

## 42 CFR Part 121

Healthcare, Hospitals, Reporting and recordkeeping requirements.

■ Therefore, under the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs and to the Administrator, Health Resources and Services Administration, 21 CFR part 1271 and 42 CFR part 121 are amended as follows:

## 21 CFR Chapter I

## PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

■ 1. The authority citation for 21 CFR part 1271 continues to read as follows:

**Authority:** 42 U.S.C. 216, 243, 263a, 264, 271.

■ 2. Section 1271.3 is amended by adding paragraph (d)(8) to read as follows:

## § 1271.3 How does FDA define important terms in this part?

\* \* \* \* \*

(d) \* \* \*

(8) Blood vessels recovered with an organ, as defined in 42 CFR 121.2, that are intended for use in organ transplantation and labeled "For use in organ transplantation only."

\* \* \* \* \*

## 42 CFR Chapter I

## PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

■ 3. The authority citation for 42 CFR part 121 continues to read as follows:

**Authority:** Sections 215, 371–376 of the Public Health Service Act (42 U.S.C. 216, 273–274d); and sections 1102, 1106, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1320b–8 and 1395hh).

■ 4. Section 121.2 is amended by adding a sentence at the end of the definition of "Organ" to read as follows:

## § 121.2 Definitions

\* \* \* \* \*

*Organ* \* \* \* Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled "For use in organ transplantation only."

\* \* \* \* \*

■ 5. Section 121.7 is amended by redesignating paragraph (e) as paragraph (f) and by adding paragraph (e) to read as follows:

## § 121.7 Identification of organ recipient.

\* \* \* \* \*

(e) *Blood vessels considered part of an organ.* A blood vessel that is considered part of an organ under this part shall be subject to the allocation requirements and policies pertaining to the organ with which the blood vessel is procured until and unless the transplant center receiving the organ determines that the blood vessel is not needed for the transplantation of that organ.

\* \* \* \* \*

Dated: December 8, 2006.

Elizabeth M. Duke,

Administrator, Health Resources and Services Administration.

Dated: February 2, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy, Food and Drug Administration.

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## DEPARTMENT OF JUSTICE

## Drug Enforcement Administration

## 21 CFR Part 1310

[Docket No. DEA–137F3]

RIN 1117–AA31

## Exemption of Chemical Mixtures

**AGENCY:** Drug Enforcement Administration (DEA), U.S. Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** On December 15, 2004, the Drug Enforcement Administration (DEA) published a Final Rule corrected January 4, 2005) that implemented new regulations concerning chemical mixtures that contain any of the 27 listed chemicals. The Final Rule added a new provision not previously raised by DEA in any proposed rulemaking. This newly introduced provision exempted 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 from the Controlled Substances Act (CSA) recordkeeping and reporting requirements. Because this exemption was not previously proposed in any rulemaking, DEA implemented this exemption on an interim basis and requested public comment on this exemption provision.

Based upon a review of all comments, DEA is finalizing this exemption. As such, domestic and import transactions in chemical mixtures containing the List

II chemicals acetone, ethyl ether, 2-butanone, and toluene shall be exempt from CSA chemical recordkeeping and reporting requirements.

**DATES:** This Final Rule is effective March 12, 2007.

**FOR FURTHER INFORMATION CONTACT:** Christine A. Sannerud, Ph.D., Chief, Drug & Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, telephone (202) 307–7183.

## SUPPLEMENTARY INFORMATION:

## I. Background

*Historical Legal Status of Chemical Mixtures*

The Chemical Diversion and Trafficking Act of 1988 (CDTA), (Pub. L. 100–690) 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)(vi), as amended by Title VII of Public Law 109–177, 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 (Pub. L. 103–200) (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)(vi), as amended by Title VII of Public Law 109–177, 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)(vi) as amended by Title VII of Pub. L. 109–177). This authority has been delegated to the Administrator of DEA by 28 CFR 0.100 and redelegated to the Deputy

Administrator under 28 CFR Appendix to Subpart R, section 12.

Prior to publication of a final rulemaking, chemical mixtures containing listed chemicals have been treated as exempt from CSA regulatory control. 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.

On December 15, 2004, DEA published a final rule which specified criteria used to determine whether chemical mixtures qualify for automatic exemption from CSA chemical regulatory controls for 27 listed chemicals (69 FR 74957; corrected at 70 FR 294, January 4, 2005). Those chemical mixtures that do not meet the exemption criteria are treated as regulated chemicals and therefore, subject to CSA chemical regulatory controls.

#### Chemical Mixture Definition

Title 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 the CSA definition. As such, the regulatory controls pertaining to each individual listed chemical are applicable.

It is DEA's longstanding policy that the combination of a listed chemical in an inert carrier is not considered a chemical mixture. 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. Persons who question if their formulations are chemical mixtures should contact DEA for guidance.

