DRUG ENFORCEMENT ADMINISTRATION

Quota Virtual Diversion Awareness Training

April 7, 2026

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Aggregate Production Quotas, Assessment of Annual Needs, and Individual Quotas

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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*
- **Subjected 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.*
- **Subjected 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 – finished product), 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)
- **Subjected to Manufacturing, Procurement and/or Import Quota**

Purpose of Quotas

- **Ensure the quantity of manufacturing and procurement of Schedule I and II 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**

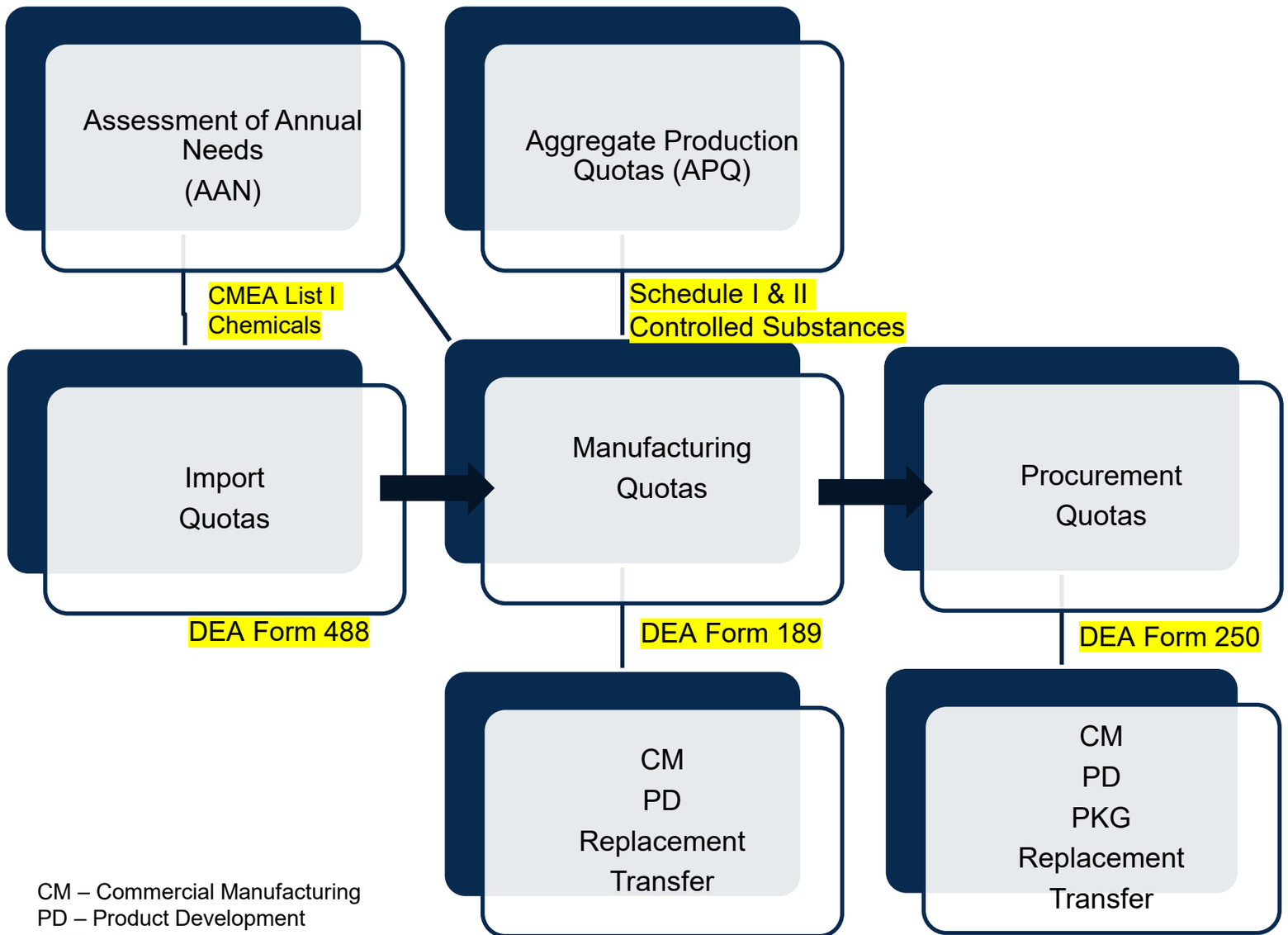
Management of Quotas for Controlled Substances and List I Chemicals

Effective on November 29, 2023
88 FR 60117, published on August 31, 2023

Overview of changes

- Formalization of subcategories for manufacturing and procurement quotas
  - Commercial sales, transfer, product development, replacement, packaging/repackaging and labeling/relabeling
- Changes to regulatory deadlines
  - Establishment of APQ and the AAN: September 1
  - Issue procurement, import and manufacturing quota: December 1
  - Adjust individual manufacturing quota: July 1
- Reduction of manufacturer's inventory allowances (discussed in later slides)
- Procurement quota certification requirements for manufacturers
  - Requiring both manufacturers and distributors to obtain certification of a buyer's quota for the requested schedule I and II controlled substances, as well as list I chemicals when the buyer is a manufacturer.

AAN and APQ: Quotas with subcategories



CM – Commercial Manufacturing
PD – Product Development
PKG – Packaging

Types of Quotas and Subcategories For Schedule I and II Controlled Substances

Pursuant to 21 CFR Part 1303

Aggregate Production Quotas (APQ)

- Schedule I and II controlled substances
- Established annually

21 CFR 1303.11 and 1303.13

Manufacturing Quotas (MQ)

- Commercial Manufacturing
- Product Development
- Replacement
- Transfer

21 CFR 1303.21 to 1303.27
DEA Form 189

Procurement Quotas (PQ)

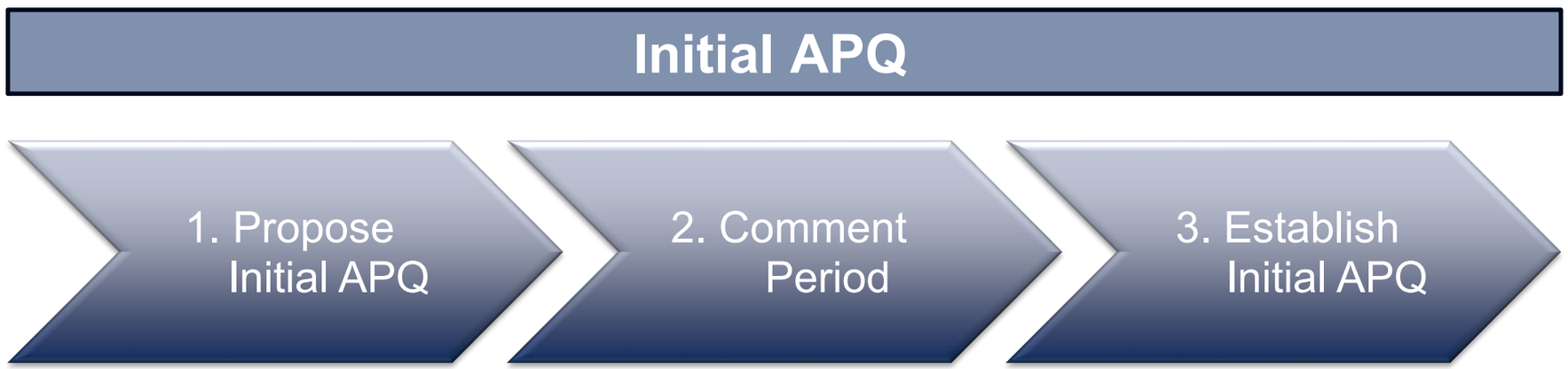
- Commercial Manufacturing
- Product Development
- Packaging/Repackaging
- Replacement
- Transfer

