



Virtual Chemical Industry Conference

Quota Update

UN Reporting & Quota Section

April 30, 2025



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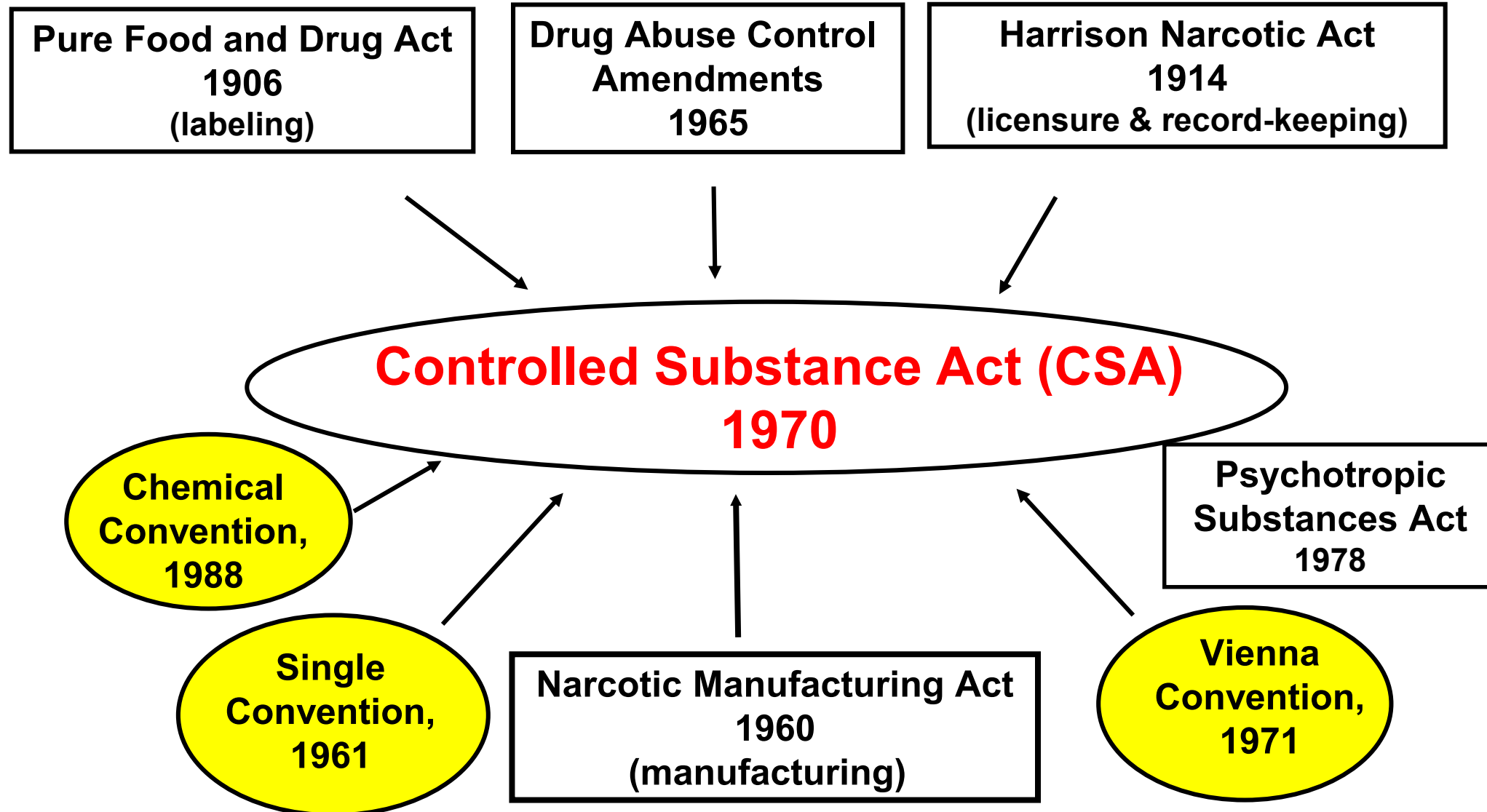
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Controlled Substance Act (CSA)



Levels of Drug Control under the CSA



Schedule I (CI)

Substance with **high** abuse potential and **no** currently accepted medical use

- *Examples: GHB, MDMA, Heroin*
- **Subject to Manufacturing and/or Procurement Quota**

Schedule II (CII)

Substances with **high** abuse potential but has a **currently accepted** medical use in treatment

- *Examples: e.g., Fentanyl, Hydrocodone, Morphine, Oxycodone.*
- **Subject to Manufacturing and/or Procurement Quota**

Schedule III, IV and V

Substances with a currently accepted medical use in treatment, but progressively lower levels of abuse potential, dependence profile and regulatory controls from Schedule III to Schedule V.

