

Controlled Substances Legislation Overview

- 👉 **1915: Harrison Narcotics Act**
 - created registration and taxation of manufacturers/distributors of opium and cocoa extract; enforced by Treasury and Bureau of Internal Revenue (BIR)

Controlled Substances Legislation Overview

☞ 1915: Harrison Narcotics Act

☞ 1919: Volstead Act (National Prohibition Act)

- U.S. law provided enforcement of the 18th Amendment; defined intoxicants as drinks containing 1/2 of 1 percent or more of alcohol
- it placed narcotic agents in Prohibition Units of the Bureau of Internal Revenue (BIR)



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- 👉 1915: Harrison Narcotics Act
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- 👉 1927: Bureau of Prohibition created from BIR Prohibition Units

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- ☞ 1919: Volstead Act (National Prohibition Act)
- ☞ 1927: Bureau of Prohibition moved Prohibition Units to their own bureau
- ☞ 1930: Treasury Dept reorganized to enforce liquor laws under Federal Bureau of Narcotics (FBN)

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- ☞ **1966: Bureau of Drug Abuse Control (BDAC) formed**
 - **BDAC placed under FDA to control stimulants and hallucinogens; stemmed from 1965 Drug Amendment Act**

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- ☞ 1966: Bureau of Drug Abuse Control (BDAC) put under FDA control
- ☞ **1968: Bureau of Narcotics & Dangerous Drugs (BNDD) formed from FBN and BDAC**

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- ☞ 1970: **Controlled Substances Act (21 USC 801 - 977)**

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- ☞ **1973: Drug Enforcement Administration (DEA) created**

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- ☞ **1974: Narcotic Addict Treatment Act**

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- ☞ **1984: Temporary scheduling of CS allowed**

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- ☞ **1988: Chemical Diversion and Trafficking Act (CDTA)**
 - Precursor, essential chemicals, and manufacturing equipment regulated

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- ☞ 1990: Anabolic Steroids regulated
- ☞ **1993: Domestic Chemical Diversion Control Act (DCDCA)**

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- ☞ 1988: Chemical Diversion and Trafficking Act (CDTA)
- ☞ 1990: Anabolic Steroids regulated
- ☞ 1993: Domestic Chemical Diversion Control Act (DCDCA)
- ☞ **1996: Methamphetamine Control Act**

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- ☞ 1996: Methamphetamine Control Act
- ☞ **1997: Controlled Substances Act Rewrite**

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👉 PENDING LEGISLATION

■ 1998: Proposed Revisions to DCDCA

- List I/ II Chemicals Recordkeeping will require all chemical mixtures - except those specifically exempted by regulation - to be subject to CSA.
- Criteria for exemption will be based upon: (1) a listed chemical at or below an established concentration, (2) the mixture falls within a specific category, and (3) the manufacturer applies for and is granted an exemption for the product.
- List I Concentration levels include:
 - ♦ N-acetylanthraanilic acid (20% or less)
 - ♦ anthranilic acid (20% or less)
 - ♦ benzyl cyanide (20% or less)
 - ♦ ethylamine (20% or less)
 - ♦ hydriodic acid (20% or less)
 - ♦ 3,4-methylenedioxyphenyl-2-propane (20% or less)
 - ♦ methylamine (20% or less)
 - ♦ nitroethane (20% or less)
 - ♦ phenylacetic acid (20% or less)
 - ♦ piperidine (20% or less)
 - ♦ piperonal (20% or less)
 - ♦ isosafrole or safrole (20% or less)
 - ♦ ephedrine and pseudoephedrine (cumulative 2% or less)
 - ♦ norpseudoephedrine/ phenylpropanolamine (0.6% or less)
 - ♦ N-methylephedrine/N-methylpseudoephedrine (0.1% or less)
 - ♦ benzaldehyde (30% or less)
 - ♦ ergonovine and ergotamine (no concentration limit)

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- **List II Concentration levels include:**
 - ♦ acetone (35% or less)
 - ♦ methyl ethyl ketone (MEK) (35% or less)
 - ♦ methyl isobutyl ketone (MIBK) (35% or less)
 - ♦ toluene (35% or less)
 - ♦ ethyl ether (35% or less)
 - ♦ acetic anhydride (20% or less)
 - ♦ benzyl chloride (20% or less)
 - ♦ hydrochloric acid (20% or less)
 - ♦ iodine and sulfuric acid (20% or less)
- **Exempted Categories of Mixtures:**
 - ♦ waste materials regulated by EPA
 - ♦ paints and coatings
 - ♦ harvested plant material

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👉 PRODUCT RESCHEDULING

- Synthetic Dronabinol (Marinol) from CII to CIII
 - proposed November 5, 1998
- Sibutramine (Meridia) into CIV
 - final rule published Feb 11, 1998
- Butorphanol (Stadol/ Tobugesic/ Tobutrol) into CIV
 - proposed July 10, 1997
- Fenfluramine (Redux) removal from CIV
 - proposed May 6, 1997
- Benzodiazepines & Related Substances
 - 19 products confirmed as appropriate for CIV
 - 13 products considered for de-scheduling
 - 2 products considered for rescheduling (diazepam & flunitrazepam)
 - published in Federal Register June 19, 1997
- Modafinil (Provigil) into CIV
 - final rule published in Federal Register Jan 27, 1999
- SONATA (Zalephon) into CIV
 - Proposed rule published in Federal Register May 5, 1999; effective Sept. 15, 1999

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☞ SPECIAL SURVEILLANCE LIST

- Chemicals, products, materials, & equipment used in clandestine production sold to DEA-banned individuals/ firms is a crime
 - proposed rule published in Federal Register Dec 1, 1998
- Civil penalties may be assessed if firm distributes products, chemicals, or equipment with 'reckless disregard' for use in clandestine production. A 2-week period following receipt of notice from DEA may help to establish a rebuttable period or presumption of reckless disregard should the matter go to trial - for instance, when a firm distributes a laboratory supply to a customer two weeks or more after such DEA notification.
 - rule published in Federal Register Mya 13, 1999 and corrected Sept 17, 1999

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☞ PROPOSED RULES

- Registration fees for List I chemicals will be adjusted:
 - Initial registration for manufacturers, distributors, importers, and exporters reduced from \$595 to \$ 326; re-registration fees for same reduced from \$477 to \$171.
 - Registration fees for retail registrants increase from \$255 to \$326 and re-registration from \$116 to \$171
 - Proposed rule published in *Federal Register* Dec 1, 1999

☞ ADVANCED NOTICE OF PROPOSED RULEMAKING

- Red Phosphorus:
 - DEA is proposing to control red phosphorus as a listed chemical since it's been identified as an important chemical in the illicit production of methamphetamine.
 - Proposed rule published in *Federal Register* Feb 2, 2000