Public Law 103-200 103d Congress

# An Act

To amend the Comprehensive Drug Abuse Prevention and Control Act of 1970 to control the diversion of certain chemicals used in the illicit production of controlled substances such as methcathinone and methamphetamine, and for other purposes.

Dec. 17, 1993 [H.R. 3216]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

### SECTION 1. SHORT TITLE.

This Act may be cited as the "Domestic Chemical Diversion Control Act of 1993".

Domestic Chemical Diversion Control Act of 1993. 21 USC 801 note.

#### SEC. 2. DEFINITION AMENDMENTS.

(a) DEFINITIONS.—Section 102 of the Controlled Substances Act. (21 U.S.C. 802) is amended-

(1) in paragraph (33), by striking "any listed precursor chemical or listed essential chemical" and inserting "any list I chemical or any list II chemical":

(2) in paragraph (34)—

(A) by striking "listed precursor chemical" and inserting "list I chemical"; and
(B) by striking "critical to the creation" and inserting "important to the manufacture":

(3) in paragraph (34) (A), (F), and (H), by inserting ", its esters," before "and";

(4) in paragraph (35)-

(A) by striking "listed essential chemical" and inserting

"list II chemical";

(B) by inserting "(other than a list I chemical)" before "specified"; and

(C) by striking "as a solvent, reagent, or catalyst";

(5) in paragraph (38), by inserting "or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine" before the period:

(6) in paragraph (39)(A)-

(A) by striking "importation or exportation of" and inserting "importation, or exportation of, or an international transaction involving shipment of,";

(B) in clause (iii) by inserting "or any category of transaction for a specific listed chemical or chemicals" after

"transaction";

(C) by amending clause (iv) to read as follows:

"(iv) any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) unless—

"(I)(aa) the drug contains ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers, or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient; or

"(bb) the Attorney General has determined under section 204 that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

"(II) the quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Attorney General."; and

(D) in clause (v), by striking the semicolon and inserting "which the Attorney General has by regulation designated as exempt from the application of this title and title III based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered;";

be readily recovered;";
(7) in paragraph (40), by striking "listed precursor chemical or a listed essential chemical" each place it appears and insert-

ing "list I chemical or a list II chemical"; and

(8) by adding at the end the following new paragraphs: "(42) The term 'international transaction' means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

"(43) The terms 'broker' and 'trader' mean a person that assists in arranging an international transaction in a listed chemical by—

"(A) negotiating contracts;

"(B) serving as an agent or intermediary; or

"(C) bringing together a buyer and seller, a buyer and transporter, or a seller and transporter.".

(b) REMOVAL OF EXEMPTION OF CERTAIN DRUGS.—

(1) PROCEDURE.—Part B of the Controlled Substances Act (21 U.S.C. 811 et seq.) is amended by adding at the end the following new section:

### "REMOVAL OF EXEMPTION OF CERTAIN DRUGS

Regulations. 21 USC 814. "Sec. 204. (a) Removal of Exemption.—The Attorney General shall by regulation remove from exemption under section 102(39)(A)(iv) a drug or group of drugs that the Attorney General finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance.

"(b) FACTORS TO BE CONSIDERED.—In removing a drug or group of drugs from exemption under subsection (a), the Attorney General shall consider, with respect to a drug or group of drugs that is

proposed to be removed from exemption-

"(1) the scope, duration, and significance of the diversion;

"(2) whether the drug or group of drugs is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

"(3) whether the listed chemical can be readily recovered

from the drug or group of drugs.

"(c) SPECIFICITY OF DESIGNATION.—The Attorney General shall limit the designation of a drug or a group of drugs removed from exemption under subsection (a) to the most particularly identifiable type of drug or group of drugs for which evidence of diversion exists unless there is evidence, based on the pattern of diversion and other relevant factors, that the diversion will not be limited to that particular drug or group of drugs.