- *Examples: NaGHB (sodium oxybate), Ketamine, Buprenorphine, Benzodiazepines.*
- Not subjected to quota

CMEA List I Chemicals

Precursor chemicals used for manufacture of cough & cold medicines and veterinary products, but can also be used for illicit manufacture of methamphetamine & amphetamine

- *Examples: Ephedrine (EPH), Pseudoephedrine (PSE) & Phenylpropanolamine (PPA)*
- CMEA = Combat Methamphetamine Epidemic Act (CMEA)
- **Subject to Manufacturing, Procurement and/or Import Quota**

Combat Methamphetamine Epidemic Act (CMEA)



- Signed into law March 9, 2006
- Added quota requirements for the manufacture and importation of:
 - Ephedrine
 - Pseudoephedrine
 - Phenylpropanolamine
- Created Import quota for these substances

Purpose of Quotas

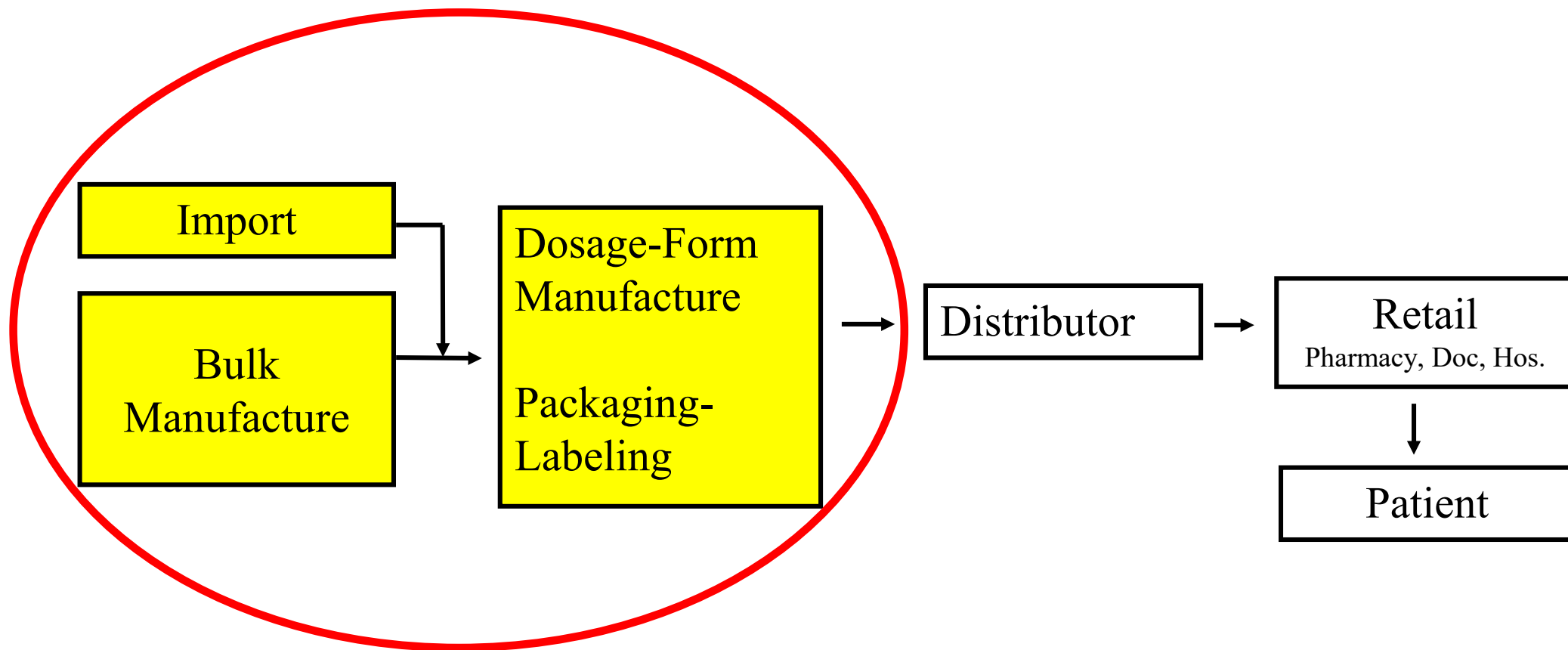


- Ensure the quantity of manufacturing and procurement of Schedule I and II controlled substances and CMEA List I chemicals, and importation of CMEA List I chemicals are sufficient to provide for legitimate medical, scientific, research, industrial needs of the U.S., as well as lawful export requirements, while reducing the risk of diversion
- Restrict the above manufacture, procurement and import to DEA registered manufacturers and importers
- Provide adequate inventories to support legitimate needs

Pharmaceutical Distribution Chain



QUOTAS



Which Substances Require Quotas



Schedule I & II Controlled Substances (CSA)

- Substances with a high abuse potential

Ephedrine, Pseudoephedrine & PPA (CMEA)

- Substances which can be used to make methamphetamine & amphetamine

Which Activities Require Quotas



Manufacturing

- Schedule I & II CS & ephedrine, pseudo & PPA
- Includes dosage form and bulk manufacturing
- Including packaging, repackaging and labeling & relabeling

Importing

- ephedrine, pseudoephedrine & PPA
- includes bulk API and finished dosage units

Procurement Quotas



- Establish the maximum amount an individual manufacturer may purchase in a calendar year
- Manufacturers cannot purchase amounts exceeding the procurement quota
- Only DEA registered manufacturers with the specific CI or CII drug codes can receive procurement quotas

Import Quotas



- Establishes maximum amount which the individual importer can *import* in a *calendar year*
- Only applies to listed chemicals EPH, PSE and PPA
- Only DEA registered importer can receive import quotas
- Importers cannot exceed import quota

Assessment of Annual Needs (AAN) & Aggregate Production Quota (APQ)



- AAN - upper ceiling of production for ephedrine, pseudo & PPA
- APQ - upper ceiling of production for CI & CII
- AAN & APQ established annually with one revision
- AAN & APQ provide for the estimated medical, scientific, industrial and export needs for the US

