application without the need to reveal each chemical present at less than one-percent. DEA will work with the applicant to obtain enough information to make a decision while minimizing the amount of detail necessary to process the application.

DEA notes that information designated as confidential or proprietary will be treated accordingly. The release of confidential business information that is protected from disclosure under Exemption 4 of the Freedom of Information Act, 5 U.S.C. 552(b)(4), is governed by section 310(c) of the CSA (21 U.S.C. 830(c)) and the Department of Justice procedures set forth in 28 CFR 16.7. DEA has a longstanding history of protecting such information from unauthorized disclosure.

12. *Comment stating that mixtures of List II solvent chemicals are useful to traffickers regardless of the concentration of listed chemical:* One comment pointed out how chemical mixtures containing List II solvent chemicals can be useful to traffickers regardless of the concentration. The List II solvent chemicals are acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene. They are referred to as solvent chemicals because they are liquids generally used to dissolve substances.

The comment argues that mixtures of these chemicals will have the same chemical properties that make the pure List II solvent chemicals desirable to traffickers. The reason for this is that different liquids are miscible (i.e. susceptible of being mixed) if they have similar chemical properties that are related to their behavior as solvents. The commenter stated that if they mix, the resultant blend must have chemical properties similar to the pure List II solvent chemical, otherwise, they would not mix in the first place. Therefore, the blend could possibly dissolve whatever the listed chemical could dissolve. Likewise, if the solvent properties of different liquids are dissimilar they may not mix when brought together.

A well-known example of this behavior is that of oil and water. The solvent properties for oil and water are different. Oil dissolves different substances than water. When brought in contact, they form separate layers. However, mixing water with vinegar, for example, causes the two liquids to blend as one. They have similar solvent properties. The resulting blend would be expected to dissolve whatever the water would dissolve.

The commenter stated that the same is true for the List II solvent chemicals. Mixing them with other liquids may cause separation or result in a single blend. If they blend, it means that the mixture has some liquid properties that are similar to the listed solvent chemical. However, the resultant blend is not exactly the same as the pure listed chemical.

DEA agrees with the comment in principle. However, the higher the concentration of listed chemical(s), the more likely it will be that the blend will more closely mimic the properties of the listed chemical(s). This means that not all mixtures containing List II chemical solvents are equally likely to be used in illicit laboratories. Thus, regulating all mixtures that contain any amount of a List II solvent chemical is unnecessary to reasonably prevent diversion. Further, solvent chemicals are mostly a concern because they are used in cocaine and heroin processing, which occurs outside the United States. Therefore, instead of regulating all chemical mixtures containing List II solvent chemicals, DEA will exempt all such domestic and import transactions containing the List II solvents acetone, ethyl ether, 2-butanone, and toluene from the definition of regulated transaction as discussed earlier. The List II chemical methyl isobutyl ketone is not included here because its transactions are already excluded. Because a chemical mixture regulated due to the presence of a List II solvent chemical is expected to mimic the

solvent properties of the listed chemical, the threshold will be calculated based on the amount of the entire mixture and not just the amount of listed chemical in the mixture.

13. *Comment stating that traffickers can use twenty-percent solutions of hydrochloric acid or sulfuric acid:* One comment mentioned that both hydrochloric and sulfuric acids are used to isolate methamphetamine. For this purpose, a 20 percent solution of either is sufficient to carry out an illicit manufacturing operation.

In response, DEA notes that domestic and import transactions in these acids have been excluded from the definition of regulated transactions pursuant to 21 CFR 1310.08. Only transactions to designated countries identified in that section are defined as regulated transactions. Those provisions also apply to mixtures of these chemicals. DEA notes that acids dissolved in water, alcohol solutions, or other pure solvents, are not regarded as chemical mixtures. Therefore, DEA decided not to lower the concentration limit for these acids.

14. *Comment stating that multifunctional formulations containing sulfuric acid should be an exempt category:* One comment requested that formulations containing sulfuric acid should be exempt when used in industrial applications. DEA regards this category as too broad and, if enacted, will create a loophole for unscrupulous persons to traffic in mixtures of sulfuric acid that could be used in illicit laboratories. Therefore, DEA has determined that this category is inappropriate for exemption.

These types of mixtures, if not useful to traffickers, may be exempt pursuant to Section 1310.13 (i.e. the application process). Several such mixtures may be exempt as a group under a single application, provided the different formulations have the same basic function. DEA notes that domestic transactions in sulfuric acid and, therefore, its mixtures, are not regarded as regulated transactions pursuant to Section 1310.08(a). Section 1310.08(b) regulates only above threshold transactions to certain designated countries. In addition, if a person consumes a chemical mixture, then that person is an end user. End users are not regarded as regulated persons and are not subject to chemical regulatory controls.

15. *Comment expressing concern that iodine concentration limit is high and does not capture mixtures being used by traffickers:* One comment believes that the proposed rule does not adequately address the regulation of iodine. The DEA has decided to address iodine issues under separate rulemaking.

The comment points out that the most common method for the production of methamphetamine on the West Coast utilizes seven-percent iodine solution. The comment states that non-traditional customers purchasing large quantities of seven-percent iodine solution have inundated retailers in Oregon, Washington, California, and Louisiana. Another comment stated that clandestine laboratories often use either iodine crystals or a seven-percent iodine tincture as a source for iodine crystals.

