

Quota Overview



UN Reporting and Quota Section
(ODQ)

Three International Conventions

- Single Convention on Narcotic Drugs, 1961
- Convention on Psychotropic Substances, 1971
- Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988

US is a party to all three treaties

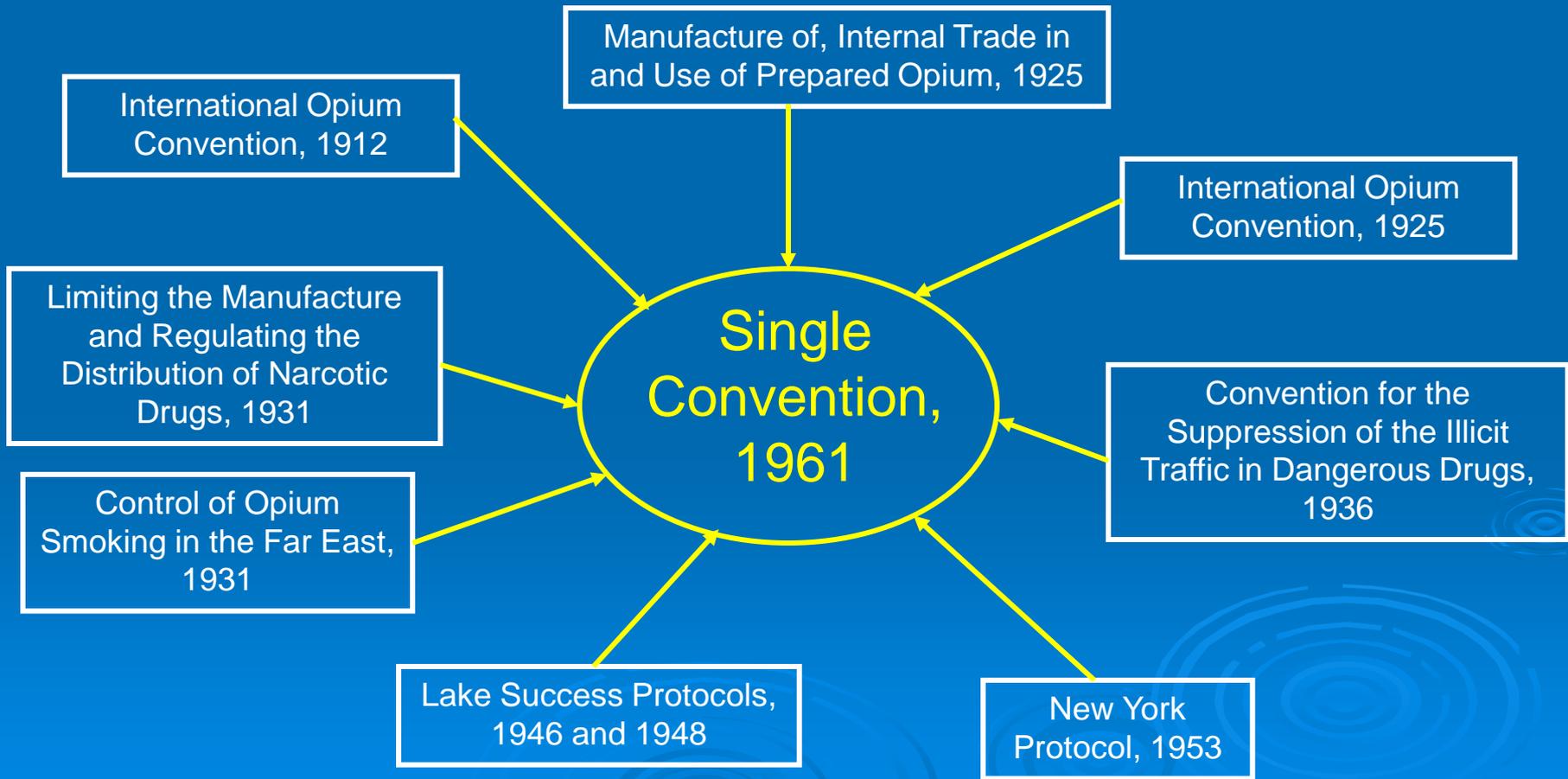
Goal: Limit the use of narcotic drugs and psychotropic substances and their precursors to legitimate medical and scientific purposes.