Chemical Quotas

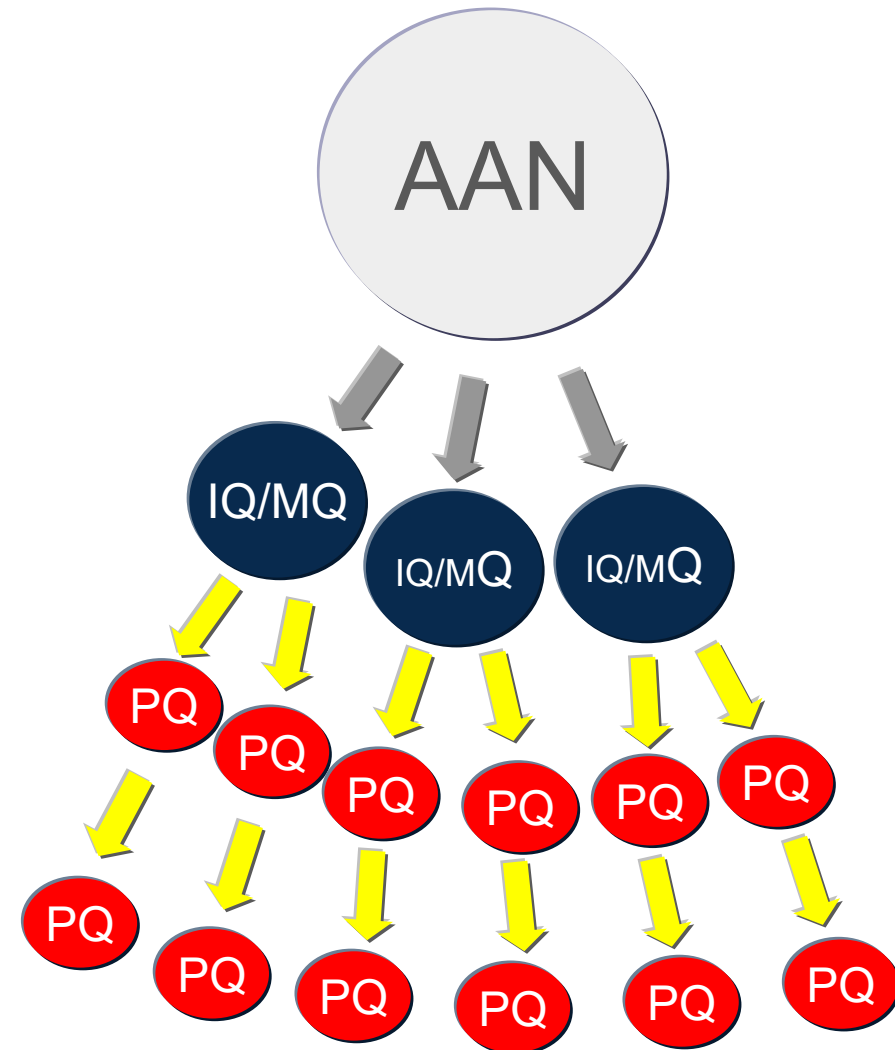


AAN – Assessment of Annual Need
Upper Ceiling of Production (ephedrine, pseudo & PPA)

IQ/MQ – Import/Manufacturing Quota
Bulk, Dosage Units and products containing

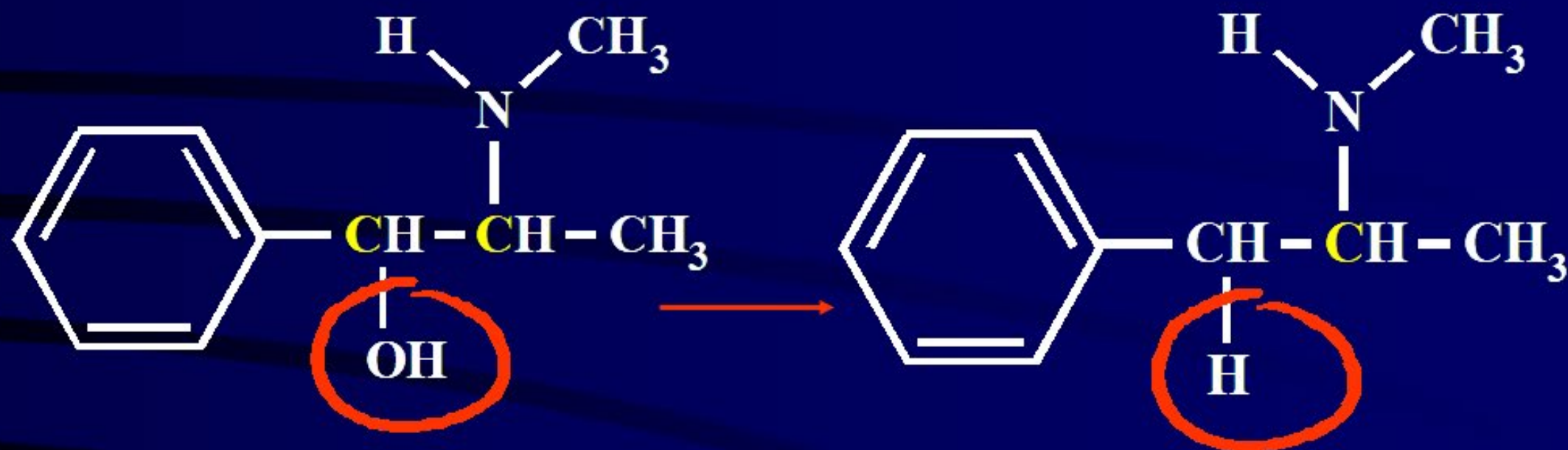
PQ –Procurement Quota
Dosage form manufacturing

PQ –Procurement Quota
Packaging/Labeling



*Packaging/Labeling are not counted against the AAN

Methamphetamine Manufacture



EPHEDRINE
OR PSEUDOEPHEDRINE

METHAMPHETAMINE

Reduction of ephedrine/pseudoephedrine to methamphetamine

Methamphetamine Epidemic



Trends



	2008 AAN (1 st year CMEA)	2025 AAN	Percent Change
Ephedrine (for sale)	11,500	3,933	-66%
Pseudoephedrine (for sale)	511,100	186,617	-64%