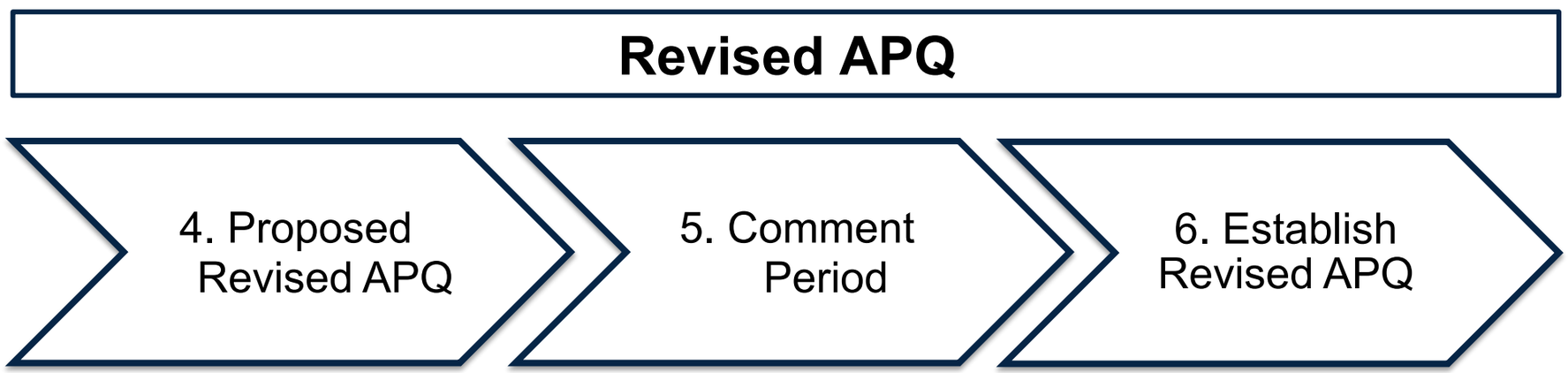
21 CFR 1303.15 to 1303.17
DEA Form 250

Aggregate Production Quotas

- Only applies to Schedules I and II controlled substances (as the basic class i.e. anhydrous base)
- Sets the upper limit of national manufacturing
- Historically established annually with one revision
- Federal Register notices required

Establishing and Revising Aggregate Production Quotas (APQ) in Federal Registers





APQ Consideration Factors

- **Data from procurement quotas applications**
  - Dispositions – domestic and export
  - Product development, yields and losses etc.
  - Inventory data
- **Data from manufacturing quotas applications**
  - Customers' procurement quotas
  - Historical share of the market
  - Product development, yields, losses etc.
  - Inventory data
- **FDA information regarding domestic needs**
  - Estimates of legitimate domestic medical need
  - New, discontinued, or recalled products
  - New indications or dosage forms
- **Diversion, abuse, consumption, trafficking data**
  - SUPPORT Act
  - CDC overdose data
  - State PDMP data
  - DEA Drug Theft Loss Data

APQ Time Machine

Basic class	Proposed 1995 quotas
Schedule I	
Acetylmethadol	2
Aminorex	2
Bufotenine	10
Cathinone	4
Difenoxin	14,000
2, 5-Dimethoxyamphetamine	15,650,000
Dimethylamphetamine	2
N-Ethylamphetamine	4
Lysergic acid diethylamide	41
Mescaline	2
4-Methoxyamphetamine	12
4-Methylaminorex	2
3-Methylfentanyl	12
Methaqualone	2
Methcathinone	9
3, 4-Methylenedioxyamphetamine	12
3, 4-Methylenedioxy-N-ethylamphetamine	2
3, 4-Methylenedioxymethamphetamine	12
Normorphine	2
Tetrahydrocannibinols	35,000
Thiophene Analog of Phencyclidine	10

