

regulation of the Attorney General as excluded from this definition as unnecessary for enforcement of this subchapter or subchapter II of this chapter." DEA is amending 21 CFR 1310.08 to exclude from the definition of a "regulated transaction," transactions involving 4,000 kilograms (net weight) or more in a single container. This amendment is in response to a comment to the NPRM and is different than what the DEA originally proposed. Adopting the suggestion in the comment is expected to give more comprehensive regulatory relief to industry without significantly increasing the risk of diversion.

DEA would like to emphasize that the exclusion applies only to transactions of one or more single containers holding 4,000 kilograms (net weight) or more of GBL. That is, in multi-container shipments, it is a regulated transaction if any container has less than 4,000 kilograms or if the 4,000 kilograms is reached only by combining the weight of GBL in each container.

## II. Comments

DEA received one comment in response to the Notice of Proposed Rulemaking "Establishment of a Threshold for Gamma-Butyrolactone" published at 66 FR 53746. The comment generally supported the proposal and offered comments on specific issues.

The comment informed DEA that some tank truck shipments of bulk chemicals are made by single segmented compartments. The minimum weight of GBL distributed by these bulk shipments is 9,000 pounds or 4,086 kilograms. Therefore, under the proposed exclusion of bulk distributions of 16,000 kilograms (net weight), these 4,086 kilogram shipments would be regulated. DEA was not aware of the lower minimum bulk shipment at the time the exclusion was proposed. DEA determined that this lower net weight for bulk shipments would not pose a greater risk of diversion and, therefore, based on the comment received, is providing an exclusion for domestic, import, and export distributions of gamma-butyrolactone weighing 4,000 kilograms (net weight) or more in a single container. This action will eliminate all industrial distributions identified by DEA that are not at significant risk of diversion.

The commenter requested clarification as to whether a DEA Form 486 will continue to be required for bulk export shipments. A DEA Form 486 is necessary only for exports involving regulated transactions. If the transaction is excluded from the definition of a "regulated transaction" pursuant to 21

CFR 1310.08, a DEA Form 486 is not necessary. If the export does not meet the conditions in 21 CFR 1310.08, a DEA Form 486 is necessary.

The commenter requested clarification of the definition of "non-regulated transaction." A non-regulated transaction is specified in 21 CFR 1310.08 as an "excluded transaction" pursuant to 21 U.S.C. 802(39)(A)(iii). An excluded transaction is not subject to the recordkeeping or reporting requirements of 21 U.S.C. 830(a) and (b) except that 21 U.S.C. 830(b)(1)(C) applies to all regulated persons. That is, all regulated persons are required to report any unusual or excessive loss or disappearance of a listed chemical.

The definition of a "regulated person" is given at 21 U.S.C. 802(38) to include anyone who manufactures, distributes, imports, or exports a listed chemical, or acts as a broker or trader for an international transaction involving a listed chemical. Except for persons acting as brokers or traders for an international transaction, regulated persons handling any List I chemical are required to register pursuant to 21 U.S.C. 822. This registration requirement also applies to those regulated persons who are involved in only "excluded transactions." In the case of this final rule, persons who only distribute 4,000 kilograms (net weight) or more of GBL in a single container are not subject to recordkeeping and reporting requirements but are required to register. A regulated person does not include someone who receives a listed chemical and consumes it by making a chemical mixture, as defined at 21 U.S.C. 802(40), or changes the listed chemical into a non-listed chemical by means of a chemical reaction.

### *Regulatory Flexibility and Small Business Concerns*

This final rule will not have a significant economic impact on small business. Pub. L. 106-172 amended the CSA to make GBL a List I chemical effective February 18, 2000. Regulatory impact due to registration requirements was addressed in the final rule "Placement of gamma-butyrolactone in List I of the Controlled Substances Act (21 U.S.C. 802(34))" (65 FR 21645). In that final rule, DEA concluded that making GBL a List I chemical would not have a significant economic impact. That conclusion was based on an estimated number of new registrants and that all distributions in GBL are regulated. This final rule does not add new regulatory controls. In fact, it eliminates some large-scale industrial transactions from the definition of "regulated transaction," thus, granting

additional relief to industry. DEA identified 4,000 kilograms as the minimum amount available by tank-truck. DEA determined that clandestine operations will have difficulty handling tank-truck shipments but will be able to divert self-contained shipments of GBL, i.e., containers of 55-gallons or less. Therefore, DEA is exempting tank-truck sized shipments (4,000 kilograms or more, net weight) from the requirements of this regulation.

New 21 CFR 1310.04(g)(1)(v) and 1310.08(k) are being added in this final rule. The designations of these new paragraphs are different than what was originally proposed because the CFR has been modified since the proposal was published.

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the 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 not a "significant regulatory action" under Executive Order 12866, Section 3(f), Regulatory Planning and Review, and accordingly this rule has not 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 Civil Justice Reform.

### *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 \$100,000,000 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.