Drugs & Chemicals
Quotas

Minh T. Dang
United Nations & Quota Section
Drug Enforcement Administration
United States CSA - Historical Perspective:

- Pure Food and Drug Act, 1906 (labeling)
- Narcotic Manufacturing Act
- Single Convention, 1961
- Vienna Convention, 1971
- Chemical Convention, 1988
- Drug Abuse Control Amendments 1965
- Harrison Narcotic Act, 1914 - (licensure and record-keeping)
- Psychotropic Substances Act, 1978

Controlled Substance Act (CSA) 1970
Controlled Substance Act (CSA)

**Schedule I** - MDMA, LSD, Heroin, Bath Salts, Spice etc
Substances with high abuse potential and no medical utility (most restrictive)

**Schedule II** - oxycodone, hydrocodone, fentanyl etc
Substances with high abuse potential and medical utility

**Schedule III, IV and V** - codeine, barbiturates etc
Substances with medical utility in the U.S. and progressively lower levels of abuse potential

**Regulated Chemicals** - isosafrole, piperidine, ephedrine, pseudoephedrine, PPA etc.
Chemicals used to make drugs

Close System of Distribution
Ephedrine/Pseudoephedrine

\[
\text{H} \quad \text{N} \quad \text{CH}_3
\]

\[
\text{CH} - \text{CH} - \text{CH}_3
\]

\[
\text{OH}
\]

EPHEDRINE OR PSEUDOEPHEDRINE
Methamphetamine Epidemic
DRUG LABS

DANGERS
• Chemical hazards
• Explosive hazards
• Poisonous Gases
• Booby Traps
Combat Methamphetamine Epidemic Act (CMEA)

- Signed into law March 9, 2006
- Added **quota** requirements to:
  - Pseudoephedrine
  - Ephedrine
  - Phenylpropanolamine
- Created Importation quota (PE, E, PPA)
- Amended 21 U.S.C. 826, 844, and 952
Which drugs require quotas?

Schedule I & II CS (CSA)

- substances with the highest abuse potential

3 List I Chemicals (CMEA)

- Ephedrine, Pseudoephedrine & PPA
  substances which can be used to make methamphetamine
Purpose of Quotas

- Establishes the upper ceiling of production for Schedule I & II CS and PE, E, and PPA for the US.
- Provide for legitimate need for schedule I & II CS and for the three list I chemicals (PE, E, and PPA).
- Restrict the manufacture and procurement to those manufacturers registered by the DEA
- Provide for inventory allowance
Who Needs QUOTAS?

- **Manufacturers**
  - Schedule I & II Controlled Substances & ephed, pseudo, PPA
    - Includes **bulk manufacturers** (manufacturers of API)
    - Manufacturers of dosage units
    - *Packagers, repackagers, labelers & relabelers*

- **Importers**
  - ephedrine, pseudoephedrine & PPA
    - Includes importers of BULK and Dosage Units
Combat Meth Epidemic Act (CMEA)
**US Quotas (AAN) in Kg**

<table>
<thead>
<tr>
<th></th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>% decrease 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ephedrine</td>
<td>11,500</td>
<td>3,400</td>
<td>3,900</td>
<td>4,200</td>
<td>4,300</td>
<td>3,500</td>
<td>-70%</td>
</tr>
<tr>
<td>(for sale)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pseudoephedrine</td>
<td>511,100</td>
<td>390,000</td>
<td>404,000</td>
<td>280,000</td>
<td>278,000</td>
<td>225,000</td>
<td>-56%</td>
</tr>
<tr>
<td>PPA</td>
<td>5,545</td>
<td>4,900</td>
<td>7,400</td>
<td>5,300</td>
<td>5,800</td>
<td>6,100</td>
<td>+10%</td>
</tr>
<tr>
<td>(for sale)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PPA</td>
<td>85,470</td>
<td>62,000</td>
<td>17,800</td>
<td>21,800</td>
<td>26,200</td>
<td>25,700</td>
<td>-70%</td>
</tr>
<tr>
<td>(for conversion)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ephedrine</td>
<td>128,760</td>
<td>120,000</td>
<td>75,000</td>
<td>18,600</td>
<td>12,000</td>
<td>15,100</td>
<td>-88%</td>
</tr>
<tr>
<td>(for conversion)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Q:** How much pseudoephedrine would be required to provide every man/woman/child/baby (315 mil) in the US with one 30 mg tablet?  
**A:** 7,749 kg
Ephedrine (for sale)

Year | Requested | AAN | Granted
--- | --- | --- | ---
2008 | 16,264 | 11,500 | 1,819
2009 | 9,451 | 3,400 | 2,214
2010 | 3,952,909 | 2,533 | 3,698
2011 | 4,200 | 2,543 |
Methamphetamine Seizures
(Includes Labs, dump sites, glassware and equipment seizures)
Clandestine Laboratories

Heroin Lab - Afghanistan

Meth Labs – United States

Ecstasy Lab - Belgium

Other Labs DEA addresses:
- Fentanyl
- MDMA
- Cocaine
- Heroin
- SPICE/Bath Salts
- PCP etc...
APQ/AAN

- Upper limit of national production and importation requirements
- Established annually with revision(s)
- Federal Register notices required
*Procurement

Import

Bulk Manufacture

*Packaging/Labeling are not counted against the AAN
Federal Registers and the APQ/AAN

1. Proposed Initial APQ Comment period

2. Established initial APQ

3. Proposed Revised APQ Comment period

4. Established Final APQ
Overview of Procedure for Setting the APQ/AAN

• To develop the APQ/AAN:
  – Applications
  – Sales/Utilization
  – Inventory
  – Demand
  – FDA Estimates
Quota Types Summary

**PROCUREMENT**
- DEA Form 250
- Dosage form MFG
- Packagers
- Labelers
- Repackager
- Relabelers

**MANUFACTURING**
- DEA Form 189
- Bulk Manufacturers

**IMPORT**
- DEA 488 & Form A
- Chemical Importers
Manufacturing Quotas

- Registered bulk manufacturer
- Upper Ceiling of Production
- Quota adjustments
Procurement Quotas

- DEA registered manufacturers
- Establishes maximum amount which may be acquired in a calendar year
- Certification of adequate quota 21 CFR 1303.12(f) & 1315.32(h)
- Quota adjustments
Import Quotas

- DEA registered importer
- Only applies to pseudo, ephedrine and PPA
- Establishes maximum amount – for import
- Quota adjustments
- DEA 488 (Import Quota)
  - Form A – Customer List
- DEA 486a - Import Declaration (E, PSE, PPA) to import into US for these substances
Controlled Substances & Chemicals Lists

* Controlled Substances Act (CSA)
* Federal Register Notices
* Diversion Website
  www.deadiversion.usdoj.gov
* Drug & Chemical Evaluation Section
  analogues, salts, isomers (202) 307-7183
How to Apply

• DEA Registration
• Apply Online
• Adjustments
• Justifications
Questions

Minh T. Dang
United Nations & Quota Section
Drug Enforcement Administration

Minh.T.Dang@usdoj.gov
202-307-4860