1995 APQ:
21 Schedule I Substances

2026 APQ:
293 Schedule I Substances

APQ Time Machine

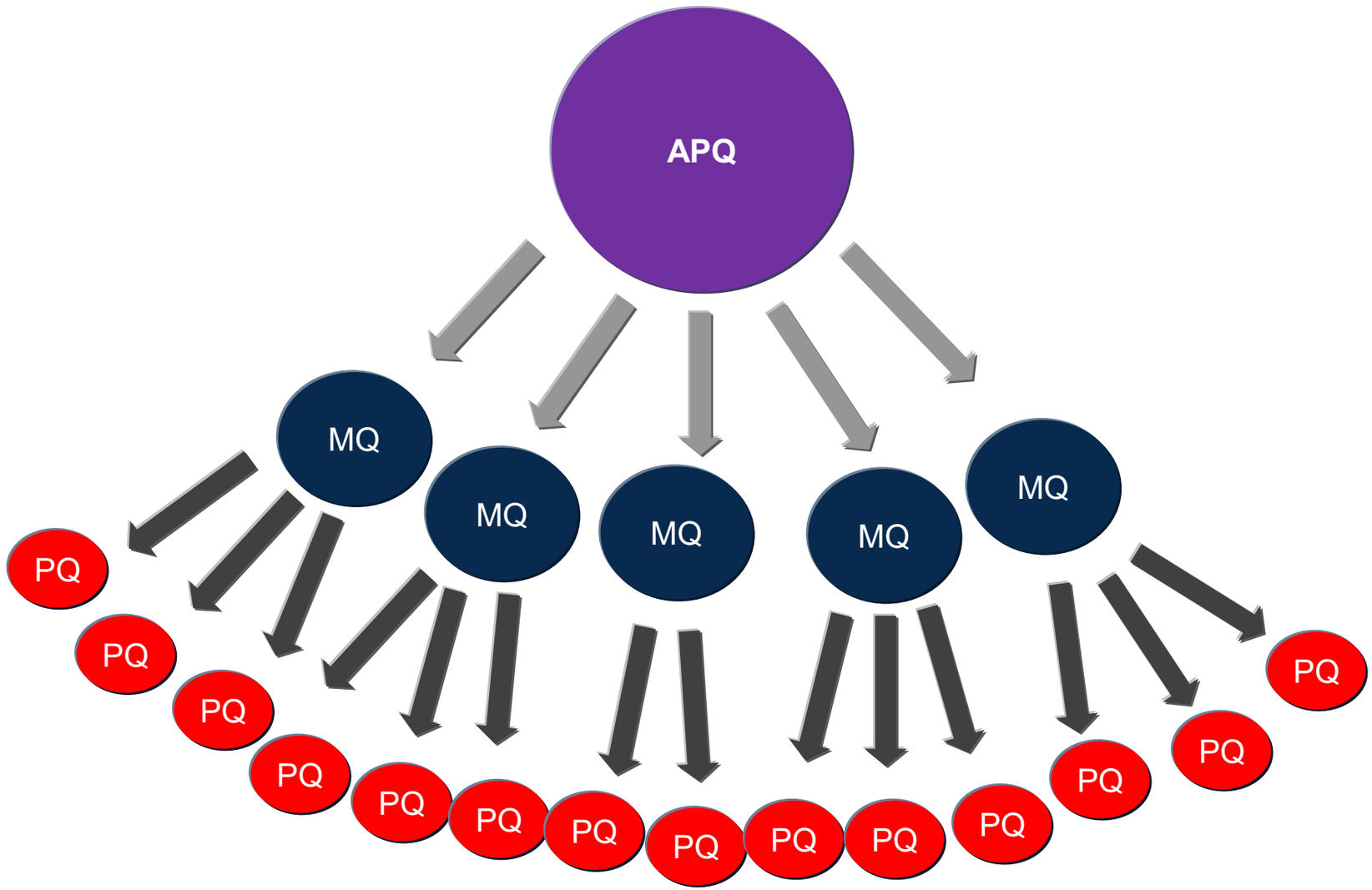
Schedule II

Alfentanil	7,000
Amobarbital	5
Amphetamine	635,000
Cocaine	550,000
Codeine (for sale)	67,312,000
Codeine (for conversion)	16,181,000
Dextropropoxyphene	124,012,000
Dihydrocodeine	202,000
Diphenoxylate	688,000
Ecgonine (for conversion)	650,000
Fentanyl	76,000
Hydrocodone	8,474,000
Hydromorphone	393,000
Levo-alpha-acetylmethadol	200,000
Levorphanol	8,000
Meperidine	8,637,000
Methadone	3,779,000
Methadone (for conversion)	364,000
Methadone Intermediate (for sale)	300,000
Methadone Intermediate (for conversion)	4,393,000
Methylphenidate	7,935,000
Morphine (for sale)	7,612,000
Morphine (for conversion)	78,105,000
Noroxymorphone (for sale)	21,000
Noroxymorphone (for conversion)	3,500,000
Opium	1,118,000
Oxycodone (for sale)	3,613,000
Oxycodone (for conversion)	6,200
Oxymorphone	2,500
Pentobarbital	15,706,000
Phencyclidine	52
Phenylacetone (for conversion)	3,528,000

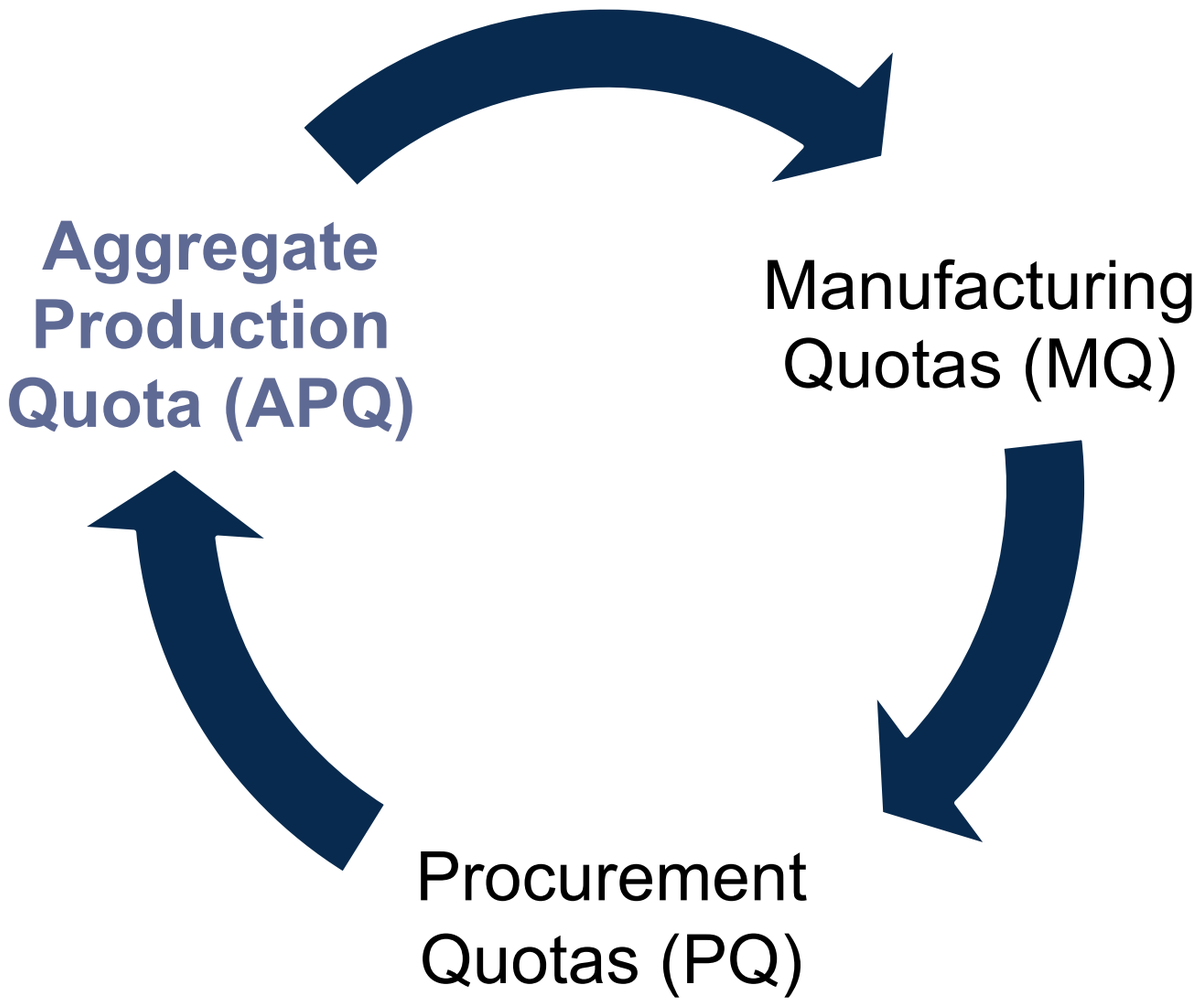
1995 APQ:
36 Schedule II Substances

2026 APQ:
77 Schedule II Substances

APQ – MQ – PQ

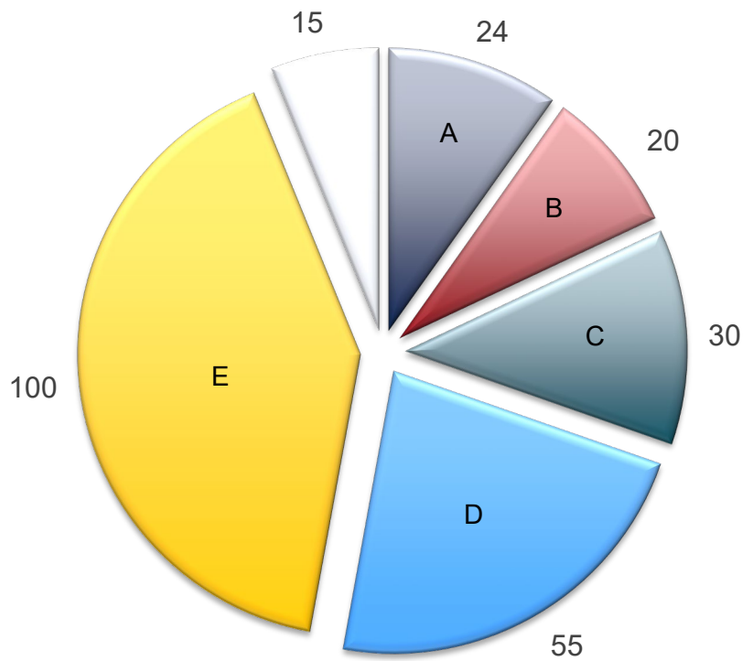


Quota – APQ Relationship



Relationship Between APQ and Manufacturing Quotas

APQ = 244 kg



Manufacturer	Amount of MQ received (kg)
MFR A	24
MFR B	20
MFR C	30
MFR D	55
MFR E	100
Total MQ granted	229
Amount APQ remained	244-229 = 15

Types of Quotas and Subcategories For Schedule I and II Controlled Substances

Pursuant to 21 CFR Part 1303

Aggregate Production Quotas (APQ)

- Schedule I and II controlled substances
- Established annually

21 CFR 1303.11 and 1303.13

Manufacturing Quotas (MQ)

- Commercial Manufacturing
- Product Development
- Replacement
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21 CFR 1303.21 to 1303.27
DEA Form 189

Procurement Quotas (PQ)

- Commercial Manufacturing
- Product Development
- Packaging/Repackaging
- Replacement
- Transfer