Super Lab



One Pot Lab

Quota Applications



PROCUREMENT

- DEA Form 250
- Dosage form Manufacturers
- Packagers/Labelers

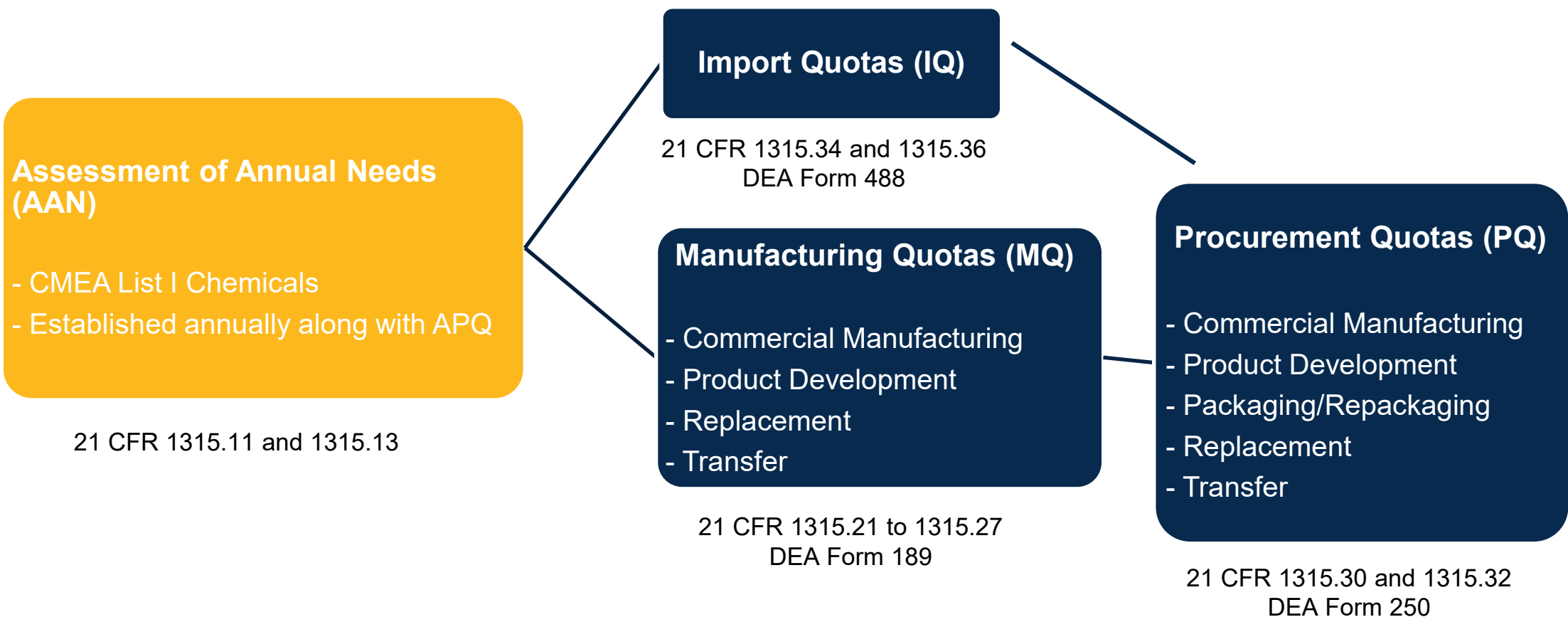
MANUFACTURING

- DEA Form 189
- Bulk Manufacturers


IMPORT

- DEA Form 488 & worksheet A
- Importers of ephedrine, pseudo & PPA

Types of Quotas and Subcategories For CMEA List I Chemicals Pursuant to 21 CFR Part 1315



Quota Applications



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL DIVISION

Application for Quota Allotment

Instructions

Each year the United States sets the Aggregate Production Quotas (APQ) for Schedule I and II controlled substances and the Annual Assessment of Needs (AAN) for the Combat Methamphetamine Epidemic Act (CMEA) List I chemicals -- ephedrine, pseudoephedrine, and phenylpropanolamine -- which determine the annual quantities of controlled substances and List I chemicals available for national medical, scientific, and industrial use.

The following entities must apply for a quota:

- Manufacturers of Schedule I and II controlled substances.
- Manufacturers of the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.
- Importers of the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

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