The Single Convention

- Single Convention on Narcotic Drugs
- Adopted March 30, 1961
- Entered into force, 1964
- This convention is specifically mentioned in the preamble and other parts of the Controlled Substances Act (CSA)
- Also referred to as the “61 Convention”

**List of Controlled Substances:
“Yellow List”**

'61 Convention - Historical Perspective: Agreements, Conventions, and Protocols



The '61 Convention

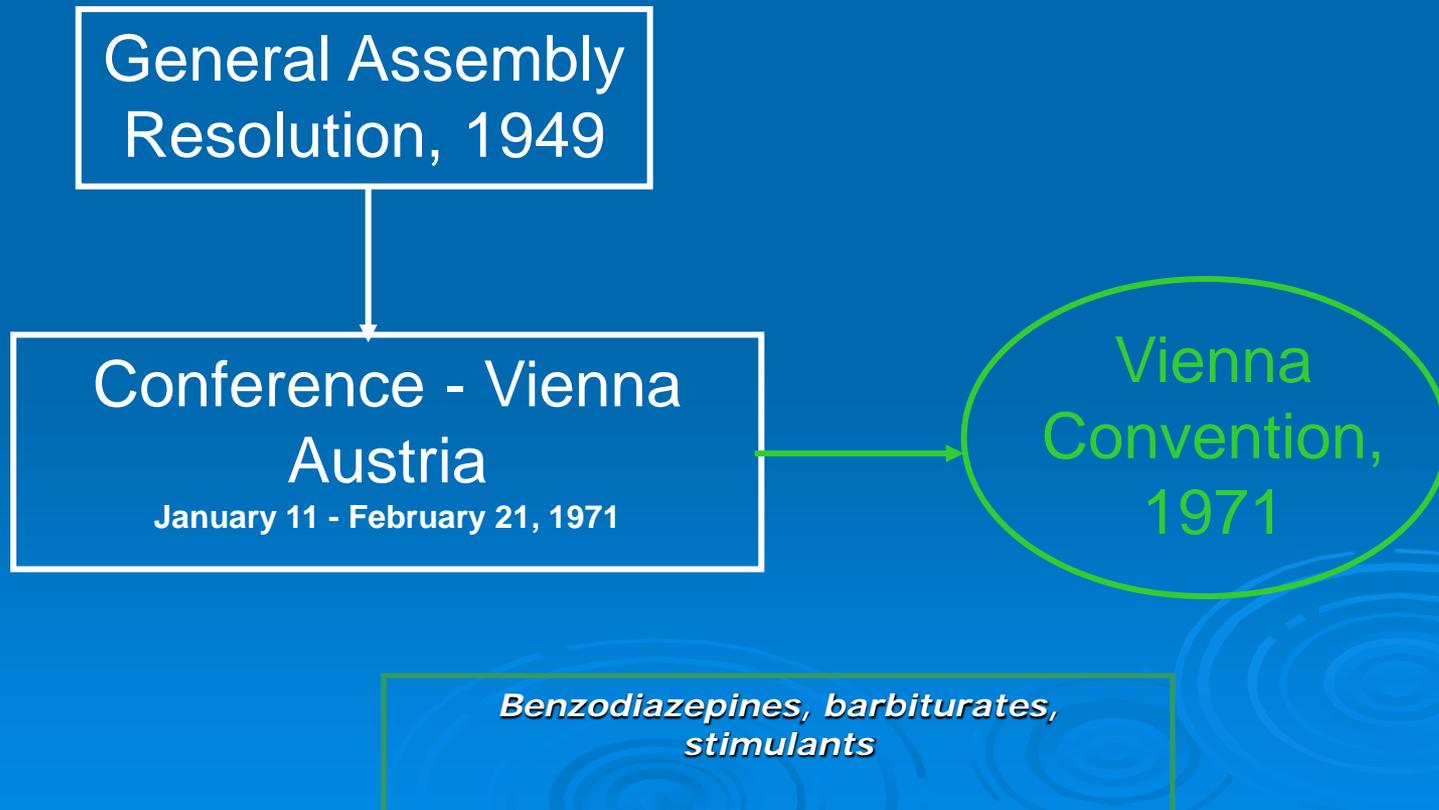
- **119** specific Narcotic drugs controlled
 - Includes **opium** and its derivatives
ex. morphine, codeine, heroin
 - Includes **synthetic opiates**
ex. meperidine, fentanyl
 - Includes **cannabis** and **coca**
ex. cocaine/ecgonine
- Legal, not pharmacological definition of narcotic
- Controls extended to isomers, esters/ethers, salts thereof, whenever existence is possible

The Psychotropic Convention

- Convention on Psychotropic Substances 1971
- Adopted in 1971 (Vienna, Austria)
- Entered into force, August 16, 1976
- Designed to control psychoactive drugs
- Ratified by US in 1980
- Referred to as the “71 Convention”

**List of Controlled Substances:
“Green List”**

'71 Convention - Historical Perspective



The '71 Convention

- **116** Psychotropic substances controlled
 - MDMA, LSD, 2,5-DMA
 - *delta*-9-tetrahydrocannabinol (d-9-THC),
dextroamphetamine, levamphetamine and
amphetamine are listed separately
 - Pentobarbital, Buprenorphine
 - Benzodiazepines, Phendimetrazine
- Controls do not always extended to isomers

1988 Convention

- Entered into force in 1990
- It provides the legal basis for the international control of precursors and essential chemicals used in the illicit manufacture of drugs.
- Requires each party state to put mechanisms in place to control manufacturing activities and distribution of these chemicals.