21 CFR 1303.15 to 1303.17
DEA Form 250

Manufacturing Quotas

- **Establish maximum amount which the individual API manufacturer may *manufacture* in a calendar year**
- **Manufacturers cannot exceed manufacturing quota**
- **Only DEA registered manufacturers with the specific CI or CII drug codes receive MQ**
- **Establish guidelines for inventory allowances**

Manufacturing Quota Subcategories

Commercial Manufacturing (CM)

- Domestic vs. Export
  - Manufacturing of bulk API
  - Conversion of material from one drug class to another

Product Development (PD)

- Domestic vs. Export
- Applicable to activities leading ***to*** FDA approval. For example, Drug Master File (DMF), New Drug Application (NDA), Abbreviated NDA (ANDA)
  - Scale up
  - Stability
  - Exhibit
  - Validation

Manufacturing Quota Subcategories

Replacement

- **Case-by-case basis only**
- Important to note that it is **not always a one-to-one replacement**

Transfer

- Processing of product that may require more than one manufacturing site

Who Needs Manufacturing Quotas

DEA registered bulk manufacturers (also known as API manufacturers) of Schedules I and II controlled substances and/or CMEA List I chemicals whose methods include:

- **Extraction from plant material**
  - coca leaf, opium, concentrated poppy straw, psychedelic mushroom
- **Synthetic routes**
  - converting morphine into hydromorphone
  - controlled substances derived from non-controlled starting materials

*API Manufacturers = Active Pharmaceutical Ingredient Manufacturers

Manufacturing Quotas Consideration Factors

Manufacturing quotas are granted to DEA registrants based on:

- Procurement Quotas
- Historical share of the market
- Inventory (saleable; bulk, in-process and finished dosage forms)
- Product development efforts
- Limited by the APQ (CI and CII), AAN (CMEA List I chemicals)

Manufacturing Quotas Inventory Allowance

21 CFR 1303.24 and 1315.24

- Normally 40% of average net disposals for current and last preceding year
- During the calendar year, inventory may not exceed 55% of estimated net disposal
- Exceeding 55% will suspend quota until inventory is less than 50% of net disposals

Manufacturing Quota Applications

Commercial Manufacturing:

- A list of YTD sales and forecasted sales for the remainder of the year aggregated by company names and corresponding DEA registration numbers
- Current inventory status
- Updated ARCOS data
- Non-recoverable waste or loss
- For conversion substances: yield %
- Minimum batch size

Product Development:

- Batch size
- Number of batches
- Purpose (e.g. exhibit, stability, scale-up, validation)

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21 CFR 1303.15 to 1303.17
DEA Form 250

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**

Procurement Quota Subcategories

Commercial Manufacturing (CM)

- Domestic vs. Export
  - Dosage form manufacturing
  - Reference standards or exempt products

Product Development (PD)

- Domestic vs. Export
- Applicable to activities leading ***to*** FDA approval. For example, FDA approved Drug Master File (DMF), New Drug Application (NDA), Abbreviated NDA (ANDA)
  - Scale up
  - Stability
  - Exhibit
  - Validation

Procurement Quota Sub-categories

Packaging (PKG)

- Domestic vs. Export
  - Packaging/Repackaging activities
  - Labeling/Relabeling activities

Replacement

- Case-by-case basis only
- Important to note that it is not always a one-to-one replacement

Transfer

- Return of defective bulk API from a customer
- Processing of product that may require more than one manufacturing site
- Move existing inventory or in-processed material. For example, from a closing facility to another registration
- Important to note that existing procurement quota does not transfer from one registration to another. Only inventory is being transferred.

Who Needs Procurement Quotas

Manufacturers who *procure* Schedule I or II controlled substances, or CMEA List I chemicals 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
- Performing product development activities

Procurement Quotas Consideration Factors

Procurement quotas are granted to DEA registrants based on:

- Dispositions (domestic sales and exports)
- Manufacturing loss and destruction
- Inventory of saleable material
- Acquisitions from both domestic manufacturers and importers
- Product development, packaging and repackaging activities

Procurement Quotas Inventory Allowance

21 CFR 1303.16 and 1315.31

Solid dosage form manufacturers:

- Normally 35% of average net disposals for current and last preceding year
- During the calendar year, inventory may not exceed 50% of estimated net disposal
- Exceeding 50% will suspend quota until inventory is less than 45% of net disposals

Liquid injectable dosage form manufacturers:

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

Procurement Quotas

Certification of adequate quota needed to purchase API

- 21 CFR 1303.15(f) and 1315.32(h)

- Manufacturers must provide written certification to their supplier(s) before procuring schedule I & II controlled substances and CMEA List I chemicals ephedrine, pseudoephedrine and phenylpropanolamine

Procurement Quota Applications

Commercial Manufacturing:

- A list of YTD sales aggregated by company names and corresponding DEA registration numbers (opioids and stimulants)
- Current inventory status
- Updated ARCOS data
- Non-recoverable waste or loss
- Destruction
- Minimum batch size
- API Suppliers' names and DEA Registrations

Product Development Or Packaging:

- Strength (mg)
- Batch size (number of tablets per batch)
- Number of batches
- Purpose (e.g. exhibit, stability, scale-up, validation) for product development
- API Suppliers' names and DEA Registrations

Procurement Quota - FAQ

What if the registration number changes?

- The new registration should submit a PQ request to transfer inventory from old registration.
- New PQ is needed to start activity under new registration. Existing quota from the old registration does not transfer to the new registration.
- Must submit new quota applications online once all necessary drug codes have been added to registration

NOTE: QUOTA DOES NOT TRANSFER FROM ONE REGISTRATION TO ANOTHER

Procurement Quota - FAQ

Which substances/chemicals receive semi-annual quota?

Procurement of schedule II-controlled substances for the purpose of commercial manufacturing receive semi-annual quota, **except injectables, which receive annual quota.**

When to apply for quota for second half of the year?

Quota applications for second half of the year should be submitted by **June 1**.

