COSMOS
Navigate the Compliance Universe

21 U.S. Code § 830

Regulation of listed chemicals and certain machines

(a) Record of regulated transactions

(1) Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction for two years after the date of the transaction.

(2) A record under this subsection shall be retrievable and shall include the date of the regulated transaction, the identity of each party to the regulated transaction, a statement of the quantity and form of the listed chemical, a description of the tableting machine or encapsulating machine, and a description of the method of transfer. Such record shall be available for inspection and copying by the Attorney General.

(3) It is the duty of each regulated person who engages in a regulated transaction to identify each other party to the transaction. It is the duty of such other party to present proof of identity to the regulated person. The Attorney General shall specify by regulation the types of documents and other evidence that constitute proof of identity for purposes of this paragraph.

(b) Reports to Attorney General

(1) Each regulated person shall report to the Attorney General, in such form and manner as the Attorney General shall prescribe by regulation—

(A) any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this subchapter;

(B) any proposed regulated transaction with a person whose description or other identifying characteristic the Attorney General furnishes in advance to the regulated person;

(C) any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person; and

(D) any regulated transaction in a tableting machine or an encapsulating machine.

Each report under subparagraph (A) shall be made at the earliest practicable opportunity after the regulated person becomes aware of the circumstance involved. A regulated person may not complete a transaction with a person whose description or identifying characteristic is furnished to the regulated person under subparagraph (B) unless the transaction is approved by the Attorney General. The Attorney General shall make available to regulated persons guidance documents describing transactions and circumstances for which reports are required under subparagraph (A) and subparagraph (C).

(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 802(39)(A)(iv) of this title.

(3)**Mail order reporting.—**

(A) As used in this paragraph:

(i) The term "drug product" means an active ingredient in dosage form that has been approved or otherwise may be lawfully marketed under the Food, Drug, and Cosmetic Act[1] [21 U.S.C. 301 et seq.] for distribution in the United States.

(ii) The term "valid prescription" means a prescription which is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.

(B) Each regulated person who engages in a transaction with a nonregulated person or who engages in an export transaction which—

(i) involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals); and

(ii) uses or attempts to use the Postal Service or any private or commercial carrier;

shall, on a monthly basis, submit a report of each such transaction conducted during the previous month to the Attorney General in such form, containing such data, and at such times as the Attorney General shall establish by regulation.

(C) The data required for such reports shall include—

(i) the name of the purchaser;

(ii) the quantity and form of the ephedrine, pseudoephedrine, or phenylpropanolamine purchased; and

(iii) the address to which such ephedrine, pseudoephedrine, or phenylpropanolamine was sent.

(D) Except as provided in subparagraph (E), the following distributions to a nonregulated person, and the following export transactions, shall not be subject to the reporting requirement in subparagraph (B):

(i) Distributions of sample packages of drug products when such packages contain not more than two solid dosage units or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.

(ii) Distributions of drug products by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as specified in section 802(49) of this title, except that this clause does not apply to sales of scheduled listed chemical products at retail.

(iii) Distributions of drug products to a resident of a long term care facility (as that term is defined in regulations prescribed by the Attorney General) or distributions of drug products to a long term care facility for dispensing to or for use by a resident of that facility.

(iv) Distributions of drug products pursuant to a valid prescription.

(v) Exports which have been reported to the Attorney General pursuant to section 954 or 971 of this title or which are subject to a waiver granted under section 971(f)(2) of this title.

(vi) Any quantity, method, or type of distribution or any quantity, method, or type of distribution of a specific listed chemical (including specific formulations or drug products) or of a group of listed chemicals (including specific formulations or drug products) which the Attorney General has excluded by regulation from such reporting requirement on the basis that such reporting is not necessary for the enforcement of this subchapter or subchapter II.

(E) The Attorney General may revoke any or all of the exemptions listed in subparagraph (D) for an

individual regulated person if he finds that drug products distributed by the regulated person are being used in violation of this subchapter or subchapter II. The regulated person shall be notified of the revocation, which will be effective upon receipt by the person of such notice, as provided in section 971(c)(1) of this title, and shall have the right to an expedited hearing as provided in section 971(c)(2) of this title.