List of Controlled Chemicals:

“Red List”

The Controlled Substances Act

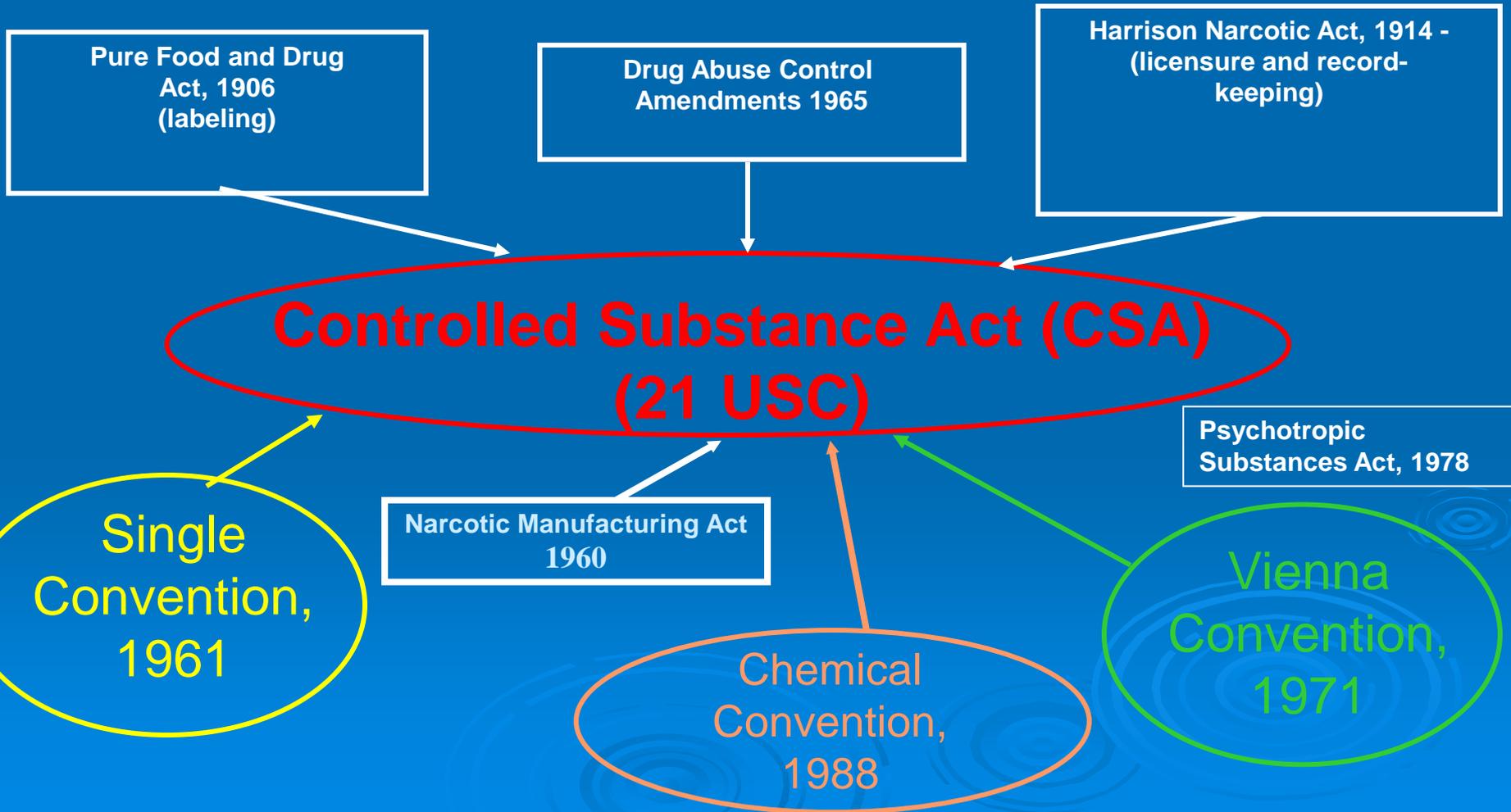
- Enacted in 1970

- Federal policy under which activities of controlled substances are regulated
- Amended in 2005 to include the CMEA chemicals

- Substances Covered:

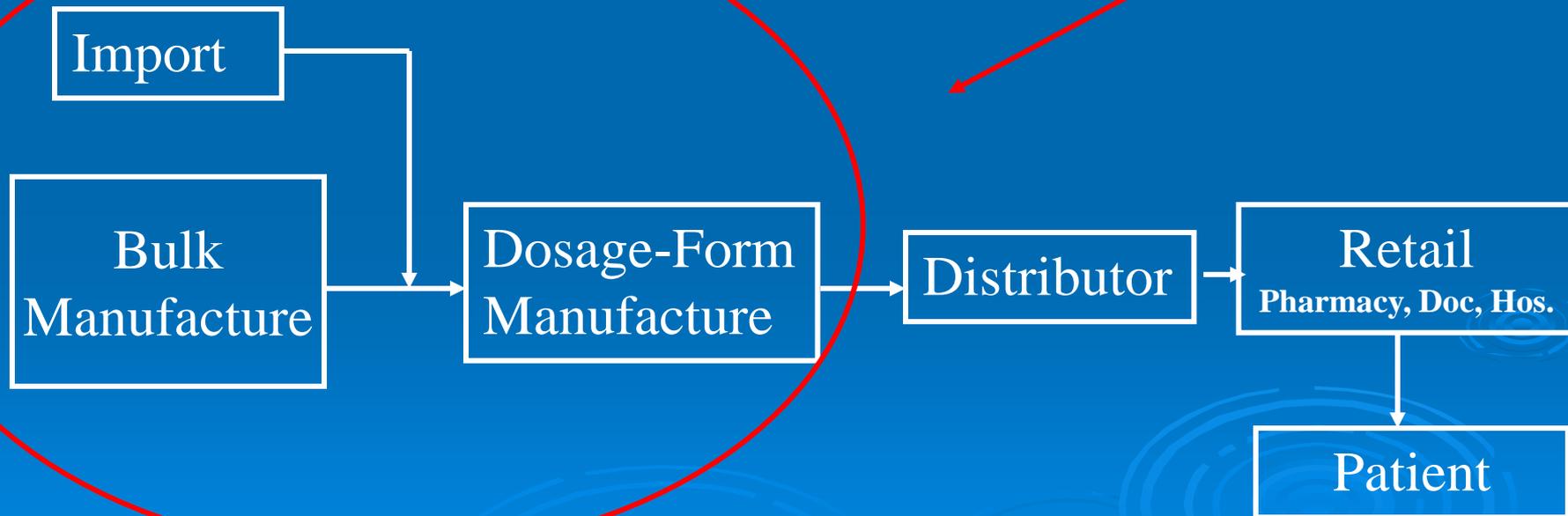
- All substances on the “yellow” and “green” lists
- “...derivatives, its salts, isomers, and salts of isomers.”
- Anabolic Steroids
- “red” list 1 chemicals – ephedrine, pseudoephedrine, phenylpropanolamine

CSA - Historical Perspective:



The CSA creates a tightly controlled “closed system” of drug distribution.

Preventing diversion at this level of drug distribution is paramount to the success of the Diversion Program



Quota Management

- Controlled Substances Act of 1970
 - Requirements established in Section 306(a) of CSA for Schedule I and II
 - 21 USC 826
- Regulations pursuant to
 - 21 CFR Part 1303
 - 21 CFR Part 1315

Purpose of Quotas

- Provide for legitimate need of controlled substances
- Restrict the manufacture and procurement to those manufacturers registered by DEA
- Limit the quantity of drugs in Schedules I and II which may be manufactured or produced
- Provide adequate inventories