Seven-percent iodine solution and tincture are regarded as chemical mixtures subject to this final rule but are a viable source of iodine crystals. Iodine crystals can be readily extracted from these chemical mixtures and used in the illicit manufacture of methamphetamine or amphetamine. DEA agrees that regulatory action is necessary to prevent the illicit use of iodine readily obtained from these sources.

At the time that the NPRM was being drafted, the DEA did not regard iodine chemical mixtures as an important source of iodine crystals. Since publication of the NPRM, the use of iodine chemical mixtures as a source for iodine crystals increased dramatically. The El Paso Intelligence Center (EPIC) maintains a database on clandestine laboratories seized by Federal, State, and local law enforcement agencies. Although the database does not account for all seizures in clandestine laboratories, it serves as an indicator of what is being used by traffickers.

In 1998, the year in which the NPRM was published, EPIC reported 10 incidences of iodine tincture out of 1,485 for all sources of diverted iodine found in illicit methamphetamine laboratories. In 1999, 2000, 2001, and 2002, the number of iodine tincture seizures compared to the number of all forms of diverted iodine reported by EPIC is 71 out of 2,888; 397 out of 3,432; 1,147 out of 4,734; and 1,619 out of 4,921, respectively. These statistics show that iodine tincture is a significant source of iodine crystals for the illicit manufacture of methamphetamine.

Based on the comments to the NPRM and the documented diversion of certain chemical mixtures containing iodine, the DEA determined that the proposed concentration limit for iodine is relatively high compared to the concentration found in chemical mixtures useful to traffickers. To address adequately the diversion of iodine, DEA must consider new approaches other than what was proposed. Therefore, the regulation of iodine chemical mixtures is being addressed in a separate NPRM. This will give persons an opportunity to comment on any approach DEA suggests.

16. *Request for exemption of crime labs from quantitative analysis of mixtures:* One comment stated that city and county laboratories in California perform qualitative analysis for only controlled substances. The commenter requested that local crime laboratories be exempt from requirements to analyze the contents of non-controlled substances or reporting of mixtures.

DEA has no role in determining such policy. How state and local crime laboratories handle their analysis is based on their own policy. Because this rulemaking does not impose mandatory testing, exemption is not necessary.

17. *Request for exemption of adhesive intermediates under the category of paints/coatings:* One comment questioned whether solutions that are intermediates for the manufacture of adhesives are exempt under the category of paints and coatings. These adhesive intermediates are formulated as a vehicle for further additions of chemical ingredients that will eventually form an adhesive. DEA determined that if these solvent mixtures contain listed chemicals above the concentration limit, they are regarded as regulated chemicals. They are not ''fully formulated'' as required to be exempt under the category of paints and coatings and, therefore, not automatically exempt.

DEA decided not to exempt all chemical mixtures that are used to form adhesives because that would include solvent systems containing listed chemicals in any concentration. Unscrupulous persons could then distribute solvent blends rich in List II chemicals to traffickers unchecked. Adhesive mixtures that contain listed chemicals are regarded as exempt when they are completely formulated and have less risk of diversion. If not exempt, distributions are regulated only if distributed at or above threshold quantities.

DEA does not impose recordkeeping or reporting requirements for listed chemicals that are consumed in a manufacturing process (21 CFR 1310.03(a)). If the blend is converted to an adhesive on-site, then transactions in it are not regulated and, because the listed chemical is consumed, recordkeeping and reporting requirements are not required. In addition, as stated previously, DEA is exempting, on an interim basis, domestic and import transactions of mixtures containing the List II solvent chemicals that are a concern to this interest.

18. *Inks as part of the category of paints and coatings:* One comment requested the inclusion of inks in the category of paints and coatings by changing the category to paints, coatings, and inks. The commenter expressed concerns that the public will not recognize inks as being within the category of paints and coatings.

DEA recognizes that inks may be overlooked within Section 1310.12(d)(2), which identifies the category of paints and coatings as being exempt chemical mixtures. It was the intention of DEA to have inks included in this category. The preamble of the original NPRM (63 FR 49510) states that completely formulated inks are included in this category.

DEA determined that adding inks as a new category in addition to the existing category of paints and coatings is not appropriate. Inks are already included within the category of coatings. This situation will be corrected by adding a sentence to section 1310.12(d)(3): ''Included in this category are clear coats, topcoats, primers, varnishes, sealers, adhesives, lacquers, stains, shellacs, inks, and temporary protective coatings.'' In this way, all products intended to be included in the category of paints and coatings will be apparent.

19. *Request for allowance of a concentration variation of 2 percent absolute and 10 percent nominal:* One comment suggested that DEA allow a plus or minus concentration range of 10 percent nominal and 2 percent absolute rather than require a new application for exemption for each and every mixture. This range is to reflect variation in raw material and inaccuracies in the manufacturing process.

The exemption application process already allows for a range of concentrations without the need to reapply, as long as this concentration range is specified in the approved application. Therefore, the suggested variation is not necessary to prevent the need for reapplication. (Please note, however, that any concentration greater than the established range for exemption would cause the mixture to be subject to the regulatory provisions of the CSA.)

For non-exempt mixtures, the concentration limit (as specified in the Table of Concentration Limits) is established as a maximum concentration of listed chemical that a chemical mixture may contain to be automatically exempt. Mixtures containing more than this established limit are regarded by DEA as regulated chemicals. Manufacturers that produce chemical mixtures having the listed chemical near the concentration limit are responsible for knowing whether the actual concentration exceeds the limit.