Procurement Quota - FAQ

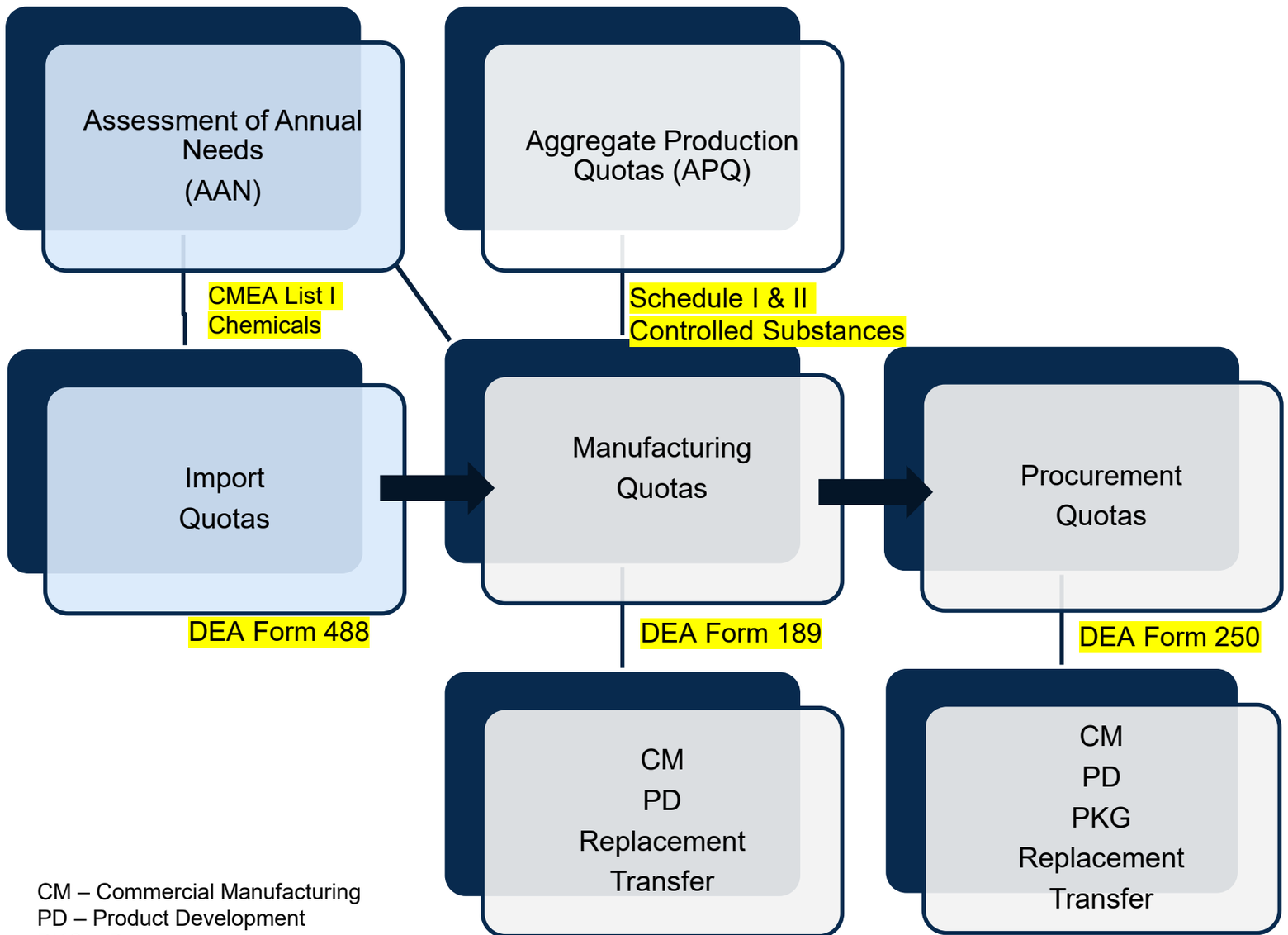
Analytical exempted Standards

No quota is needed as per 21 CFR 1303.15 (e)(2)

Research

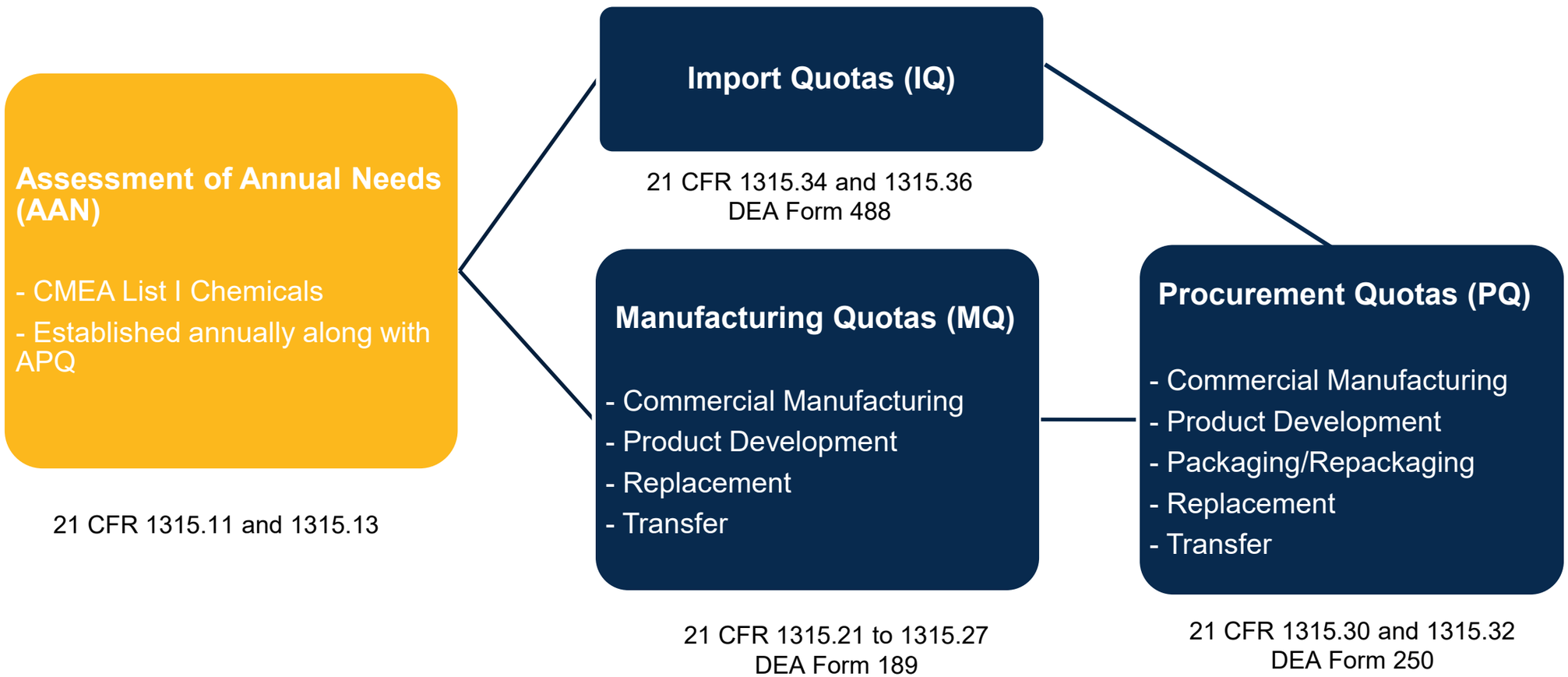
- No quota needed for research registration per 21 CFR 1303.15 (e)(3)
- Be aware of what is considered **research versus manufacturing**

AAN and APQ: Quotas with subcategories



CM – Commercial Manufacturing
PD – Product Development
PKG – Packaging

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



Combat Methamphetamine Epidemic Act 2005 (CMEA)

Enacted on March 9, 2006

Ephedrine (EPH), Pseudoephedrine (PSE), and Phenylpropanolamine (PPA)

- Additional legislative and regulatory controls on the manufacture, distribution, importation, and exportation of these CMEA List I chemicals

- Registration now required for each physical location (manufacturer, distributor, importer or exporter)

Quota Provisions of CMEA

- **API manufacturers who synthesize EPH, PSE and PPA must obtain a manufacturing quota**

- **Manufacturers who purchase EPH, PSE and PPA must obtain a procurement quota**
  - Dosage form manufacturers, packagers, labelers, repackagers and relabelers

- **Importers who import EPH, PSE and PPA (or products containing EPH, PSE, and PPA) must obtain an import quota**

Quota Provisions of CMEA

- **Before issuing individual quotas, DEA had to first establish the annual needs of the United States for EPH, PSE and PPA**