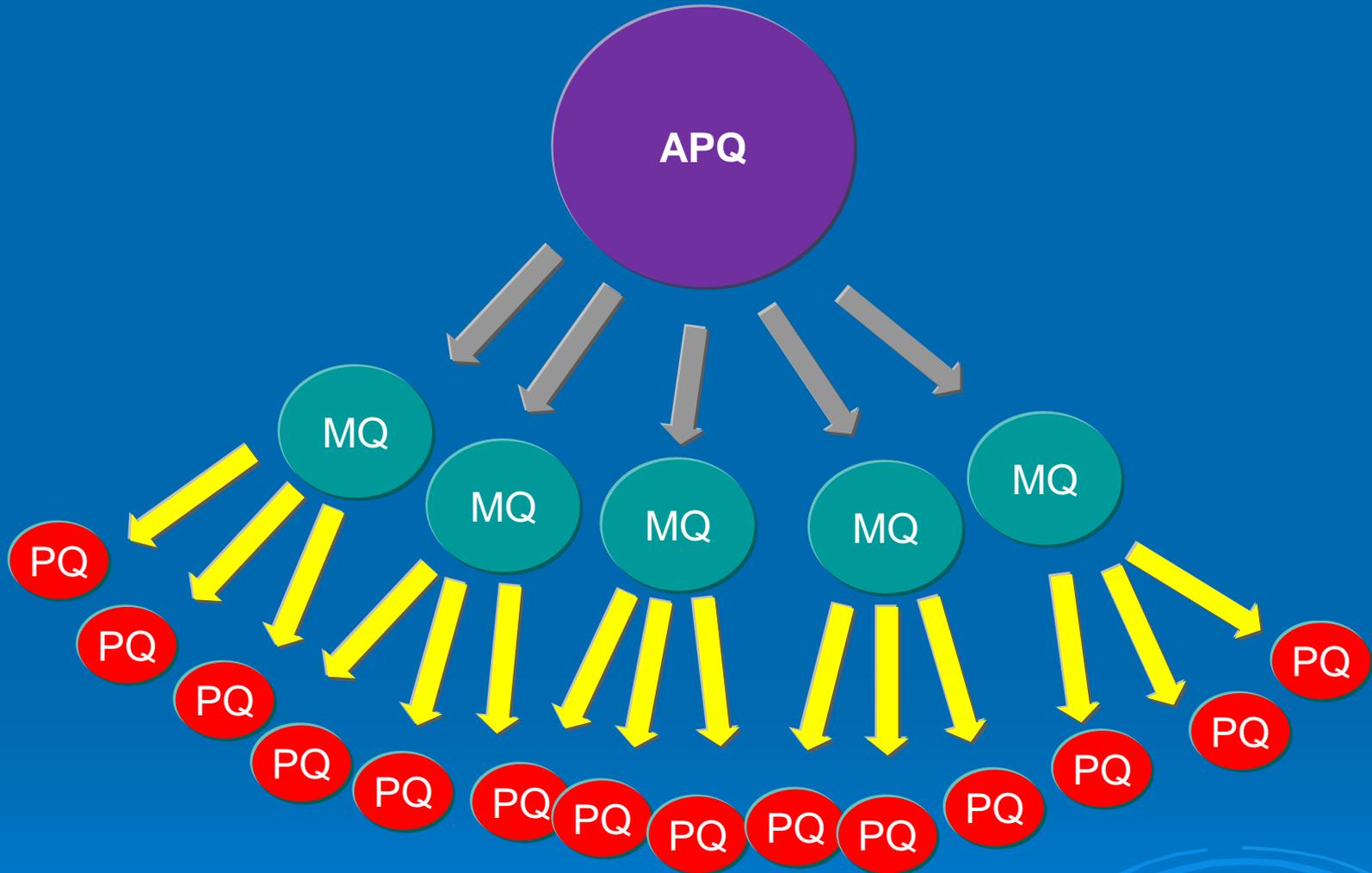
CSA Levels of Drug Control

- Schedule I – **NEED QUOTA**
 - Substances with high abuse potential and no medical utility (most restrictive)
- Schedule II – **NEED QUOTA**
 - Substances with high abuse potential and medical utility
- Schedule III, IV, and V –
 - Substances with medical utility in the U.S. and progressively lower levels of abuse potential, dependence profile and regulatory controls
- CMEA List 1 chemicals - **NEED QUOTA**
 - Substances used for manufacture of cough & cold medicines and vet products. Can also be used for manufacture of methamphetamine & amphetamine

Quota Requirements Schedule I and II Controlled Substances

- **Aggregate Production** Quotas
(21 CFR 1303.11 and 1303.13)
- **Individual Manufacturing** Quotas
(21 CFR 1303.21 through 1303.27)
- **Procurement** Quotas
(21 CFR 1303.12)

APQ-MQ-PQ



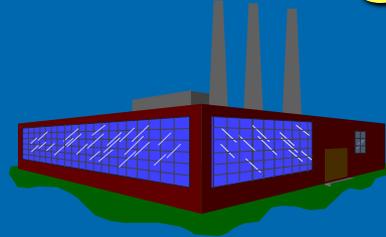
*Packaging/Labeling are not counted against the APQ/AAN

Aggregate Production Quotas

- Upper limit of national production
- Established annually with possible revisions during the calendar year
- Federal Register notices required
- Schedules I and II controlled substances (basic classes)