"(d) REINSTATEMENT OF EXEMPTION WITH RESPECT TO PARTICU-

LAR DRUG PRODUCTS.-

"(1) REINSTATEMENT.—On application by a manufacturer Regulations. of a particular drug product that has been removed from exemption under subsection (a), the Attorney General shall by regulation reinstate the exemption with respect to that particular drug product if the Attorney General determines that the particular drug product is manufactured and distributed in a manner that prevents diversion.

"(2) FACTORS TO BE CONSIDERED.—In deciding whether to reinstate the exemption with respect to a particular drug product under paragraph (1), the Attorney General shall consider-

"(A) the package sizes and manner of packaging of

the drug product;

"(B) the manner of distribution and advertising of the drug product;
"(C) evidence of diversion of the drug product;

"(D) any actions taken by the manufacturer to prevent

diversion of the drug product; and

"(E) such other factors as are relevant to and consistent with the public health and safety, including the factors described in subsection (b) as applied to the drug product.

"(3) STATUS PENDING APPLICATION FOR REINSTATEMENT.— A transaction involving a particular drug product that is the subject of a bona fide pending application for reinstatement of exemption filed with the Attorney General not later than 60 days after a regulation removing the exemption is issued pursuant to subsection (a) shall not be considered to be a regulated transaction if the transaction occurs during the pendency of the application and, if the Attorney General denies the application, during the period of 60 days following the date on which the Attorney General denies the application, unless-

"(A) the Attorney General has evidence that, applying the factors described in subsection (b) to the drug product,

the drug product is being diverted; and

"(B) the Attorney General so notifies the applicant. AMENDMENT AND MODIFICATION.—A regulation reinstating an exemption under paragraph (1) may be modified or revoked with respect to a particular drug product upon

a finding that—

"(A) applying the factors described in subsection (b) to the drug product, the drug product is being diverted;

"(B) there is a significant change in the data that

led to the issuance of the regulation."

(2) CLERICAL AMENDMENT.—The table of contents of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (84 Stat. 1236) is amended by adding at the end of that portion relating to part B of title II the following new item:

"Sec. 204. Removal of exemption of certain drugs.".

(c) REGULATION OF LISTED CHEMICALS.—Section 310 of the Controlled Substances Act (21 U.S.C. 830) is amended—

(1) in subsection (a)(1)—

(A) by striking "precursor chemical" and inserting "list

I chemical"; and

(B) in subparagraph (B), by striking "an essential chemical" and inserting "a list II chemical"; and

(2) in subsection (c)(2)(D), by striking "precursor chemical" and inserting "chemical control".

# SEC. 3. REGISTRATION REQUIREMENTS.

(a) RULES AND REGULATIONS.—Section 301 of the Controlled Substances Act (21 U.S.C. 821) is amended by striking the period and inserting "and to the registration and control of regulated persons and of regulated transactions.".

(b) Persons Required To Register Under Section 302.-Section 302 of the Controlled Substances Act (21 U.S.C. 822) is

amended-(1) in subsection (a)(1), by inserting "or list I chemical" after "controlled substance" each place it appears;

(2) in subsection (b)-

(A) by inserting "or list I chemicals" after "controlled substances"; and

(B) by inserting "or chemicals" after "such substances";(3) in subsection (c), by inserting "or list I chemical" after

"controlled substance" each place it appears; and

(4) in subsection (e), by inserting "or list I chemicals"

after "controlled substances".

(c) REGISTRATION REQUIREMENTS UNDER SECTION 303.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended

by adding at the end the following new subsection:

"(h) The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under section 102(39)(A)(iv). In determining the public interest for the purposes of this subsection, the Attorney General shall consider-

"(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate

channels;

"(2) compliance by the applicant with applicable Federal,

State, and local law;

"(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

"(4) any past experience of the applicant in the manufacture

and distribution of chemicals; and

"(5) such other factors as are relevant to and consistent with the public health and safety.".