III. Final Regulatory Actions: Individual Discussion for Each Listed Chemical

1. Chemical Mixtures Containing List I Chemicals

List I chemicals compose the largest number of listed chemicals, but only a few have been identified that are routinely used in chemical mixtures. Mixtures containing those List I chemicals are utilized by a small number of industries. DEA identified food flavoring manufacturers, fragrance manufacturers, and a segment of the dietary supplements industry as the main commercial sectors that utilize mixtures containing List I chemicals.

The food flavoring and fragrance manufacturing sectors handle most chemical mixtures containing List I chemicals being addressed in this rulemaking. The chemicals of concern to these interests, at the proposed concentration limits, are benzaldehyde, anthranilic acid, and phenylacetic acid. None of the remaining List I chemicals were mentioned in the comments, except those associated with some dietary supplements. The comments pertaining to dietary supplements containing Ephedra were addressed in a separate final rule (68 FR 23195, May 1, 2003).

Only one comment addressed issues relating to the List I chemicals benzaldehyde, anthranilic acid, and phenylacetic acid. This comment was submitted by an industry group representing both the Flavor and Extract Manufacturers Association of the United States and the Fragrance Materials Association of the United States (food flavoring and fragrance manufacturing sectors).

DEA originally proposed concentration limits of 35 percent for benzaldehyde, and 20 percent for anthranilic acid and phenylacetic acid. The concentration limit for benzaldehyde was proposed higher than the 20 percent proposed for most other precursor chemicals because DEA was aware that the food flavoring manufacturers used benzaldehyde in complex formulations not likely to be diverted. The comment from this interested party expressed the opinion that their formulations are not likely to be diverted even if the concentration limits for benzaldehyde, anthranilic acid, and phenylacetic acid are set at 85 percent, 50 percent, and 40 percent, respectively.

After a thorough review of the comments, DEA is finalizing concentration limits of 50 percent for benzaldehyde, 50 percent for anthranilic acid and 40 percent for phenylacetic acid. The DEA concluded that chemical mixtures containing lower concentrations of these chemicals do not present a significant risk of diversion. (For a discussion on what DEA considered in order to exempt this interest, see under Comments.)

This concentration limit is expected to exempt the majority of List I chemical mixtures identified by DEA. Most, if not all, mixtures in anthranilic acid and phenylacetic acid are expected to be exempt because available products are formulated whereby they are not useful to traffickers.

No comments were received concerning other List I chemicals being addressed in this rulemaking. Therefore, DEA concludes that the concentration limits proposed for the remaining List I chemicals are not a major concern to industry. Finalizing regulations based on the proposed concentration limits for these chemicals is not expected to increase significantly the number of new registrants. Chemical mixtures that do not qualify for automatic exemption can be considered for exemption based on the application process (21 CFR 1310.13; finalized at 68 FR 23195).

2. Chemical Mixtures Containing List II Chemicals

The List II chemicals being addressed in this rulemaking are acetone, ethyl ether, 2-butanone (methyl ethyl ketone), methyl isobutyl ketone, toluene, acetic anhydride, benzyl chloride, hydrochloric acid, sulfuric acid, potassium permanganate, and iodine. The first five chemicals are used as solvents and, based on the comments, are responsible for the majority of chemical mixtures addressed by this rulemaking. The chemicals acetic anhydride and benzyl chloride have limited use as solvents and have not been the subject of any comment. The remaining List II chemicals are reagents. DEA received comments on iodine, hydrochloric acid, and sulfuric acid. Iodine is being addressed under a separate rulemaking. The types of mixtures containing the remaining chemicals are limited and will not significantly add to the number of newly regulated transactions. There were no comments received for mixtures containing potassium permanganate.

a. The List II Solvent Chemicals

The List II solvent chemicals acetone, ethyl ether, 2-butanone, methyl isobutyl

ketone, and toluene are mostly a concern to DEA because of their use in the illicit production of cocaine. Suspicious shipments of mixtures containing List II solvents to cocaine producing areas have been identified by DEA. Additionally, diversion of chemical mixtures for the illicit production of cocaine in foreign countries has been established by DEA.

DEA continually monitors the chemical composition of seized cocaine hydrochloride samples. The DEA laboratory system is able to detect the trace quantities of solvents present in seized cocaine hydrochloride, which is a ''street form'' of cocaine. Such solvents are utilized in the final stage of cocaine production whereby cocaine base is converted to cocaine hydrochloride. Recent data indicates that a broader range of solvents and solvent combinations are being used in cocaine processing. This laboratory data supports intelligence information that chemical mixtures are used in the illicit production of cocaine hydrochloride.

DEA is aware of chemical mixtures containing List II solvent chemicals and solid material. The solids may be dissolved, suspended, emulsified, or in some way formulated into the liquid component. These mixtures are used by different industries to formulate silicones, paints, adhesives, polymers, and various related materials. DEA realizes that, in general, mixtures formulated with solids will not likely be used ''as is'' in the production of a controlled substance, including cocaine. However, recovery of the listed chemical (*e.g.*, distillation) may allow the mixture to be used by traffickers. Traffickers, especially those involved in the illicit production of cocaine, are known to recycle solvents by distillation.

After considering all comments, DEA has decided to exempt domestic and import transactions of all mixtures containing acetone, ethyl ether, 2-butanone, and toluene, unless they contain other listed chemicals above the concentration limit.

