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A SURVEY OF UNITED STATES LAWS RESTRICTING THE EXPORT OF CONTROLLED AND HAZARDOUS SUBSTANCES

*Donald M. Goldberg**

INTRODUCTION

This paper describes the United States legal and regulatory regimes for the export of various controlled and hazardous substances, including drugs, pesticides, chemicals, radioactive materials, and hazardous wastes. These substances are controlled by a variety of statutes: drugs by the Food, Drug, and Cosmetic Act (FDCA), pesticides by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); chemicals intended for commercial use by the Toxic Substances Control Act (TSCA); chemicals for consumer use by the Consumer Product Safety Act (CPSA) and, if hazardous, the Federal Hazardous Substances Act (FHSA); ozone depleting chemicals by Title VI of the Clean Air Act Amendments of 1990; radioactive materials by the Atomic Energy Act (AEA); and hazardous wastes by the Resource Conservation and Recovery Act (RCRA).[1]

A comparison of these statutes and implementing regulations reveals that there is no single, unified approach in United States law to regulating the export of controlled or hazardous substances. Most of these statutes have notification, recording, reporting, and labelling requirements, but specific provisions vary from statute to statute. For example, most, but not all, of these statutes require that the exporter notify the appropriate regulatory agency prior to shipment. While some require notification to the importing country, only one requires that the importing country consent to the shipment. Five statutes have labelling requirements, but only one requires that the label be in the language of the importing country. Two statutes restrict retransfer to third countries, but only one places additional restrictions on the importer's practices.

This paper provides a comparative overview of these statutes and their implementing regulations, followed by more detailed, statute-by-statute descriptions. Although they have yet to be incorporated into the U.S. regulatory regime, the export provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Waste and Their Disposal have been included as an appendix.[2]

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*The author is an attorney with the Center for International Environmental Law (CIEL). This paper was prepared with the generous assistance of Chris A. Wold, also an attorney with CIEL.

[1]This paper does not cover the U.S. laws controlling the export of chemicals used in the manufacture of weapons or illegal drugs.

[2]As of Jan. 31, 1992, the Convention is one ratification short of the number required for entry into force. The U.S. has signed the Convention but has not yet ratified it or adopted implementing legislation.

OVERVIEW

NOTIFICATION

All the statutes but FIFRA and Title VI of the Clean Air Act require the exporter to notify the lead regulatory agency prior to shipment. No statute requires the exporter to notify the importing country, however. While all the statutes except FDCA and Title VI provide for notification by the agency to the importing country, only RCRA and, under some circumstances, FIFRA provide for notification to transit countries. FIFRA provides, in addition, that EPA must notify the importing country and appropriate international agencies if registration of the exported pesticide has been cancelled in the U.S. The EPA has proposed changing U.S. pesticide export regulations to bring them into conformity with the international FAO/UNEP Prior Informed Consent program (PIC).

CONSENT

While CPSA and FHSA require the Consumer Product Safety Commission to seek acknowledgement from the importing country that it has been notified, only RCRA requires that the importing country consent to the shipment. Indeed, under TSCA, the receiving country may not receive notification from EPA until after the substance has been shipped. No statute requires the consent of transit countries to the shipment. FIFRA requires the exporter to provide EPA with a purchaser acknowledgement, prior to shipment, stating that the purchaser understands that the pesticide is not registered and cannot be sold in the United States. FDCA requires the exporter to include with his application to export a written agreement from each importer that the drug will not be exported to any unapproved country.

REGISTRATION AND RECORDING

FIFRA and FDCA require that the exporter's manufacturing facility be registered, but only FDCA requires registration of the exported substance. Under TSCA and FDCA exporters must keep health records, which they must provide or make available on request to the lead regulatory agency. TSCA requires manufacturers, processors, and distributors to keep records of all known or alleged adverse reactions, and to submit to EPA all known or reasonably ascertainable health and safety studies. FDCA requires exporters, in certain circumstances, to provide the agency with information pertaining to the health effects of the exported substance. While FIFRA requires producers to record their own delivery, holding, or disposal of pesticides, only RCRA requires the exporter to maintain a complete "cradle-to-grave" record of the location and disposal of the exported hazardous wastes.