(d) DENIAL, REVOCATION, OR SUSPENSION OF REGISTRATION.-Section 304 of the Controlled Substances Act (21 U.S.C. 824) is amended-

(1) in subsection (a)-

(A) by inserting "or a list I chemical" after "controlled substance" each place it appears; and

(B) by inserting "or list I chemicals" after "controlled

substances"

(2) in subsection (b), by inserting "or list I chemical" after

"controlled substance"

(3) in subsection (f), by inserting "or list I chemicals" after "controlled substances" each place it appears; and

(4) in subsection (g)-(A) by inserting "or list I chemicals" after "controlled substances" each place it appears; and

(B) by inserting "or list I chemical" after "controlled

substance" each place it appears.

(e) Persons Required To Register Under Section 1007.-Section 1007 of the Controlled Substances Import and Export Act (21 U.S.C. 957) is amended-

(1) in subsection (a)-

(A) in paragraph (1), by inserting "or list I chemical" after "controlled substance"; and
(B) in paragraph (2), by striking "in schedule I, II, III, IV, or V," and inserting "or list I chemical,"; and (2) in subsection (b)-

(A) in paragraph (1), by inserting "or list I chemical" after "controlled substance" each place it appears; and (B) in paragraph (2), by inserting "or list I chemicals"

after "controlled substances" (f) REGISTRATION REQUIREMENTS UNDER SECTION 1008.—Section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958) is amended-

(1) in subsection (c)—

(A) by inserting "(1)" after "(c)"; and

(B) by adding at the end the following new paragraph: "(2)(A) The Attorney General shall register an applicant to import or export a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the import or export of a drug product that is exempted under section 102(39)(A)(iv).

"(B) In determining the public interest for the purposes of subparagraph (A), the Attorney General shall consider the factors

specified in section 303(h)."

(2) in subsection (d)-

(A) in paragraph (3), by inserting "or list I chemical

or chemicals," after "substances,"; and

(B) in paragraph (6), by inserting "or list I chemicals" after "controlled substances" each place it appears;

(3) in subsection (e), by striking "and 307" and inserting "307, and 310"; and

(4) in subsections (f), (g), and (h), by inserting "or list I chemicals" after "controlled substances" each place it appears. (g) PROHIBITED ACTS C.—Section 403(a) of the Controlled Substances Act (21 U.S.C. 843(a)) is amended—

(1) by amending paragraphs (6) and (7) to read as follows:

"(6) to possess any three-neck round-bottom flask, tableting machine, encapsulating machine, or gelatin capsule, or any equipment, chemical, product, or material which may be used to manufacture a controlled substance or listed chemical, knowing, intending, or having reasonable cause to believe, that it will be used to manufacture a controlled substance or listed

chemical in violation of this title or title III:

"(7) to manufacture, distribute, export, or import any threeneck round-bottom flask, tableting machine, encapsulating machine, or gelatin capsule, or any equipment, chemical, product, or material which may be used to manufacture a controlled substance or listed chemical, knowing, intending, or having reasonable cause to believe, that it will be used to manufacture a controlled substance or listed chemical in violation of this title or title III or, in the case of an exportation, in violation of this title or title III or of the laws of the country to which it is exported;";

(2) by striking the period at the end of paragraph (8)

and inserting "; or"; and

(3) by adding at the end the following new paragraph: "(9) to distribute, import, or export a list I chemical without the registration required by this title or title III.".

# SEC. 4. REPORTS BY BROKERS AND TRADERS; CRIMINAL PENALTIES.

(a) NOTIFICATION, SUSPENSION OF SHIPMENT, AND PENALTIES WITH RESPECT TO IMPORTATION AND EXPORTATION OF LISTED CHEMICALS.—Section 1018 of the Controlled Substances Import and Export Act (21 U.S.C. 971) is amended by adding at the end the

following new subsection:

"(d) A person located in the United States who is a broker or trader for an international transaction in a listed chemical that is a regulated transaction solely because of that person's involvement as a broker or trader shall, with respect to that transaction, be subject to all of the notification, reporting, recordkeeping, and other requirements placed upon exporters of listed chemicals by this title and title II.".