Since the NPRM did not discuss this exemption for domestic and import transactions, the public did not have the opportunity to comment on the exclusion of these transactions from the definition of a regulated transaction. To avoid unnecessary burdens on affected companies during the pendency of proceedings in this matter, DEA has decided to implement this exemption on an interim basis, with a request for comments. DEA will then publish a final rulemaking regarding this exemption after a review of such comments. (See Section V for further discussion of this interim exemption). Because of their identified potential for use in illicit cocaine production, as discussed above, this rulemaking will not automatically exempt by regulation export transactions in these mixtures.

b. The List II Chemicals Hydrochloric Acid and Sulfuric Acid

Distributions of hydrochloric acid (except domestic distributions of anhydrous hydrogen chloride) and sulfuric acid are regulated only as exports to certain geographical regions. Domestic transactions in sulfuric acid and hydrochloric acid (except anhydrous hydrogen chloride) are excluded from the recordkeeping and reporting requirements of the CSA pursuant to 21 CFR 1310.08(a). Therefore, their chemical mixtures are also excluded.

Anhydrous hydrogen chloride, which is regulated domestically, has not been identified as part of any chemical mixture. These chemicals are used in synthetic chemistry and to stabilize materials in solution, both in legitimate industries and illicit operations. Formulations of sulfuric acid have been identified that are used in papermaking, treatment of industrial water cooling systems, and for treating oil wells.

Although one comment informed DEA that chemical mixtures at the proposed concentration limit of 20 percent for hydrochloric acid could be used in the illicit production of methamphetamine, DEA is not lowering this concentration limit. Methamphetamine production is mostly a domestic concern while domestic transactions in hydrochloric acid are not regulated.

DEA regards any concentration of hydrogen chloride dissolved in an inert carrier, such as water or alcohol, as a regulated chemical under the heading of hydrochloric acid. The 20 percent concentration limit pertains to hydrochloric acid mixed with an additional non-listed chemical. The concentration limit is determined by taking the weight of hydrogen chloride in the mixture and does not include the weight of the carrier solvent.

DEA received only one comment on mixtures containing sulfuric acid. Only exports to South American countries and Panama above threshold are regulated transactions. The comment did not state if their mixtures are for export to these specific regions. The mixtures, as described in the comment, may be suitable for a group exemption by the application process. DEA concludes that newly regulated mixtures containing hydrochloric acid or sulfuric acid will be minimal at the concentration limits proposed.

c. The List II Reagent Chemicals Iodine and Potassium Permanganate

Iodine and potassium permanganate are List II chemicals that function as reagents. Reagents are chemicals that cause, or help to cause, a chemical reaction to occur. Iodine and potassium permanganate are important in methamphetamine and cocaine production, respectively.

Iodine is found in a variety of formulations. Strong iodine solution and strong iodine tincture contain seven-percent iodine and are regarded as chemical mixtures. DEA proposed a 20 percent concentration limit for iodine but was informed, by comment, that seven-percent solutions are being diverted for their iodine content. In addition, DEA has documented the use of seven-percent iodine mixtures as a source for iodine crystals in clandestine methamphetamine production. Chemical mixtures containing iodine are being addressed under a separate NPRM to allow adequate comment on the regulation of iodine desirable to traffickers.

DEA has not identified mixtures of potassium permanganate being diverted for illicit drug production or being formulated in a concentration greater than the proposed 15 percent. DEA has determined that legitimately produced chemical mixtures containing less than 15 percent potassium permanganate do not have a significant potential for diversion. Therefore, the concentration limit for potassium permanganate was proposed to be 15 percent. No comments were received to suggest that there are any chemical mixtures containing greater than 15 percent potassium permanganate.

d. The List II Precursor Chemicals Acetic Anhydride and Benzyl Chloride

The List II chemicals acetic anhydride and benzyl chloride may be regarded as precursor chemicals. Precursors are substances that are chemically modified to become part of the final product. Acetic anhydride is important in the production of heroin while benzyl chloride can be used to make methamphetamine. These chemicals also have limited use as solvents. No comments were received regarding these chemicals and DEA has not identified them as being routinely used in chemical mixtures. The concentration limit for acetic anhydride and benzyl chloride was proposed to be 20 percent and is being finalized at the 20 percent limit.

IV. Final Rule Provisions

a. Specific Requirements That Will Apply to Regulated Chemical Mixtures Containing List I Chemicals Upon Publication of This Final Rule

A chemical mixture that is regulated because it contains a List I chemical will be treated as a List I chemical. Transactions that meet or exceed the cumulative monthly threshold for the listed chemical shall be regulated transactions. Persons interested in handling a regulated mixture must comply with the following:

Registration. Any person who manufactures or distributes a regulated mixture, or proposes to engage in the manufacture or distribution of a regulated mixture containing a List I chemical, shall obtain a registration pursuant to the CSA (21 U.S.C. 822). Regulations describing registration for list I chemical handlers are set forth in 21 CFR part 1309.

Separate registration is required for retail distribution, non-retail distribution, importing, and exporting. A separate registration is required for each principal place of business at one general physical location where List I chemicals are distributed, imported, or exported by a person (21 CFR 1309.23). Effective February 14, 2005, any person distributing, importing, or exporting any amount of a regulated mixture will become subject to the registration requirement under the CSA. DEA recognizes, however, that it is not possible for persons who are subject to the registration requirement to immediately complete and submit an application for registration and for DEA to immediately issue registrations for those activities. Therefore, in order to allow continued legitimate commerce in regulated mixtures, DEA is establishing in 21 CFR 1310.09 a temporary exemption from the registration requirement for persons desiring to engage in activities with regulated mixtures that are subject to registration requirements, provided that DEA receives a properly completed application for registration on or before February 14, 2005. The temporary exemption for such persons will remain in effect until DEA takes final action on their application for registration.