REPORTING

Under RCRA primary exporters are required to file an annual report with EPA, summarizing the types, quantities, frequency, and ultimate destination of all hazardous waste

exported during the previous year. Title VI requires exporters to report quarterly the amounts of controlled substances exported. FDCA requires all manufacturers to report continually on all approved new drugs, listing all clinical experience and other data relating to their safety or effectiveness. TSCA also has health reporting requirements, and is the only statute to require the exporter to report adverse environmental effects of the exported substances.

LABELLING

Six statutes, FIFRA, TSCA, CPSA, FHSA, FDCA, and Title VI, have labelling requirements, but only FIFRA requires that the label be in the language of the importing country, as well as in English. While FIFRA and Title VI require that the label contain information about the product, TSCA, CPSA, FHSA, and with respect to non-"new drugs" FDCA require only that the label state that the product is intended for export. New drugs pending approval for sale in the United States may be shipped to most OECD countries and in some cases to non-OECD countries, provided the drug has been approved in the receiving country. For such shipments FDCA requires only that the label state that the drug may not be sold within the U.S.

PACKAGING AND PREPARATION

RCRA, FIFRA, FDCA, and AEA require that the packaging and preparation of exported substances meet certain standards or specifications. Under RCRA the shipment must conform to the terms of the receiving country, while FIFRA requires the exporter to prepare and package the pesticide according to the directions or specifications of the foreign purchaser. FDCA requires that all exported drugs meet the foreign purchaser's specifications and conform to the laws of the importing country. New drugs for export must, in addition, comply with Food and Drug Administration "current good manufacturing practice" regulations and may not be "adulterated" within the meaning of the FDCA.

BAN ON EXPORT OR RETRANSFER

All statutes ban export when certain requirements are not met. For example, products which fail to comply with safety standards of the CPSA and FHSA cannot be exported if they have been distributed, sold, or offered for sale in the U.S. Title VI prohibits the export of controlled ozone depleting substances unless domestic consumption is reduced accordingly, so that the level of domestic production remains unchanged. While TSCA, FHSA, AEA and CPSA prohibit the export of substances that would pose a health or safety risk to the United States, no statute prohibits export upon a finding of risk to the importing country – although FDCA prohibits export of unapproved new drugs to all but 21 listed (OECD) countries. Only FDCA and AEA restrict the retransfer of controlled substances to third party countries.

A SURVEY OF UNITED STATES LAWS RESTRICTING THE EXPORT OF CONTROLLED AND HAZARDOUS SUBSTANCES

I. EXPORTING CHEMICALS

Chemicals are regulated under a number of different statutes, depending on the use for which the chemical is intended, the hazard posed by its use, and its effect on the ozone layer. Chemicals intended for commercial use are regulated by the Toxic Substances Control Act (TSCA),[1] while chemicals for consumer use are regulated by the Consumer Product Safety Act (CPSA)[2] or, if they are hazardous, the Federal Hazardous Substances Act (FHSA).[3] In addition, a separate regulatory regime has been established within the Clean Air Act to control and eventually phase out chemicals that deplete the ozone layer.[4]

A. *CHEMICALS FOR COMMERCIAL USE*

While TSCA regulates chemicals, mixtures, and articles containing chemicals or mixtures for commercial use, most provisions of TSCA do not apply to chemicals, mixtures, or articles that are intended for export and are properly marked as such.[5] Two provisions which do apply are the requirements to keep records and report to EPA. If, however the EPA determines that a "substance, mixture, or article will present an unreasonable risk of injury to health within the United States or to the environment of the United States," then all sections of TSCA apply, whether or not the substance, mixture, or article is intended for export.[6]

1. REPORTING REQUIREMENTS

In all cases, exporters must meet the reporting and recording requirements of 15 U.S.C. § 2607. These requirements vary according to the substance, but generally,

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[1]15 U.S.C. §§ 2601 *et seq.*

[2]15 U.S.C. §§ 2051 *et seq.*

[3]15 U.S.C. §§ 1261 *et seq.*

[4]P.L. 101-549.

[5]15 U.S.C § 2611(1).