Manufacturing Quotas

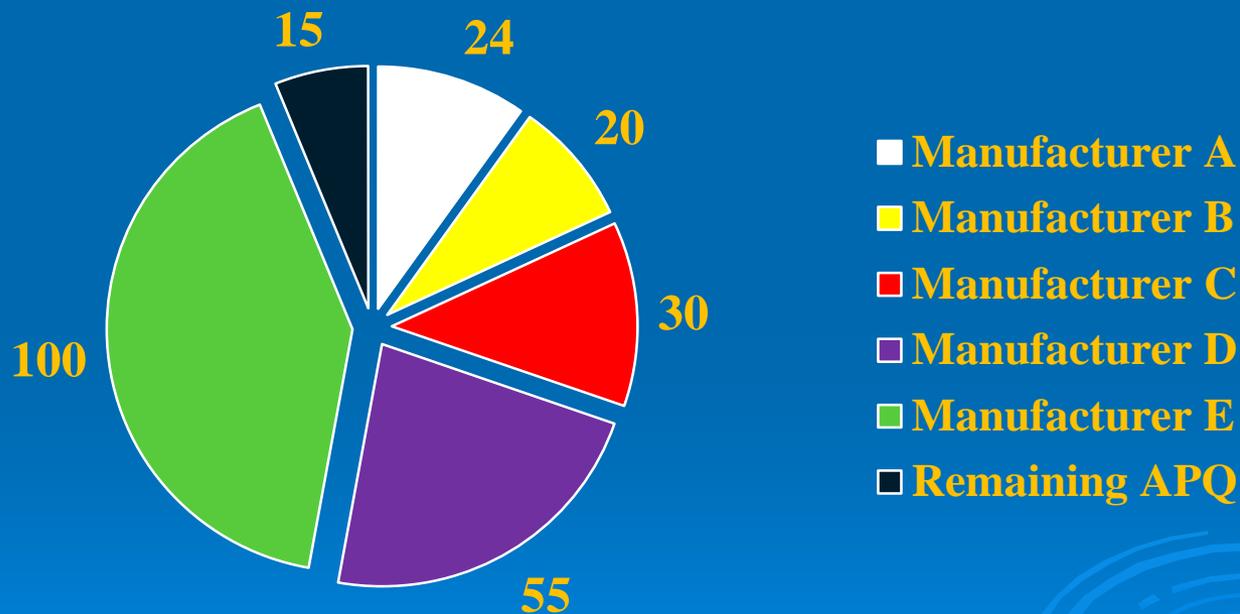


Establish the **maximum** quantity to be manufactured by **Bulk manufacturers** of Schedules I and II controlled substances whose methods include:

- Extraction from plant material i.e. coca leaf, opium, poppy straw concentrate
- Synthetic routes i.e. hydrocodone from codeine

Relationship Between Aggregate and Manufacturing Quotas

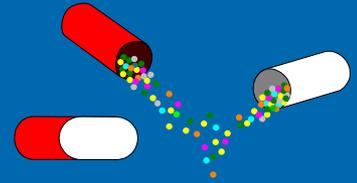
APQ = 244 kg



Manufacturing Quota Inventory Allowance

- 21 CFR 1303.24
- Normally 50% of average net disposals for current and preceding year
- During calendar year may not exceed 65% of estimated net disposal
- Exceeding 65% will suspend quota until inventory is less than 60% of net disposals

Procurement Quotas



- Establish the maximum quantity to be **procured** by manufacturers who require a Schedule I or II controlled substance, or List 1 chemical for the purposes of:
 - Converting bulk API into finished dosage forms
 - Formulating products such as exempt chemical preparations or reference standards
 - Packaging, repackaging, labeling or re-labeling a commercial container or dosage form

PQ always received for these activities

Combat Methamphetamine Epidemic Act 2005 (CMEA)

Enacted on March 9, 2006

Pseudoephedrine, Ephedrine, and
Phenylpropanolamine

- Additional legislative and regulatory controls on the manufacture, distribution, importation, and exportation of these List 1 chemicals
- Registration now required for each physical location (manufacturer, distributor, importer or exporter)

Import Quota

- List 1 chemical importers for the purposes of:
 - Distributing bulk API to a registered manufacturer
 - Distributing finished dosage forms for legitimate medical and scientific needs