Any person whose application for exemption is subsequently rejected by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for these persons, if 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.

The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, are effective on January 14, 2005. Therefore, all transactions of the chemical mixture will be regulated, if at or above threshold, while an application for registration or exemption is pending. This is necessary because not regulating these transactions could result in increased diversion of chemicals desirable to drug traffickers.

Additionally, the temporary exemption does not suspend applicable federal criminal laws relating to the regulated mixture, nor does it supersede state or local laws or regulations. All handlers of a regulated mixture must comply with applicable state and local requirements in addition to the CSA regulatory controls.

Records and Reports. The CSA (21 U.S.C. 830) requires certain records to be kept and reports to be made involving listed chemicals. Regulations describing recordkeeping and reporting requirements are set forth in 21 CFR 1310. A record must be made and maintained for two years after the date of a regulated transaction involving a List I chemical. Only a distribution, receipt, sale, importation, or exportation of a regulated mixture at or above the established threshold is a regulated transaction (21 CFR 1300.02(b)(28)).

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.

21 CFR 1310.05 requires that each regulated person shall report to DEA any regulated transaction involving an extraordinary quantity, an uncommon method of payment or delivery, or any other circumstance that causes the regulated person to believe that the listed chemical will be used in violation of the CSA.

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

Imports/Exports. All import/exports and brokered transactions of regulated mixtures 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 1313. Separate registration is necessary for each activity (21 CFR 1309.22).

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 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.

b. Specific Requirements That Will Apply to Regulated Chemical Mixtures Containing List II Chemicals Upon Publication of This Final Rule

A chemical mixture that is regulated because it contains a List II chemical will be treated as a List II chemical. Transactions that meet or exceed the cumulative monthly threshold for the listed chemical shall be regulated transactions. The regulatory requirements for regulated chemical mixtures containing List II chemicals are the same as for regulated chemical mixtures containing List I chemicals, except that registration requirements do not apply. Therefore, the same requirements for records and reports, imports/exports (except that pertaining to 21 U.S.C. 957), and administrative inspection, as outlined above, apply to handlers of List II regulated chemical mixtures.

Persons who submit an application for exemption (Section 1310.13) and whose application is pending or subsequently rejected by DEA must comply with all chemical control requirements, including recordkeeping and reporting, effective on January 14, 2005. Therefore, all transactions of the chemical mixture will be regulated, if at or above threshold, while an application for exemption is pending or awaiting correction. This is necessary because not regulating these transactions could result in increased diversion of chemicals desirable to drug traffickers.

c. Persons Affected by This Final Rule

This rulemaking will affect only persons who manufacture, distribute, import, or export chemical mixtures containing listed chemicals that DEA determined are useful to traffickers for the illicit production of controlled substances. DEA received comments on

only a few specific listed chemicals. Therefore, DEA concludes that the concentration limits proposed in the NPRM for the remaining majority of listed chemicals were acceptable to chemical handlers.

The goal of this rulemaking is to deny traffickers unregulated access to useful chemical mixtures while minimizing the burden on legitimate industry. This final rule seeks to target those chemical mixtures having the greatest potential for illicit use.

Comments to the NPRM informed DEA of ways to provide additional regulatory relief to the affected industry. DEA determined that some of these suggested changes would not compromise law enforcement objectives. Based on this new information, this final rule exempts the vast majority of potentially regulated chemical mixtures without compromising the needs of law enforcement. Certain chemical mixtures that are a concern to the paints and coatings industries, the food flavoring industries, fragrance manufacturers, the silicone industries, ink manufacturers, and others are being identified by regulation as exempt from CSA regulatory controls. Because DEA is able to adjust some of its proposed regulations based on information received in the comments, those persons who trade in chemical mixtures containing listed chemicals should be minimally impacted or not affected at all by this rulemaking.

Of those persons whose mixtures are regulated, only those who distribute above the threshold for the listed chemical(s) are regulated transactions (21 U.S.C. 802(39)(A)). A threshold is a quantity of chemical, as specified in 21 CFR 1310.04. Distributions at or above the specified threshold amount are regulated transactions. Thresholds are determined by totaling the amount of chemical in all distributions to the same person within a calendar month.

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 the listed chemical and change it into a non-listed chemical or formulate it into an exempt chemical mixture.

V. Exemption Authority

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 a regulated transaction that are unnecessary for enforcement of the CSA. Based on comments to the **Federal Register** proposed rule ''Exemption of Chemical Mixtures'' (63 FR 49506), DEA identified certain transactions in mixtures of acetone, ethyl ether, 2-butanone, and toluene that are unlikely sources for diversion. DEA was informed that tens of thousands of domestic transactions in these chemical mixtures occur annually. DEA has determined that the regulation of domestic and import transactions in mixtures containing the chemicals acetone, ethyl ether, 2-butanone, and toluene are unnecessary for enforcement of the CSA and should be removed from the definition of a regulated transaction.

Since the NPRM to this rulemaking did not discuss this exemption, the public did not have the opportunity to comment on the exclusion of these transactions from the definition of a regulated transaction. However, DEA has determined that good cause exists under the Administrative Procedure Act (5 U.S.C. 553 *et seq.*) (APA) to forgo a notice of proposed rulemaking on these exemptions. The APA states that an agency may forego a Notice of Proposed Rulemaking if it is impracticable, unnecessary, or contrary to the public interest.