(b) PROHIBITED ACTS A.—Section 1010(d) of the Controlled Substances Import and Export Act (21 U.S.C. 960(d)) is amended to

read as follows:

"(d) A person who knowingly or intentionally—

"(1) imports or exports a listed chemical with intent to manufacture a controlled substance in violation of this title

or title II;

"(2) exports a listed chemical in violation of the laws of the country to which the chemical is exported or serves as a broker or trader for an international transaction involving a listed chemical, if the transaction is in violation of the laws of the country to which the chemical is exported;

"(3) imports or exports a listed chemical knowing, or having reasonable cause to believe, that the chemical will be used to manufacture a controlled substance in violation of this title

or title II; or

"(4) exports a listed chemical, or serves as a broker or trader for an international transaction involving a listed chemical, knowing, or having reasonable cause to believe, that the chemical will be used to manufacture a controlled substance

in violation of the laws of the country to which the chemical is exported. shall be fined in accordance with title 18, imprisoned not more

than 10 years, or both.".

# SEC. 5. EXEMPTION AUTHORITY; ANTISMUGGLING PROVISION.

(a) NOTIFICATION REQUIREMENT.—Section 1018 of the Controlled Substances Import and Export Act (21 U.S.C. 971), as amended by section 1505(a) of this Act, is amended by adding

at the end the following new subsection:

"(e)(1) The Attorney General may by regulation require that the 15-day notification requirement of subsection (a) apply to all exports of a listed chemical to a specified country, regardless of the status of certain customers in such country as regular customers, if the Attorney General finds that such notification is necessary to support effective chemical diversion control programs or is required by treaty or other international agreement to which

the United States is a party.

"(2) The Attorney General may by regulation waive the 15-day notification requirement for exports of a listed chemical to a specified country if the Attorney General determines that such notification is not required for effective chemical diversion control. If the notification requirement is waived, exporters of the listed chemical shall be required to submit to the Attorney General reports of individual exportations or periodic reports of such exportation of the listed chemical, at such time or times and containing such information as the Attorney General shall establish by regulation.

"(3) The Attorney General may by regulation waive the 15day notification requirement for the importation of a listed chemical if the Attorney General determines that such notification is not necessary for effective chemical diversion control. If the notification requirement is waived, importers of the listed chemical shall be required to submit to the Attorney General reports of individual importations or periodic reports of the importation of the listed chemical, at such time or times and containing such information as the Attorney General shall establish by regulation."

(b) PROHIBITED ACTS A.—Section 1010(d) of the Controlled Substances Import and Export Act (21 U.S.C. 960(d)), as amended

by section 4(b) of this Act, is amended—

(1) by striking "or" at the end of paragraph (3);

(2) by striking the comma at the end of paragraph (4)

and inserting a semicolon; and

(3) by adding at the end the following new paragraphs: "(5) imports or exports a listed chemical, with the intent to evade the reporting or recordkeeping requirements of section 1018 applicable to such importation or exportation by falsely representing to the Attorney General that the importation or exportation qualifies for a waiver of the 15-day notification requirement granted pursuant to section 1018(e) (2) or (3) by misrepresenting the actual country of final destination of the listed chemical or the actual listed chemical being imported or exported; or

"(6) imports or exports a listed chemical in violation of

section 1007 or 1018,

#### SEC. 6. ADMINISTRATIVE INSPECTIONS AND AUTHORITY.

Section 510 of the Controlled Substances Act (21 U.S.C. 880) is amendedReports. Regulations.

Reports. Regulations.

Exports and imports.