[6]15 U.S.C. § 2611(a)(2). This language was presumably included to address the problem of reimportation to the U.S. No specific regulation has been discovered, however, which addresses this issue.

manufacturers and processors of listed chemicals and mixtures[7] are required by EPA to record and report to EPA

- the names of chemicals manufactured or processed,
- their intended uses,
- the amounts produced,
- byproducts,
- environmental and health effects,
- number of people exposed, and
- method of disposal.[8]

2. RECORDING REQUIREMENTS

Manufacturers, processors, and distributors must keep records of all known or alleged significant adverse reactions and submit to the EPA all known or reasonably ascertainable health and safety studies.[9]

3. NOTICE REQUIREMENTS

(a) *Exporter Notice Requirements*

In addition to meeting the above requirements, exporters must notify EPA in writing of the intent to export substances if

- they are hazardous substances for which testing and submission of data are required under TSCA §§ 4 or 5(b),[10]
- an order has been issued or a rule has been proposed or promulgated limiting or prohibiting manufacture, processing, distribution, use, or disposal of such substances, under TSCA §§ 4, 5, or 6, or

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[7]The chemicals are listed in 40 C.F.R §§ 704.25-.175 and .225.

[8]15 U.S.C. § 2607(a)(2).

[9]15 U.S.C. § 2607(c), (d).

[10]§§ 4 and 5(b) require testing and submission of data for all substances that may pose, or are manufactured by a process that may pose, an unreasonable risk of injury to health or to the environment. 15 U.S.C. §§ 2603 or 2604(b).

- court action is pending or EPA has been granted relief by the court to protect health or the environment, under TSCA §§ 5 or 7.[11]

In these circumstances, notice to EPA is required for the first export or intended export in a calendar year and postmarked within seven days of forming the intent to export or, at the latest, on the date of export.[12] The notice must be based on a definite contractual obligation or equivalent inter-company agreement[13] and must include

- the name of the regulated chemical,
- the name and address of the exporter,
- the countries of import,
- the dates of export, and
- the section of TSCA under which EPA has taken action.[14]

(b) *EPA Notice Requirements*

Within five working days of receipt of the notice from the exporter, EPA must notify the official designated by the importing country. This notice shall

- identify the regulated chemical,
- summarize the regulatory action taken, or indicate the availability of data,
- identify an EPA official to contact for further information, and
- include a copy of the pertinent *Federal Register* notice of the chemical's regulatory status.[15]

B. *CHEMICALS FOR CONSUMER USE*

Consumer chemicals are regulated by the Consumer Product Safety Act (CPSA).[16] They are also regulated by the Federal Hazardous Substances Act (FHSA)[17] if they are

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[11]15 U.S.C § 2611(b); 40 C.F.R 707.65(a).

[12]40 C.F.R 707.65(a).

[13]Id.

[14]40 C.F.R § 707.67.

[15]40 C.F.R § 707.70.

[16]15 U.S.C §§ 2051 et seq.

[17]15 U.S.C §§ 1261 et seq.

"hazardous substances" within the meaning of the Act.[18] Both acts are under the jurisdiction of the Consumer Product Safety Commission, and exports are regulated in the same manner with respect to both acts.[19]

A consumer product is *not* subject to the Consumer Product Safety Act if

- it is manufactured, sold, or held for sale or export from the United States, and
- it contains a label stating the intent to export, unless
- it is placed within commerce within the United States, or
- it presents an unreasonable risk to U.S. consumers.[20]

There are similar provisions for hazardous substances under the FHSA except that the label must meet the foreign countries specifications.[21]

1. NOTIFICATION REQUIREMENTS

Exporters are required to notify the Commission of intent to export products which fail to meet applicable consumer product safety rules issued under §§ 7 and 9 of the CPSA, which are banned under §§ 8 and 9 of the CPSA, or which are improperly labeled or banned hazardous substances under § 2(p) or (q) of the FHSA.[22]

Notification of intent to export noncomplying chemicals must be received by the Commission at least thirty days before the goods are to leave the customs territory of the United States.[23] The exporter must provide separate notification to the Commission for

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[18]The term "hazardous substance" means "any substance which is toxic, corrosive, an irritant, a strong sensitizer, flammable, combustible, or generates pressure through decomposition, heat, or other means, if such substance may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use including reasonably foreseeable ingestion by children." 15 U.S.C § 1261(f). Pesticides subject to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. §§ 135 et seq.) and foods, drugs, and cosmetics subject to the Federal Food, Drug, and Cosmetic Act (21 U.S.C §§ 301 et seq.) are not hazardous substances under FHSA. 15 U.S.C § 1261(f). Nor are they consumer products within the meaning of the CPSA. 15 U.S.C. § 2052(a).