If this rulemaking did not exempt these transactions upon publication, DEA would need to establish the exemption by notice and comment. If exemption of these transactions were delayed, affected parties would need to implement a system of recordkeeping and reporting for all these regulated transactions. This would involve several thousand transactions annually in chemical mixtures that otherwise may not be regulated if the exemptions became effective immediately.

If a proposed rule were published in the **Federal Register** to exclude these transactions from the definition of regulated transactions, each affected entity might find it necessary to establish compliance procedures although the requirement might prove to be only temporary. To avoid unnecessary burdens on affected companies during the pendency of proceedings in this matter, DEA has decided to include as part of this rulemaking an interim rule, with request for comment, that removes these transactions from the definition of a regulated transaction.

VI. Regulatory Certifications

Regulatory Flexibility Act

DEA, pursuant to 21 U.S.C. 802(39)(A)(v), is finalizing provisions to identify exempt chemical mixtures. The chemical mixtures being addressed are those that contain one or more of the 27 listed chemicals given in the Table of Concentration Limits. A Final Rule establishing provisions that exempt chemical mixtures containing ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine was published in a separate rulemaking (68 FR 23195, May 1, 2003).

Provisions to exempt chemical mixtures in the listed chemicals gamma-butyrolactone, red phosphorus, white phosphorus, and hypophosphorous acid (and its salts) are not being finalized at this time. These chemicals were not regulated when the NPRM ''Exemption of Chemical Mixtures'' (63 FR 49506) was published. Therefore, regulations addressing their mixtures were not proposed. DEA is treating mixtures containing these listed chemicals as exempt until promulgation of regulations that identify exempt chemical mixtures in these chemicals.

To identify exempt chemical mixtures, a concentration limit is placed on each chemical, or combination of chemicals, which determines the mixture's regulatory status. Categories of exempt chemical mixtures are also defined. In addition, DEA can determine that a mixture is exempt via an application process (Section 1310.13).

Comments to the NPRM informed DEA that a substantial number of chemical mixtures that are not useful to traffickers could potentially be regulated if the proposed rule were finalized as written. DEA determined that the regulation of these chemical mixtures is not necessary for enforcement of the CSA. Therefore, DEA decided to exempt these chemical mixtures from regulatory controls by identifying new concentration limits and exemption of certain types of transactions.

DEA notes that the List II solvent chemicals acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene contribute to the largest number of potentially regulated chemical mixtures of List II chemicals. To limit the number of potentially regulated chemical mixtures to those necessary for enforcement of the CSA, DEA decided to define all domestic and import transactions of mixtures in these List II solvent chemicals as exempt transactions. This exemption applies to all persons that handle these chemical mixtures and not only to those who are represented in the comments. Although effective upon publication of this final rule, DEA is accepting post-

promulgation comments regarding this regulation.

The regulated industry only expressed concerns through comments to the NPRM with respect to three List I chemicals, anthranilic acid, benzaldehyde, and phenylacetic acid. The food flavoring and fragrance industries use these chemicals, as discussed by a single comment representing both the Flavor and Extract Manufacturers Association of the United States, and the Fragrance Materials Association of the United States. No other List I chemicals were addressed in the comments, therefore, DEA concludes that no other List I chemicals are a concern to handlers of chemical mixtures at the concentration limits proposed.

The concentration limits are being increased for the List I chemicals anthranilic acid and phenylacetic acid to the levels suggested by comment. Based on the comment, this increase is expected to exempt all chemical mixtures in anthranilic acid and phenylacetic acid identified by DEA that are not at substantial risk of diversion. However, DEA decided that traffickers could use chemical mixtures containing over 50 percent benzaldehyde, although a comment suggested that even higher concentrations would not be diverted. Therefore, DEA increased the concentration limit of benzaldehyde from 35 percent to 50 percent to regulate only those chemical mixtures identified by DEA as necessary for enforcement of the CSA. Therefore, some commercially available chemical mixtures in benzaldehyde are expected to be regulated.

Benzaldehyde is a chemical used in food flavorings. The comment states that the number of persons that manufacture or use flavors is 97. Provided the number of persons that will be newly registered to handle chemical mixtures in benzaldehyde is 97, the initial total registration cost would be $57,715, based on the current new application fee of $595.00 for each company. The total annual re-registration cost, based on the present renewal fee of $477.00 for each company, would be $46,269. In addition to the specific dollar cost, the registration requirement would require an annual reporting burden of approximately 48.5 hours. This is based on the estimated one-half hour required to complete and submit an application for registration or re-registration.

The comment stated that 66 members of the commenting industry association manufacture or sell fragrances. Assuming that all persons involved with the manufacture of food flavorings or fragrances (163) must register for each of the three chemicals, the combined current estimated cost for all new application fees is $290,955.

DEA adopted those suggestions that will not adversely impact enforcement of the CSA while eliminating the greatest number of transactions in List I and List II chemical mixtures identified by DEA. Only three List I chemicals and four List II chemicals contribute to the largest number of potential newly regulated chemical mixtures.

The remaining listed chemicals addressed in the rulemaking were not addressed in the comments and make up only a small number of new potentially regulated chemical mixtures. DEA does not anticipate a significant number of regulated chemical mixtures due to the remaining listed chemicals. For those chemical mixtures that fall within the regulatory parameters, the manufacturer can obtain exempt status for a chemical mixture by the application process. Once a chemical mixture has been granted exempt status by application, all down-stream activities in that unaltered mixture are exempt.

Therefore, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Deputy Administrator has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities.

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, Section 1(b), Principles of Regulation. DEA has 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.