#### New Interim Chemical Mixture Exemption Category

The Final Rule published on December 15, 2004, (69 FR 74957; corrected at 70 FR 294, January 4, 2005) also added, on an interim basis, a new exemption category. 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.

Therefore, the December 15, 2004 rulemaking created 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 were removed, on an interim basis, 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, was 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.

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 published on September 16, 1998 (63 FR 49506). Therefore, this exemption was implemented on an interim basis with opportunity for public comment in the December 15, 2004 rulemaking (69 FR 74957; corrected at 70 FR 294, January 4, 2005). DEA solicited comments on this portion of the rulemaking.

#### II. Comments Received Regarding the Interim Regulations

DEA received three comments in response to the December 15, 2004, rulemaking (69 FR 74957) from interested parties. Two comments were from trade associations, and one comment was from a chemical manufacturer. In general, the comments

supported efforts by DEA to regulate chemical mixtures that have potential use to drug traffickers. Each comment specifically supported finalization of the exemption for domestic and import transactions for chemical mixtures containing the List II solvent chemicals acetone, ethyl ether, 2-butanone, and toluene.

Two comments, however, requested that the exemption be expanded to include certain exports of such chemical mixtures. The comments suggested that DEA only regulate exports of such mixtures to certain specific countries of concern. Given the applicability of such solvents for both cocaine and heroin processing, however, the geographic regions of concern are extremely widespread. Additionally, DEA has concerns that exports of solvent chemical mixtures can be subject to re-exportation from destination countries. DEA believes that such exports of chemical mixtures should not be exempted since exports of these chemical mixtures could have significant potential for diversion. Therefore, these chemical mixtures, unless otherwise exempt, are subject to the export and other CSA chemical regulatory requirements.

One commenter expressed concerns regarding the regulatory language found in 21 CFR 1310.08(l) stating that, "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" shall be excluded transactions. The commenter stated that the regulatory language does not make it clear that this exemption applies if the mixture contains more than one of these chemicals (i.e. contains two or more of the following: acetone, ethyl ether, 2-butanone or toluene). The commenter expressed concerns that enforcement officials may deem chemical mixtures containing more than "one" of these solvents as regulated if the total quantity exceeded the List II concentration limits. DEA agrees. Therefore, DEA is modifying 21 CFR 1310.08(l) to read, "Domestic and import transactions in chemical mixtures that contain acetone, ethyl ether, 2-butanone, and/or toluene, unless regulated because of being formulated with other List I or List II chemical(s) above the concentration limit" shall be excluded.

#### Clarification of Concentration Limits

As DEA stated in its Final Rule establishing concentration limits for the vast majority of chemical mixtures (69 FR 74957, December 15, 2004), and

codified at 21 CFR 1310.14(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 from specified provisions set forth in that section. The concentration limit is set at 35 percent (by weight or volume) for the cumulative amount of acetone, methyl ethyl ketone (MEK), methyl isobutyl ketone (MIBK), toluene, and ethyl ether. Therefore, the table in 21 CFR 1310.14(c) specifies that for exports, the limit applies to the specific chemical 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. For example, an export involving a chemical mixture containing 20 percent acetone and 20 percent ethyl ether would not be exempt because the cumulative total of 40 percent exceeds the 35 percent concentration limit.

#### *Final Action Taken in This Rulemaking*

After considering all comments, DEA has decided to exempt domestic and import transactions in chemical mixtures that contain acetone, ethyl ether, 2-butanone, and/or toluene 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.

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

The above exemption only exempts such chemical mixtures from the domestic recordkeeping and import notification requirements. All other CSA chemical regulatory provisions, as specified in detail in the December 15, 2004 rule [69 FR 74957; corrected at 70 FR 294, January 4, 2005], shall apply.

### **III. 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, September 16, 1998), 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 determined that the regulation of domestic and import transactions in mixtures containing the chemicals acetone, ethyl ether, 2-butanone, and toluene were 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, to avoid unnecessary burdens on affected companies during the pendency of proceedings in this matter, DEA decided to include as part of its December 15, 2004, Final Rule an interim rule, with request for comment, removing these transactions from the definition of a regulated transaction. Now that DEA has had the opportunity to solicit and review comments, the exemption is being finalized in this rule.

### **IV. Regulatory Certifications**

#### *Regulatory Flexibility Act*

DEA has become aware that a substantial number of chemical mixtures that are not useful to traffickers could potentially be regulated if the chemical mixtures that are subject to this rulemaking were not excluded from certain regulatory requirements. 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 exemption of certain types of transactions.

DEA notes that the List II solvent chemicals acetone, ethyl ether, 2-butanone, 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. DEA previously implemented this exemption and is finalizing the exemption in this rulemaking.

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. This rule finalizes an exemption for domestic and import transactions involving the List II chemicals acetone, ethyl ether, 2-butanone, and toluene.

