

DEA Chemical Regulatory Actions

DEA Chemical Industry Conference
October 31 – November 1, 2006
Louisville, Kentucky



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Agenda

- Implementation of the Combat Methamphetamine Epidemic Act of 2005
- Other chemical regulatory actions

Implementation of CMEA

- Retail sales/regulated sellers
- “Spot market” & foreign chain of distribution
- Quotas
- Others

Retail Sales/Regulated Sellers

- Interim Final Rule with Request for Comment
71 FR 56008, September 26, 2006
- Comment period ends November 27, 2006

Regulated Seller Requirements

- Self-certification
- Employee training & maintenance of records of training
- Daily sales limit
- Product packaging & placement
- Logbook requirements
- Warning notice
- Privacy protection

Self Certification

As of 10/24/2006

- 49,102 Regulated Sellers
 - 497 General Merchandise Stores
 - 2,687 Convenience Stores
 - 2,863 Discount Department Stores
 - 4,642 Gas Stations w/ Convenience Store
 - 5,974 Grocery Stores
 - 91 Other Health and Personal Care
 - 29,482 Pharmacy and Drug Stores
 - 7 Specialty Food Stores
 - 2,858 Warehouse Clubs and Superstores

Self Certification

As of 10/24/2006

● Top Five States

● 3,966

Florida

● 3,001

California

● 2,755

Texas

● 2,464

New York

● 2,052

Georgia

Regional Interest

● 1,067

Kentucky

● 1,367

Indiana

Mail Order Distributor Requirements

- Verification of identity of purchaser and recipient
- Monthly mail order reports to DEA
- Daily sales limit
- 30-day sales limit

“Spot Market”

- Importers, exporters, brokers and traders must provide additional information to DEA on the person(s) to whom chemicals proposed to be transferred
- After transaction completed, must provide return declaration to DEA with actual information on shipment/distribution
- Applies to all listed chemicals

Foreign Chain of Distribution

- Importers must provide to DEA all information known to the importer on the foreign chain of distribution from the manufacturer to the US importer
- Attorney General may seek other information from foreign manufacturers
- Applies to imports of ephedrine, pseudoephedrine, and phenylpropanolamine

Quotas

- CMEA requires establishment of production quotas for ephedrine, pseudoephedrine, phenylpropanolamine
- CMEA establishes import quotas for ephedrine, pseudoephedrine, phenylpropanolamine
- DEA must publish regulations to implement procedures for issuance of individual manufacturing and import quotas
- Publication of proposed Assessment of Annual Needs

Registration

- DEA must ensure that all persons who will need to apply for quota are registered with DEA to handle ephedrine, pseudoephedrine, phenylpropanolamine

Removal of Thresholds

- To ensure that DEA is aware of all importation and manufacturing involving ephedrine, pseudoephedrine, and phenylpropanolamine, all transactions must be captured
- Thresholds for ephedrine, pseudoephedrine, and phenylpropanolamine must be removed – reduced to zero

Other Regulatory Activities

- Sodium permanganate
- Iodine

Sodium Permanganate

- Final Rule 71 FR 60823, October 17, 2006
- Effective December 18, 2006
- Controls sodium permanganate as a List II chemical

Sodium Permanganate

- 55 kg threshold for domestic transactions
- 500 kg threshold for import, export, international transactions
- Chemical mixtures with concentration limits greater than 15% subject to control

Iodine

- Notice of Proposed Rulemaking 71 FR 46144, August 11, 2006
- Comment period closed October 10, 2006

Iodine

- Proposed moving iodine from List II to List I
- Proposed reducing threshold from 0.4 kg to zero kg – no threshold
- Proposed addition of import, export, international transaction controls
- Proposed chemical mixtures with concentration limits greater than 2.2% be subject to control

Questions