Executive Order 12988

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 $114 million 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.

Paperwork Reduction Act

This Final Rule requires that persons handling nonexempt chemical mixtures containing a List I chemical must register with DEA to handle the regulated mixture. Persons will register using DEA Form 510 ''Application for Registration under Domestic Chemical Diversion Control Act of 1993'' addressed in OMB information collection 1117–0031. As it is not possible for DEA to determine the number of persons whose chemical mixtures might be exempted from regulation by one of the three criteria established for exempting such mixtures, it is not possible for DEA to quantify at this time the number of persons affected by the requirement of registration. As information regarding the number of persons registering with DEA due to this rule becomes available, DEA will adjust its collection of information accordingly.

List of Subjects in 21 CFR Part 1310

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

■ For the reasons set out above, 21 CFR part 1310 is amended to read as follows:

PART 1310—[AMENDED]

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

Authority: 21 U.S.C. 802, 830, 871(b), 890.

■ 2. Section 1310.04 is amended by revising paragraph (h) and adding new paragraphs (i) and (j) to read as follows:

§ 1310.04 Maintenance of records.

* * * * *

(h) The thresholds and conditions in paragraphs (f) and (g) of this section will apply to transactions involving regulated chemical mixtures. For purposes of determining whether the weight or volume of a chemical mixture meets or exceeds the applicable quantitative threshold, the following rules apply:

(1) For chemical mixtures containing List I chemicals or List II chemicals other than those in paragraph (h)(2) of this section, the threshold is determined by the weight of the listed chemical in the chemical mixture.

(2) For the List II chemicals acetone, ethyl ether, 2-butanone, toluene, and methyl isobutyl ketone, the threshold is determined by the weight of the entire chemical mixture.

(3) If two or more listed chemicals are present in a chemical mixture, and the quantity of any of these chemicals equals or exceeds the threshold applicable to that chemical, then the transaction is regulated.

■ 3. Section 1310.08 is amended by adding a new paragraph (l) to read as follows:

§ 1310.08 Excluded transactions.

* * * * *

(l) Domestic and import transactions in chemical mixtures that contain acetone, ethyl ether, 2-butanone, or toluene unless regulated because of being formulated with another listed chemical above the concentration limit.

■ 4. Section 1310.09 is amended by adding new paragraphs (f) and (g) to read as follows:

§ 1310.09 Temporary exemption from registration.

* * * * *

(f) Except for chemical mixtures containing the listed chemicals in paragraph (e) of this section, each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export regulated chemical mixtures, pursuant to §§ 1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption on or before February 14, 2005. The exemption will remain in effect for each person who has made such application until the Administration 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.

(g) Any person who 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.

■ 5. Section 1310.12 is amended by revising paragraph (c) and adding new paragraphs (d)(2) and (3) to read as follows:

§ 1310.12 Exempt chemical mixtures.

* * * * *

(c) Mixtures containing a listed chemical in concentrations equal to or less than those specified in the ''Table of Concentration Limits'' are designated as exempt chemical mixtures for the purpose set forth in this section. The concentration is determined for liquid-liquid mixtures by using the volume or weight and for mixtures containing solids or gases by using the unit of weight.

TABLE OF CONCENTRATION LIMITS

	DEA chemical code number	Concentration	Special conditions
List I Chemicals			
N-Acetylanthranilic acid, its salts and esters	8522	20% by Weight	Concentration based on any combination of N-acetylanthranilic acid and its salts and esters.
Anthranilic acid, and its salts and esters	8530	50% by Weight	Concentration is based on any combination of anthranilic acid and its salts and esters.
Benzaldehyde	8256	50% by Weight or Volume.	
Benzyl cyanide	8570	20% by Weight or Volume.	
Ephedrine, its salts, optical isomers, and salts of optical isomers.	8113	5% by Weight, net weight includes capsule, if any.	Concentration based on any combination of ephedrine, pseudoephedrine, and their salts, optical isomers and salts of optical isomers.
Ergonovine and its salts	8675	Not exempt at any concentration.	Chemical mixtures containing any amount of ergonovine, including its salts, are not exempt.
Ergotamine and its salts	8676	Not exempt at any concentration.	Chemical mixtures containing amount of any ergotamine, including its salts, are not exempt.
Ethylamine and its salts	8678	20% by Weight or Volume.	Ethylamine or its salts in an inert carrier solvent is not considered a mixture. Concentration is based on ethylamine in the mixture and not the combination of ethylamine and carrier solvent, if any.
Hydriodic acid	6695	20% by Weight or Volume.	
Isosafrole	8704	20% by Weight or Volume.	Concentration in a mixture cannot exceed 20% if taken alone or in any combination with safrole.
Methylamine and its salts	8520	20% by Weight	Methylamine or its salts in an inert carrier solvent is not considered a mixture. Weight is based on methylamine in the mixture and not the combined weight of carrier solvent, if any.
3,4-Methylenedioxyphenyl-2-propanone	8502	20% by Weight.	