IQ always received for these activities

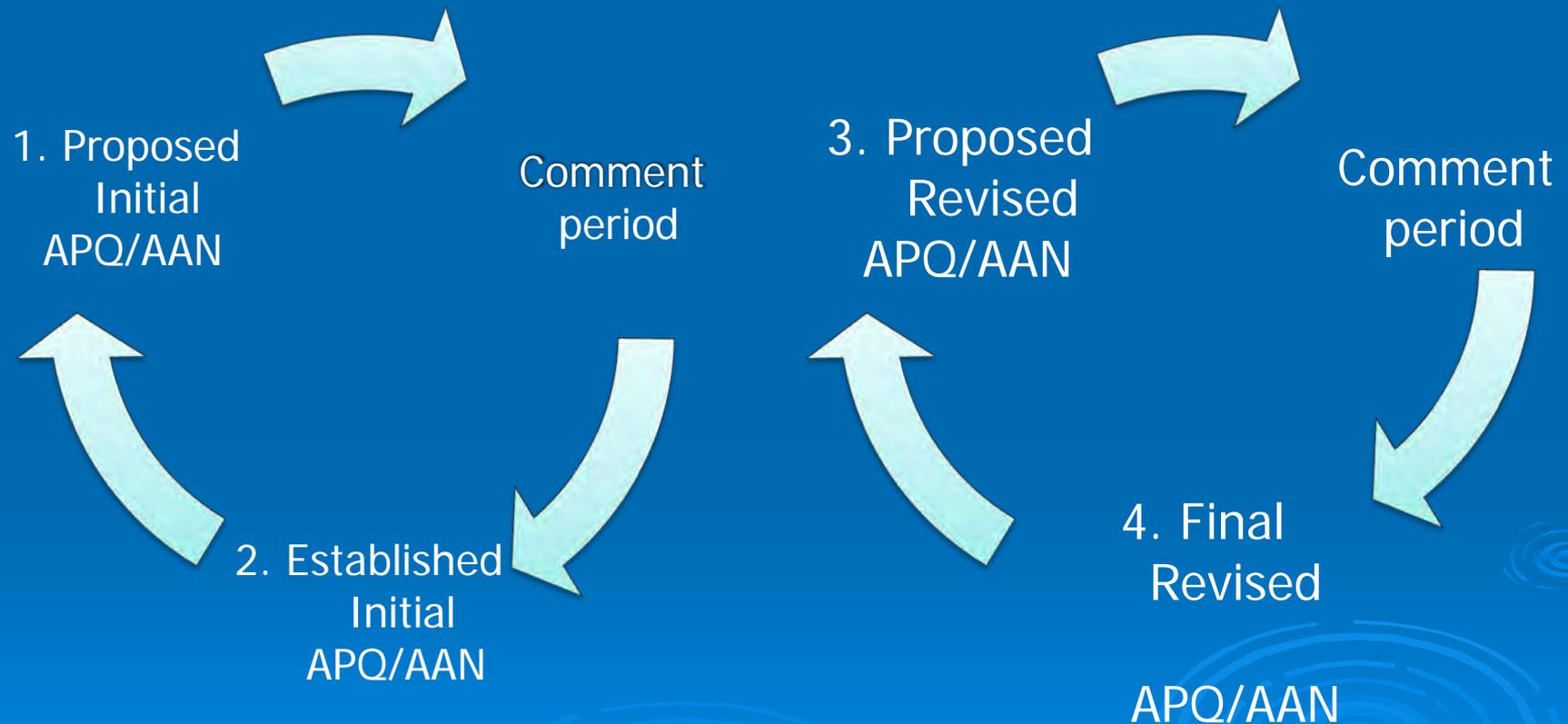
Quota Provisions of CMEA

- Bulk manufacturers who synthesize EPH, PSE and PPA must obtain a manufacturing quota (DEA-189).
- Manufacturers who purchase EPH, PSE and PPA must obtain a procurement quota (DEA-250).
 - Dosage form manufacturers, packagers, labelers, re-packagers and re-labelers
- Importers who import EPH, PSE and PPA (or products containing EPH, PSE, and PPA) must obtain an import quota (DEA-488).

CMEA Quota Requirements

- **Assessment of Annual Needs**
(21 CFR 1315.11 and 1315.13)
- **Individual Manufacturing Quotas**
(21 CFR 1315.21 through 1315.27)
- **Procurement Quotas**
(21 CFR 1315.30 and 1315.32)
- **Import Quotas**
(21 CFR 1315.34 and 1315.36)

Aggregate Production Quotas (APQ) Assessment of Annual Needs (AAN) Federal Registers



Benefits of web-based applications

- Registration verified as active and current
- Correct drug code is listed on registration
- Historical data preloaded into forms
- Program performs calculations
- Surety of receipt

Online Quota Application

- Procurement applications due by April 1
- Import applications due by April 1
- Manufacturing applications due by May 1
- Quantities reported should expressed as:
 - Anhydrous acid, base or alkaloid
 - GRAMS
- Adjustments to any quota can be requested throughout the year

Online Quota Application

Must request specific optical isomers:

- **Amphetamine**
 - d-amphetamine
 - l-amphetamine
 - d,l-amphetamine
- **Methamphetamine**
 - d-methamphetamine
 - l-methamphetamine
 - d,l-methamphetamine
- **Tetrahydrocannabinols**
 - Delta-9-THC
 - All Other Tetrahydrocannabinols

Online Quota Application

“For Sale” vs. “For Conversion”

- Codeine
- D-Amphetamine
- D-Methamphetamine
- Diphenoxylate
- Hydrocodone
- Morphine
- Noroxymorphone
- Oxycodone
- Oxymorphone

Online Quota Application

For Sale: substance used to manufacture products containing same basic class obtained from the bulk manufacturer.

- involves ~95% of the quota applications

ex: Codeine (for sale) → codeine/APAP

For Conversion: substance used to synthesize a different basic class.

ex: Codeine (for conversion) → hydrocodone

Sub Category Determinations

Product Development

- Non-FDA approved dosage forms
- Experimental
- Pivot
- Stability
- Exhibit
- Scale up
- Registration
- Validation

Commercial

- FDA approved dosage forms
- Launch quotas

Year-end Reporting

Reports need to be completed by:

- DEA REGISTERED MANUFACTURERS
 - Schedule I and II controlled substances
 - Psychotropic drugs

- ★ • DEA REGISTERED LIST 1 IMPORTERS ★
 - Ephedrine
 - Pseudoephedrine
 - Phenylpropanolamine

Year-end Reporting

- Due by January 31
- A separate report is required for each substance for which:
 - quota was issued for the prior CY
 - inventory was carried over from an earlier CY
- Quantities reported should be expressed as:
 - Anhydrous acid, base or alkaloid
 - In GRAMS

UN Psychotropic Substance Report

- For specified psychotropic substances in UN Schedules III and IV, member countries can voluntarily submit statistics to UN
 - Check the DEA Diversion web site (www.deaiversion.usdoj.gov)
 - Check the INCB web site (www.incb.org)
- Bulk and non-bulk manufacturers should report.