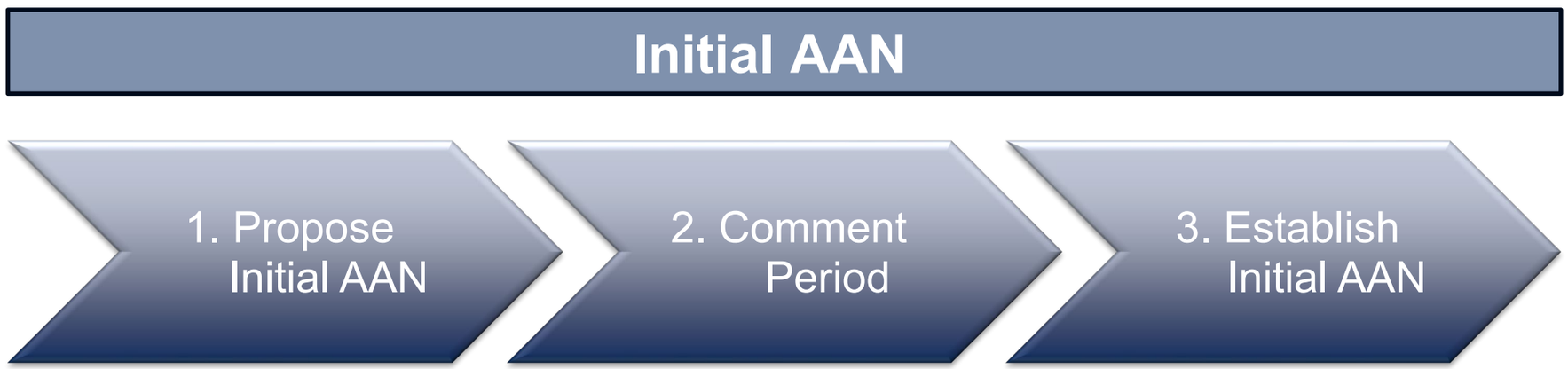
- **The 2008 Assessment of Annual Needs (AAN) was published in the Federal Register on December 27, 2007**

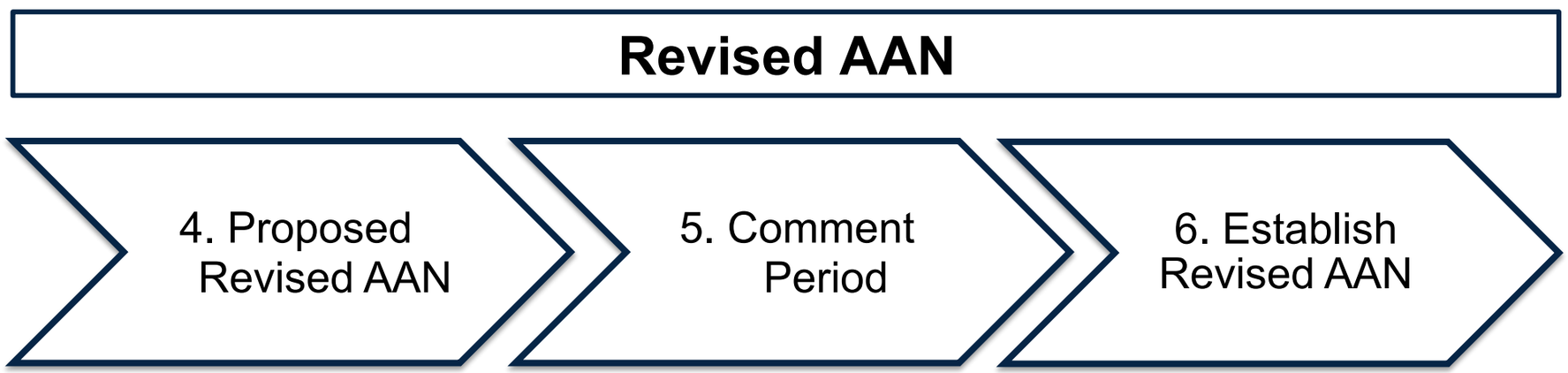
- **DRQ began issuing individual quotas on December 30, 2007 for the calendar year 2008**

Assessment of Annual Needs

- Only applies to CMEA List I chemicals
- Sets the upper limit of national import and manufacturing CMEA List I chemicals
- Established annually and revised as required
- Federal Register Notices required for both establishment and revision of AAN

Establishing and Revising Assessment of Annual Needs (AAN) in Federal Registers

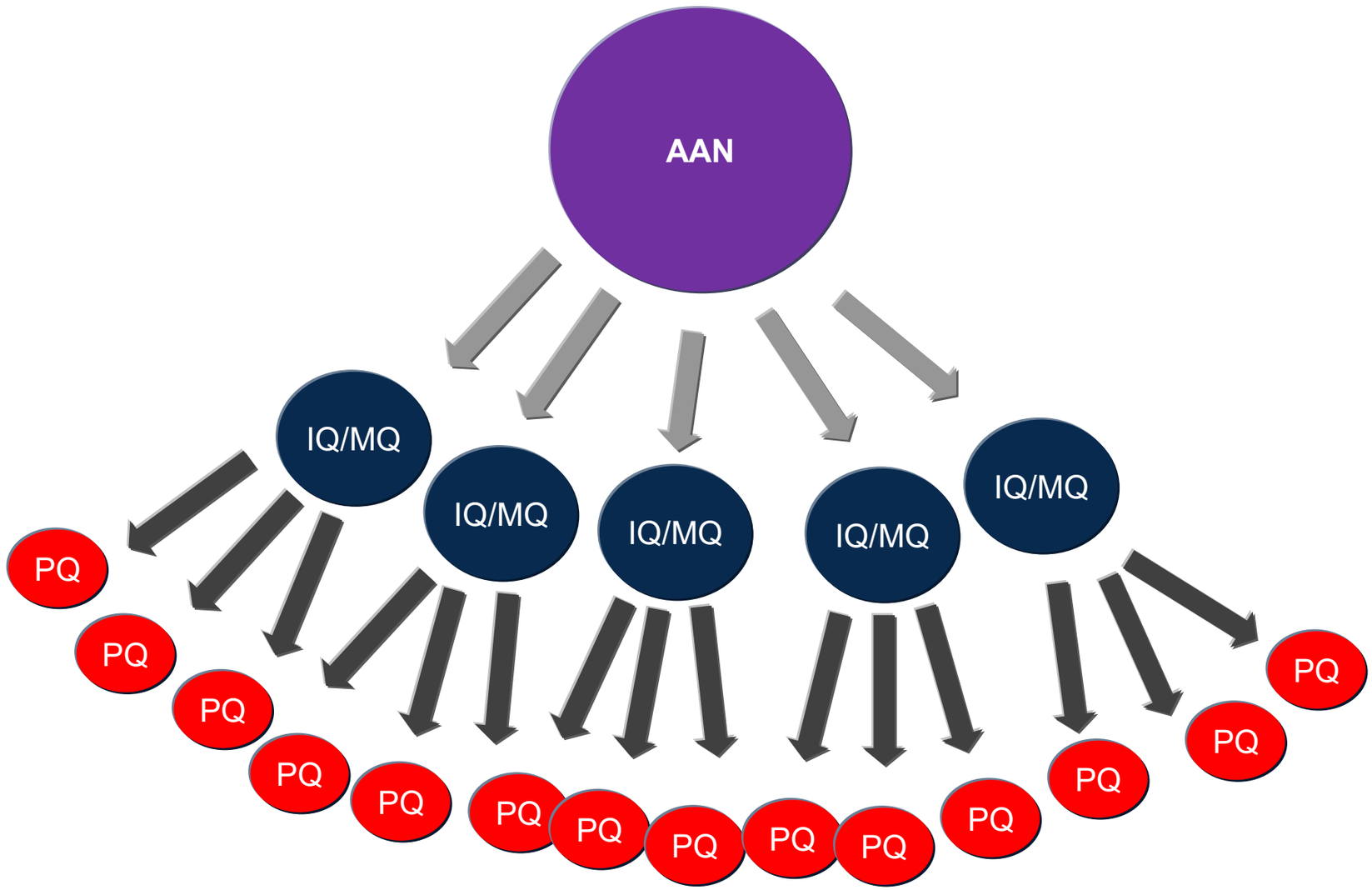




AAN Consideration Factors

- **Import, manufacturing and procurement quota applications from DEA Registered manufacturers and importers**
- **The national rate of disposals (sales/utilization)**
- **Actual and estimated inventories**
- **FDA estimates of legitimate domestic medical needs**