#### *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 \$118,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

#### *Congressional Review Act*

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). 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 rulemaking finalizes an exemption provision which reduced the paperwork burden on handlers of acetone, ethyl ether, 2-butanone and toluene. By exempting domestic and import transactions involving chemical mixtures containing these List II chemicals DEA is not subjecting these

transactions to CSA recordkeeping and reporting requirements. Domestic and import transactions involving chemical mixtures containing acetone, ethyl ether, 2-butanone and toluene are not subject to the following information collections: DEA information collection 1117-0023: Import/Export Declaration for List I and List II Chemicals [imports only]; and DEA information collection 1117-0029: Annual Reporting Requirement for Manufacturers of Listed Chemicals.

#### 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, 827(h), 830, 871(b), 890.

■ 2. Section 1310.08 is amended by revising 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, and/or toluene, unless regulated because of being formulated with other List I or List II chemical(s) above the concentration limit.

Dated: March 1, 2007.

**Michele M. Leonhart,**

*Deputy Administrator.*

[FR Doc. E7-4314 Filed 3-9-07; 8:45 am]

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## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 925

[Docket No. MO-039-FOR]

#### Missouri Regulatory Program

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.

**ACTION:** Final rule; approval of amendment.

**SUMMARY:** We, the Office of Surface Mining Reclamation and Enforcement (OSM), are approving an amendment to the Missouri regulatory program (Missouri program) regarding bonding under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the

Act). Previously, we approved an emergency rule that allowed Missouri to transition from a “bond pool” approach to bonding to a “full cost bond” approach in a timely manner. We are now approving Missouri’s permanent rule concerning this same topic. Missouri proposed to revise its program to improve operational efficiency.

**DATES:** *Effective Date:* March 12, 2007.

#### FOR FURTHER INFORMATION CONTACT:

Andrew R. Gilmore, Chief, Alton Field Division. Telephone: (618) 463-6460. E-mail: [MCR\\_AMEND@osmre.gov](mailto:MCR_AMEND@osmre.gov).

#### SUPPLEMENTARY INFORMATION:

- I. Background on the Missouri Program
- II. Submission of the Amendment
- III. OSM’s Findings
- IV. Summary and Disposition of Comments
- V. OSM’s Decision
- VI. Procedural Determinations

#### I. Background on the Missouri Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, “a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act \* \* \*; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.” See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Missouri program on November 21, 1980. You can find background information on the Missouri program, including the Secretary’s findings, the disposition of comments, and conditions of approval, in the November 21, 1980, **Federal Register** (45 FR 77017). You can also find later actions concerning the Missouri program and program amendments at 30 CFR 925.10, 925.12, 925.15, and 925.16.

#### II. Submission of the Amendment

By letter dated October 11, 2006 (Administrative Record No. MO-666), Missouri sent us a “permanent rule” amendment to its program regarding bonding under SMCRA (30 U.S.C. 1201 *et seq.*). This amendment was sent as a replacement for Missouri’s “emergency rule” that we previously approved on June 8, 2006 (71 FR 33243). The “emergency rule” allowed Missouri to transition from a “bond pool” approach to bonding to a “full cost bond” approach in a timely manner. The “permanent rule” amendment, when approved, will become a permanent part of Missouri’s program.

We announced receipt of Missouri’s proposed “emergency rule” amendment in the November 29, 2005, **Federal Register** (70 FR 71425). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. We did not hold a public hearing or meeting because no one requested one and we did not receive any comments. We also stated in this **Federal Register** document that if Missouri submitted a “permanent rule” with language that has the same meaning as the “emergency rule,” we would publish a final rule and Missouri’s “permanent rule” would become part of the Missouri program. Because Missouri’s “permanent rule” has the same meaning as the “emergency rule,” we are proceeding with the final rule.

#### III. OSM’s Findings

Following are the findings we made concerning Missouri’s “permanent rule” amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. We are approving the amendment as described below. Any revisions that we do not specifically discuss below concern nonsubstantive wording or editorial changes.

##### A. Minor Revisions to Missouri’s Regulations

Missouri’s definition for “regulatory authority,” found at 10 CSR [Code of State Regulations] 40-8.010(82), means the Land Reclamation Commission (commission), the director, or their designated representatives and employees unless otherwise specified in the State’s rules. Missouri proposed to replace the words “commission” or “regulatory authority” with the word “director” in the following regulations: 10 CSR 40-7.011(2)(A), (3)(C), (4)(B), (6)(B)1., 5., 6., and 7., (6)(C)1. and 8., (6)(D)2., and (6)(D)2.B, 3.B, 3.B(I) and 5.C; and 10 CSR 40-7.041(1)(A), (B)1. and (B)2. Missouri proposed to improve operational efficiency by specifying that the director is to perform certain duties. We find that the substitution of the word “director” for the words “commission” or “regulatory authority” will not render Missouri’s regulations less effective than the Federal regulations because in accordance with Missouri’s definition for regulatory authority, the director is a regulatory authority as is the commission and the certain duties specified in the regulations cited above are not duties reserved solely for the commission according to section 444.810 of Missouri’s surface coal mining law.