TABLE OF CONCENTRATION LIMITS—Continued

	DEA chemical code number	Concentration	Special conditions
N-Methylephedrine, its salts, optical isomers, and salts of optical isomers.	8115	0.1% by Weight	Concentration based on any combination of salts N-methylephedrine, N-methylpseudoephedrine and their salts, optical isomers and salts of optical isomers.
N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8119	0.1% by Weight	Concentration based on any combination of N-methylpseudoephedrine, N-methylephedrine, and their salts, optical isomers and salts of optical isomers.
Nitroethane	6724	20% by Weight or Volume.	
Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8317	0.6% by Weight	Concentration based on any combination of norpseudoephedrine, phenylpropanolamine and their salts, optical isomers and salts of optical isomers.
Phenylacetic acid, and its salts and esters	8791	40% by Weight	Concentration is based on any combination of phenylacetic acid and its salts and esters.
.			
Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.	1225	0.6% by Weight	Concentration based on any combination of phenylpropanolamine, norpseudoephedrine and their salts, optical isomers and salts of optical isomers.
Piperidine, and its salts	2704	20% by Weight or Volume.	Concentration based on any combination of piperidine and its salts. Concentration based on weight if a solid, weight or volume if a liquid.
Piperonal	8750	20% by Weight or Volume.	
Propionic anhydride	8328	20% by Weight or Volume.	
Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8112	5% by Weight, net weight includes capsule, if any.	Concentration based on any combination of pseudoephedrine, ephedrine, and their salts, optical isomers and salts of optical isomers.
Safrole	8323	20% by Volume	Concentration in a mixture cannot exceed 20% if taken alone or in any combination with isosafrole.
List II Chemicals			
Acetic Anhydride	8519	20% by Weight or Volume.	
Acetone	6532	35% by Weight or Volume.	Exports only; Limit applies to acetone or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Benzyl chloride	8568	20% by Weight or Volume.	
2-butanone	6714	35% by Weight or Volume.	Exports only; Limit applies to 2-butanone or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Ethyl ether	6584	35% by Weight or Volume.	Exports only; Limit applies to ethyl ether or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Hydrochloric acid	6545	20% by Weight or Volume.	Hydrogen chloride in an inert carrier solvent, such as aqueous or alcoholic solutions, is not considered a mixture. Weight is based on hydrogen chloride in the mixture and not the combined weight of the carrier solvent, if any.
Methyl isobutyl ketone	6715	35% by Weight or Volume.	Exports only pursuant to § 1310.08; Limit applies to methyl isobutyl ketone or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Potassium permanganate	6579	15% by Weight.	

TABLE OF CONCENTRATION LIMITS—Continued

	DEA chemical code number	Concentration	Special conditions
Sulfuric acid	6552	20% by Weight or Volume.	Sulfuric acid in an inert carrier solvent, such as aqueous or alcoholic solutions, is not considered a mixture. Weight is based on sulfuric acid in the mixture and not the combined weight of the carrier solvent, if any.
Toluene	594	35% by Weight or Volume.	Exports only; Limit applies to toluene or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.

(d) The following categories of chemical mixtures are automatically exempt from the provisions of the Controlled Substances Act as described in paragraph (a) of this section:

(1) * * *

(2) Chemical mixtures that are distributed directly to an incinerator for destruction or directly to an authorized waste recycler or reprocessor where such distributions are documented on United States Environmental Protection Agency Form 8700–22; persons distributing the mixture to the incinerator or recycler must maintain and make available to agents of the Administration, upon request, such documentation for a period of no less than two years.

(3) Completely formulated paints and coatings: Completely formulated paints and coatings are only those formulations that contain all the components of the paint or coating for use in the final application without the need to add any additional substances except a thinner if needed in certain cases. A completely formulated paint or coating is defined as any clear or pigmented liquid, liquefiable or mastic composition designed for application to a substrate in a thin layer that is converted to a clear or opaque solid protective, decorative, or functional adherent film after application. Included in this category are clear coats, topcoats, primers, varnishes, sealers, adhesives, lacquers, stains, shellacs, inks, and temporary protective coatings.

* * * * *

Dated: December 9, 2004.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 04–27449 Filed 12–14–04; 8:45 am]

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PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4022 and 4044

Benefits Payable in Terminated Single-Employer Plans; Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation's regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans prescribe interest assumptions for valuing and paying benefits under terminating single-employer plans. This final rule amends the regulations to adopt interest assumptions for plans with valuation dates in January 2005. Interest assumptions are also published on the PBGC's Web site (*http://www.pbgc.gov*).

EFFECTIVE DATE: January 1, 2005.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: The PBGC's regulations prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Three sets of interest assumptions are prescribed: (1) A set for the valuation of benefits for allocation purposes under section 4044 (found in Appendix B to part 4044), (2) a set for the PBGC to use to determine whether a benefit is payable as a lump sum and to determine lump-sum amounts to be paid by the PBGC (found in Appendix B to part 4022), and (3) a set for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology (found in Appendix C to part 4022).

Accordingly, this amendment (1) adds to Appendix B to part 4044 the interest assumptions for valuing benefits for allocation purposes in plans with valuation dates during January 2005, (2) adds to Appendix B to part 4022 the interest assumptions for the PBGC to use for its own lump-sum payments in plans with valuation dates during January 2005, and (3) adds to Appendix C to part 4022 the interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology for valuation dates during January 2005.

For valuation of benefits for allocation purposes, the interest assumptions that the PBGC will use (set forth in Appendix B to part 4044) will be 4.10 percent for the first 20 years following the valuation date and 4.75 percent thereafter. These interest assumptions (in comparison to those in effect for December 2004) represent an increase of 0.30 percent for the first 20 years following the valuation date and a decrease of 0.25 percent for all years thereafter.

The interest assumptions that the PBGC will use for its own lump-sum payments (set forth in Appendix B to part 4022) will be 3.00 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. These interest assumptions represent an increase (from those in effect for December 2004) of 0.25 percent for the period during which a