Psychotropic Substances to be Reported

71 Schedule III:

- Buprenorphine
- Butalbital
- Cathine
- Cyclobarbitol
- Flunitrazepam
- Pentazocine

71 Schedule IV:

- Allobarbitol
- Alprazolam
- Barbitol
- Benzphetamine
- Bromazepam
- Brotizolam
- Camazepam
- Chlordiazepoxide
- Clobazam
- Clonazepam
- Clorazepate

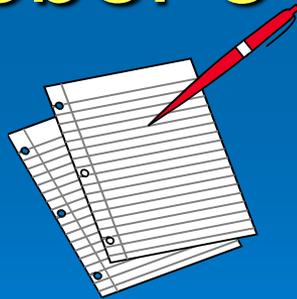
- Clotiazepam
- Cloxazolam
- Delorazepam
- Diazepam
- Diethylpropion
- Estazolam
- Ethchlorvynol
- Ethinamate
- Ethyl loflazepate
- Fencamfamin
- Fenproporex
- Fludiazepam
- Flurazepam
- Halazepam
- Haloxazolam
- Ketazolam
- Loprazolam
- Lorazepam
- Lormetazepam
- Mazindol
- Medazepam
- Mefenorex

- Meprobamate
- Mesocarb
- Methylphenobarbital
- Methypylon
- Midazolam
- Nimetazepam
- Nitrazepam
- Nordazepam
- Oxazepam
- Oxazolam
- Pemoline
- Phendimetrazine
- Phenobarbital
- Phentermine
- Pinazepam
- Pipradrol
- Prazepam
- Pyrovalerone
- Secbutabarbitol
- SPA (lefetamine)
- Temazepam
- Tetrazepam
- Triazolam
- Vinylbital
- Zolpidem

International Organizations

- International Narcotics Control Board (INCB)
 - <http://www.incb.org>
- Commission on Narcotic Drugs (CND)
 - <http://www.unodc.org/unodc/en/commissions/CND/index.html>
- World Health Organization (WHO)
 - www.who.org
- United Nations Office on Drugs and Crime (UNODC)
 - <http://www.unodc.org>

Clarification of Coincident
Activities **Federal Register**
October 31, 1995



Researcher Coincident Activities

21 CFR 1301.13(e)(1)



➤ Schedule I:

- Manufacture or import substances for research purposes as set forth in approved protocol
(21 CFR 1301.18)
- Distribute to persons registered to conduct research or chemical analysis

Researcher Coincident Activities

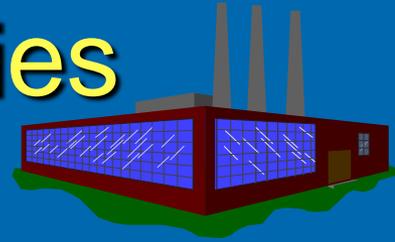
21 CFR 1301.13(e)(1)



- Schedules II through V:
 - chemical analysis
 - manufacture as set forth in statement
 - import substances for research purposes
 - distribute to persons registered to conduct research, chemical analysis, instructional activities

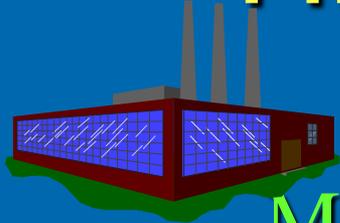
Manufacturer Coincident Activities

21 CFR 1301.13(e)(1)



- Schedule I through V:
 - distribute a substance or class for which registration was issued
- Schedule II through V:
 - conduct chemical analysis and preclinical research with substances authorized to manufacture

Historical Determinations



Manufacturing



Research

- Validation
- Dosage forms for approval and testing, including clinical trials
- Stability
- Exhibit batches
- Rework processes
- Granulation development

- Process parameters in laboratory
- Adhesive studies
- Laboratory testing
- Dosage release rate studies
- Clinical trials
- Synthesis route

Information

- ❖ www.deadiversion.usdoj.gov
 - ❖ Reporting
 - ❖ Quotas
 - ❖ Year-End Reports
 - ❖ Resources
 - ❖ List of Controlled Substances
 - ❖ Conversion Factors
- ❖ [ODE Quota@usdoj.gov](mailto:ODE_Quota@usdoj.gov)
 - ❖ [\(202\) 307-7184](tel:(202)307-7184)