AAN-IQ/MQ-PQ


AAN
IQ/MQ
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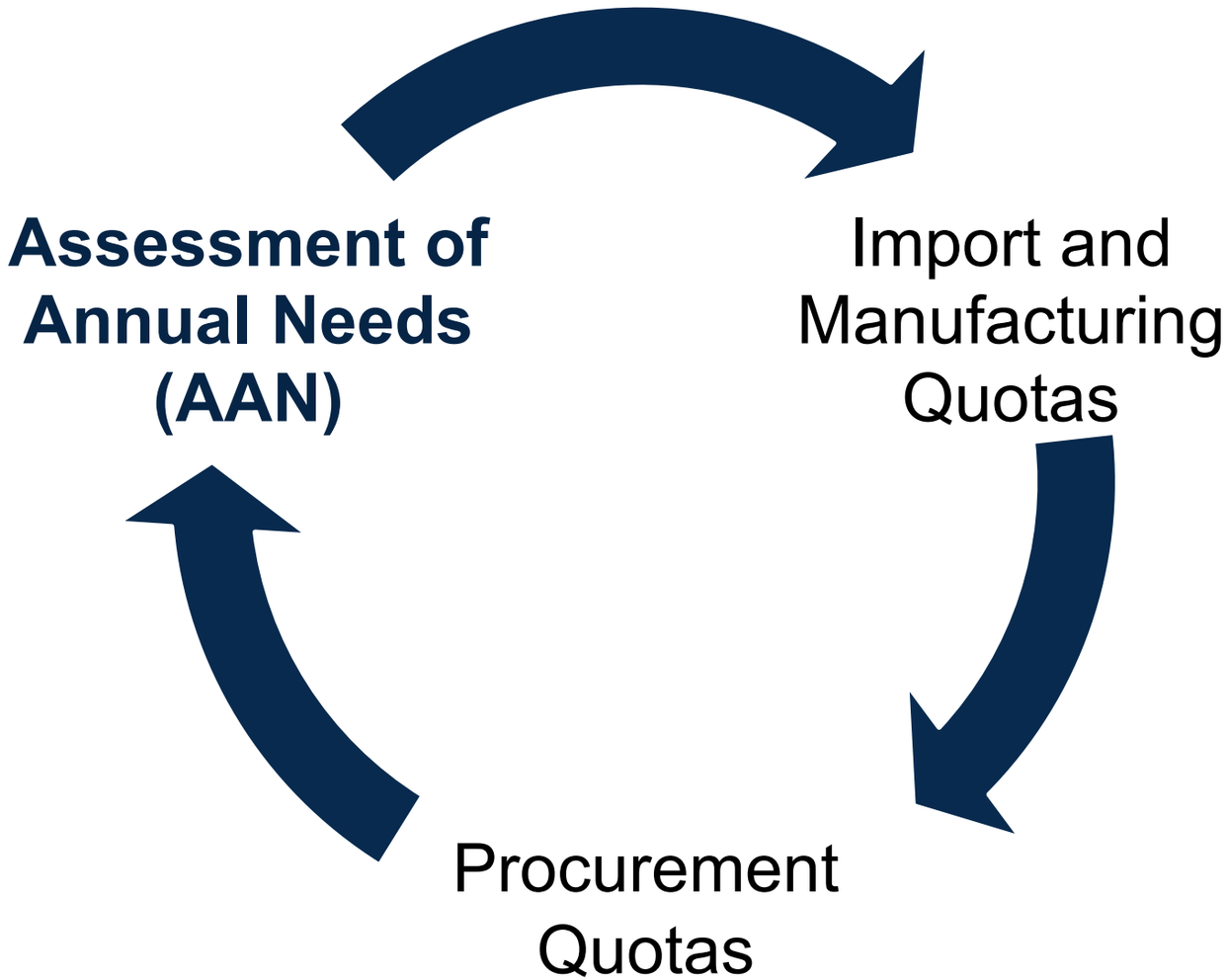
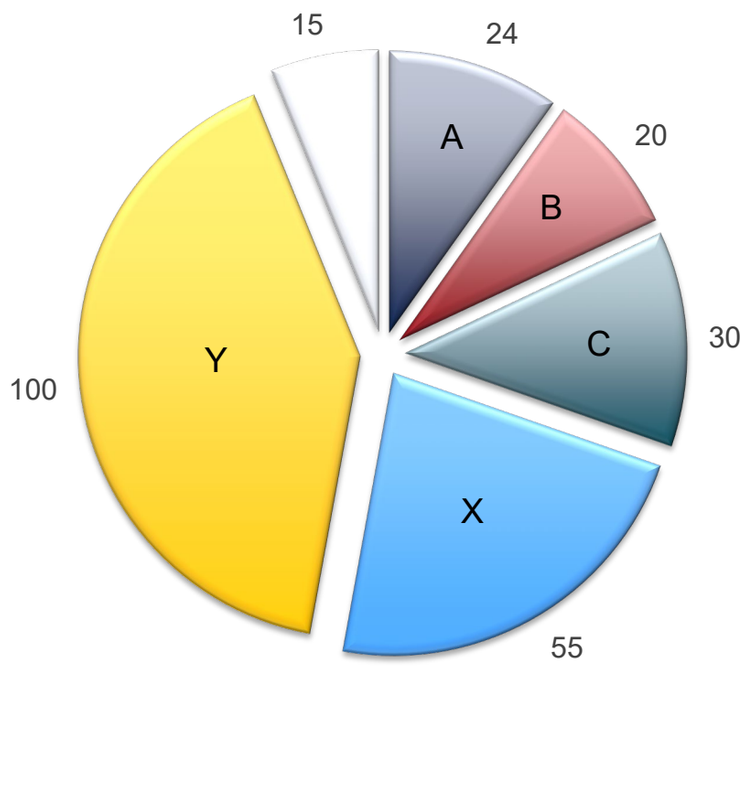
Quota-AAN Relationship



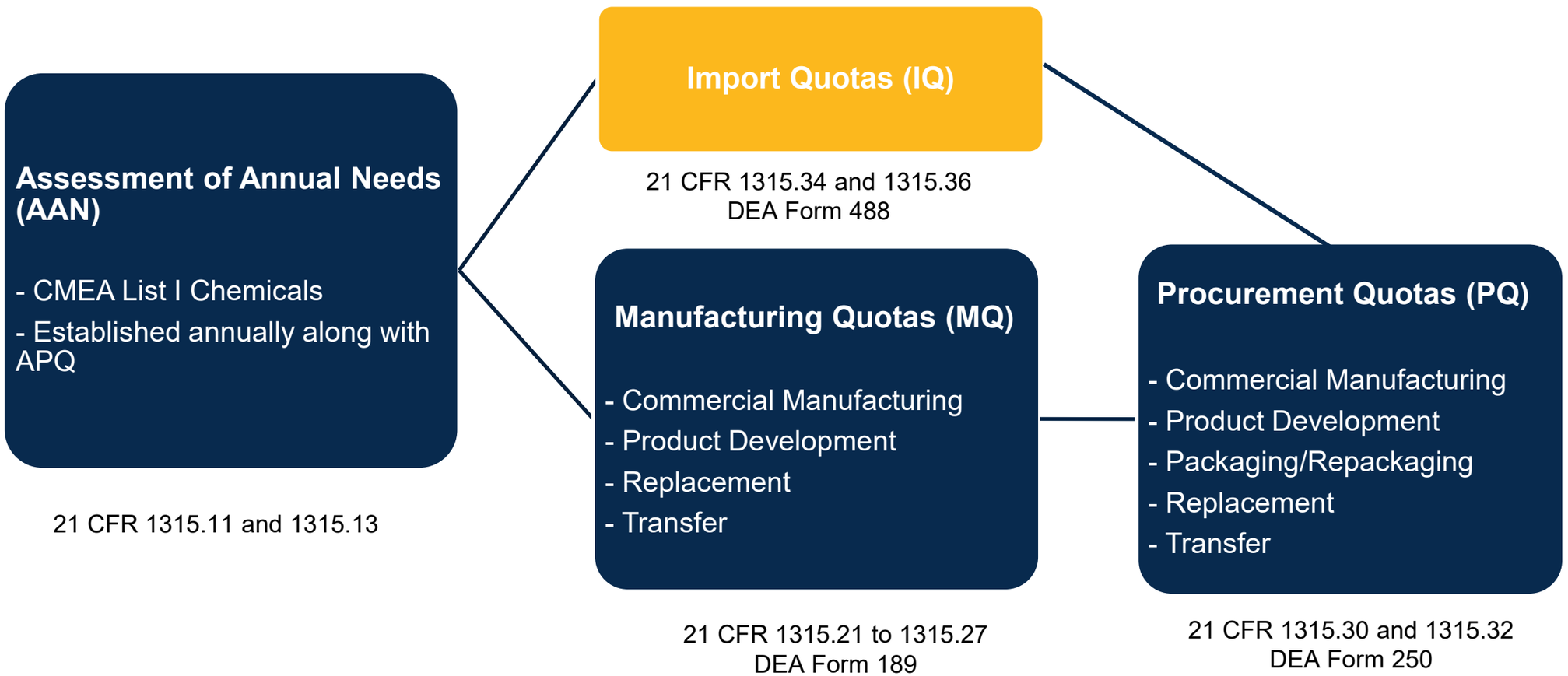
Relationship Between AAN and Import and Manufacturing Quotas