(1) by amending subsection (a)(2) to read as follows:

"(2) places, including factories, warehouses, and other establishments, and conveyances, where persons registered under section 303 (or exempt from registration under section 302(d) or by regulation of the Attorney General) or regulated persons may lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of controlled substances or listed chemicals or where records relating to those activities are maintained."; and

(2) in subsection (b)(3)—

 (A) in subparagraph (B), by inserting ", listed chemicals," after "unfinished drugs"; and
 (B) in subparagraph (C), by inserting "or listed chemicals," cal" after "controlled substance" and inserting "or chemical" after "such substance".

### SEC. 7. THRESHOLD AMOUNTS.

Section 102(39)(A) of the Controlled Substances Act (21 U.S.C. 802(39)(A)), as amended by section 2, is amended by inserting "a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical," before "a threshold amount, including a cumulative threshold amount for multiple transactions".

#### SEC. 8. AMENDMENTS TO LIST I.

Section 102(34) of the Controlled Substances Act (21 U.S.C. 802(34)) is amended-

by striking subparagraphs (O), (U), and (W);

(2) by redesignating subparagraphs (P) through (T) as (O) through (S), subparagraph (V) as (T), and subparagraphs (X) and (Y) as (U) and (X), respectively;

(3) in subparagraph (X), as redesignated by paragraph (2), by striking "(X)" and inserting "(U)"; and

(4) by inserting after subparagraph (U), as redesignated by paragraph (2), the following new subparagraphs:

"(V) benzaldehyde. "(W) nitroethane.".

# SEC. 9. ELIMINATION OF REGULAR SUPPLIER STATUS AND CREATION OF REGULAR IMPORTER STATUS.

(a) DEFINITION.—Section 102(37) of the Controlled Substances

Act (21 U.S.C. 802(37)) is amended to read as follows:

"(37) The term 'regular importer' means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Attorney General.".

(b) NOTIFICATION.—Section 1018 of the Controlled Substances

Act (21 U.S.C. 971) is amended—

(1) in subsection (b)-

(A) in paragraph (1) by striking "regular supplier of the regulated person" and inserting "to an importation by a regular importer"; and

(B) in paragraph (2)—

(i) by striking "a customer or supplier of a regulated person" and inserting "a customer of a regulated person or to an importer"; and

(ii) by striking "regular supplier" and inserting

"the importer as a regular importer"; and

(2) in subsection (c)(1) by striking "regular supplier" and inserting "regular importer".

## SEC. 10. REPORTING OF LISTED CHEMICAL MANUFACTURING.

Section 310(b) of the Controlled Substances Act (21 U.S.C. 830(b)) is amended-

(1) by inserting "(1)" after "(b)";
(2) by redesignating paragraphs (1), (2), (3), and (4) as subparagraphs (A), (B), (C), and (D), respectively;
(3) by striking "paragraph (1)" each place it appears and inserting "subparagraph (A)";
(4) by striking "paragraph (2)" and inserting "subparagraph

(5) by striking "paragraph (3)" and inserting "subparagraph

(C)"; and

(6) by adding at the end the following new paragraph: "(2) A regulated person that manufactures a listed chemical shall report annually to the Attorney General, in such form and manner and containing such specific data as the Attorney General shall prescribe by regulation, information concerning listed chemicals manufactured by the person. The requirement of the preceding sentence shall not apply to the manufacture of a drug product that is exempted under section 102(39)(A)(iv).".

Regulations.

#### SEC. 11. EFFECTIVE DATE.

21 USC 802 note.

This Act and the amendments made by this Act shall take effect on the date that is 120 days after the date of enactment of this Act.

Approved December 17, 1993.

LEGISLATIVE HISTORY—H.R. 3216:

HOUSE REPORTS: No. 103-379, Pt. 1 (Comm. on Energy and Commerce).

CONGRESSIONAL RECORD, Vol. 139 (1993): Nov. 21, considered and passed House. Nov. 24, considered and passed Senate.