AAN = 244 kg



Manufacturer	Amount of MQ or IQ received (kg)
MFR A	24
MFR B	20
MFR C	30
Importer X	55
Importer Y	100
Total MQ granted	74
Total IQ granted	155
Amount AAN remained	244-74-155 = 15

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



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**

Import Quotas Consideration Factors

Import quotas are granted to DEA registrants based on:

- **Procurement** and **Manufacturing** Quotas
- Sales & inventory of imported finished dosage form products
- Limited by the AAN (CMEA List I chemicals)

Import Quota - FAQ

Can a DEA registered analytical lab import CMEA List I chemicals as a coincidental activity?

No, only DEA registered importers may import CMEA List I chemicals. Analytical labs may import **controlled substances** as a coincident activity only

21 CFR 1301.13 (e)(1)(x)

Import Quota - FAQ

Does a manufacturer who consumes all of a CMEA List I chemical internally qualify as an “end user”?

- No. All DEA registered manufacturers who procure CMEA List I chemicals for a manufacturing activity must have quota, including those who do not distribute these CMEA List I chemicals

- The absence of this information would prevent DEA from considering all relevant information required by law when establishing the AAN

Review for exercises: Who gets quota?

Importers of ephedrine, pseudoephedrine & phenylpropanolamine

- Includes importers of bulk API and Dosage Units

Manufacturers of ephedrine, pseudoephedrine and phenylpropanolamine

- Includes bulk manufacturers (manufacturers of API)
- Manufacturers of finished dosage units
- Packagers, repackagers, labelers & relabelers

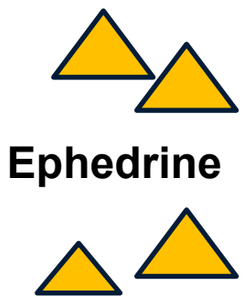
Manufacturers of Schedule I & II Controlled Substances

- Includes bulk manufacturers (manufacturers of API)
- Manufacturers of finished dosage units
- Packagers, repackagers, labelers & relabelers

Exercise 1: Who needs Quota? Following a Product From Start To Finish

- Company A imports bulk ephedrine for conversion into pseudoephedrine by their bulk manufacturer Company B
- Company B sells the pseudoephedrine to Company C which converts the bulk pseudoephedrine into dosage forms, packages and sends to Company D for distribution

Exercise 1: Who needs Quota?
Import EPH to PSE



Company A
(Chemical Importer)

Imports ephedrine

IQ - *to import ephedrine*

Company B
(Bulk Manufacturer)

Converts ephedrine to pseudoephedrine

PQ *- to procure ephedrine*
MQ *- to convert ephedrine to pseudoephedrine API*

Company C
(Dosage Form MFR)

Makes pseudoephedrine tablets

PQ *- to procure API to manufacture and package pseudoephedrine tablets*

Company D
Distributor

No PQ needed

Exercise 1: Who needs Quota?
Answers:

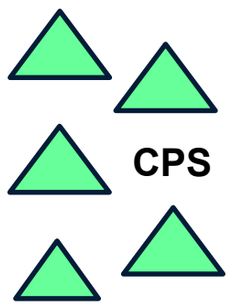
- **Company A – importer**
  - Import Quota (ephedrine) is required to import the ephedrine into the U.S. under an importer registration
- **Company B – bulk manufacturer**
  - Procurement Quota (ephedrine) is required by the manufacturing registration (if different DEA Registration #) to receive the ephedrine from their importer registration
  - Manufacturing Quota (pseudoephedrine) is required to manufacture pseudoephedrine from the ephedrine
- **Company C – dosage form manufacturer**
  - Procurement Quota (pseudoephedrine) is required to procure bulk pseudoephedrine for dosage form manufacturing
- **Company D – distributor**
  - NO QUOTA NEEDED for distributors

Exercise 2: Who needs Quota? Following a Product From Start To Finish

- Company A imports concentrated poppy straw for morphine extraction. They sell the extracted morphine to company B which converts the bulk morphine into beads and encapsulates them
- Company B sends the finished morphine capsules to their bottling and labeling company C
- Company C bottles and labels the finished dosage units and sends them to Company D for distribution

Exercise 2: Who needs Quota?

Import Poppy Straw to Manufacture Morphine Capsules for Distribution



CPS = Concentrated Poppy Straw

Company A
(Importer/MFR)

Imports CPS for extraction to morphine

***PQ** - to procure imported CPS*
***MQ** - to extract morphine*

Company B
(Dosage Form MFR)

Makes morphine capsules

***PQ** - to procure morphine API to manufacture capsules*

Company C
(Packager/Labeler)

***PQ -** procure bulk capsules & package/label*

Company D
(Distributor)

No PQ needed

Exercise 2: Who needs Quota? Answers:

- **Company A – importer & bulk manufacturer**
  - Procurement Quota (CPS) is required to procure the imported material. (NOT Import Quota since CPS is not CMEA List I Chemical)
  - Manufacturing Quota (morphine) is required to extract morphine from the poppy straw
- **Company B – dosage form manufacturer**
  - Procurement Quota (morphine) is required to procure bulk morphine for dosage form manufacturing
- **Company C – relabeler/repackager manufacturer**
  - Procurement Quota (morphine) is required to acquire the finished dosage units for packaging and product labeling
- **Company D – distributor**
  - NO QUOTA NEEDED for distributors

Final Reminders

Annual applications for quotas must be filed on or before the date indicated of the year preceding the calendar year for which the quota is being applied.

For 2027 quotas:

- DEA Form 250 Procurement Quotas must be filed on or before **April 1, 2026**.
- DEA Form 488 Import Quotas must be filed on or before **April 1, 2026**.
- DEA Form 189 Manufacture Quotas must be filed on or before **May 1, 2026**.

➢ This allows DRQ to review and consider quota requests when setting the APQ/AAN to ensure it is adequate.

For 2026 quotas:

- Applications for second allotment of semi-annual Procurement Quotas on or before **June 1, 2026**.

➢ Reminder to submit manufacture, procurement and import quota applications requesting forecasted annual amounts

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