[19]See 16 C.F.R §§ 1010.1-1010.3; 16 C.F.R §§ 1019.1-1019.8.

[20]15 U.S.C. § 2067(a).

[21]15 U.S.C. § 1264(b).

[22]16 C.F.R. § 1019.5.

[23]16 C.F.R § 1019.5.

each country to which noncomplying goods are exported.[24] The notice must be received by the Commission at least thirty days before the non-complying goods are to leave the customs territory of the United States and must include

- name, address, and telephone number of the exporter,
- name and address of each consignee,
- description of the goods to be exported, including amounts and brands,
- the requirements with which the goods fail to comply and a description of how the goods fail those requirements,
- anticipated date of shipment and port of destination.[25]

After receiving notification, the Commission is to inform on a priority basis the appropriate government agency of the receiving country of the exportation and the basis on which the goods are banned or fail to comply with Commission standards, regulations, or statutes. The Commission is also to transmit all information supplied by the exporter and to seek acknowledgement that notice was received by the importing country.[26] Although the regulations contemplate that foreign governments may wish to prohibit entry of non-complying goods, it is not required that information provided to the importing country by the Commission be received prior to shipment.

2. EXPORT BANS

Products that are improperly labeled, fail to comply with consumer product safety standards, or are banned hazardous substances, cannot be exported if

- they have been distributed, sold, or offered for sale in the U.S.,[27]
- they are not intended strictly for export and labeled as such,[28] or
- they present an unreasonable risk of injury to consumers in the U.S.[29]

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[24]16 C.F.R. § 1019.4(b).

[25]16 C.F.R. § 1019.4(c)

[26]216 C.F.R § 1019.7.

[27]16 C.F.R § 1010.3.

[28]15 U.S.C 2057(a); 15 U.S.C 1264(b); 16 C.F.R 1010.2.

[29]*Id.*

C. *OZONE DEPLETING CHEMICALS*

The Montreal Protocol on Substances That Deplete the Ozone Layer,[30] provides for the control and phaseout of ozone depleting substances, including CFCs, halons, and carbon tetrachloride. Implementing provisions of the Montreal Protocol and its 1990 London Amendment[31] are contained in Title VI of the Clean Air Act of 1990.[32]

1. REPORTING REQUIREMENTS

Title VI requires producers, importers, and exporters of controlled substances – designated by the Protocol as class I or class II substances[33] – to report on a quarterly basis, or on such other basis (not less than annually) as is determined by EPA, the amounts of those substances produced, imported, and exported.[34] Reports also must be submitted specifying the amount of class I substances that were produced, imported, or exported in the baseline year.[35]

2. EXPORT RESTRICTIONS

The Montreal Protocol does not place restrictions on the export of ozone depleting substances. It does, however, prohibit the export of technologies used to produce class I substances, and prohibits investment in facilities to produce such substances in any country which is not a party to the Protocol. Government agencies are prohibited from providing multilateral or bilateral aid for production of class I substances.[36]

Producers may exceed production limits for the purpose of exporting controlled substances to developing countries operating under Article 5 of the Protocol. This additional production may not exceed 10% of the baseline amount during the phaseout period. After the end of the phaseout period it may not exceed 15% of the baseline amount.[37]

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[30]26 I.L.M. 1550 (1987).

[31]__ I.L.M. __ (19__).

[32]P.L. 101-549.

[33]Class I substances include __. Class II substances include __.

[34]P.L. 101-549 § 603(b).

[35]P.L. 101-549 § 603(c). The baseline year for class I substances is either 1986, 1989, or is to be set by EPA, depending on the substance. P.L. 101-549 § 601(2).

[36]P.L. 101-549 § 614(c).

[37]P.L. 101-549 §§ 604(e), 605(d)(2).

Title VI also permits production allowances to be transferred between the U.S. and other Parties, provided the transferring Party lowers domestic production limits accordingly.[38]

3. LABELLING

Effective April 1993 containers containing class I or class II substances or products containing a class I substance must bear a clear, legible label stating:

> "Warning: Contains [name of substance], a substance which harms public health and environment by destroying ozone in the upper atmosphere."[39]

Similar labels on products containing class II substances will be required if EPA finds that there are substitute products or manufacturing processes:

- that do not rely on the use of such class II substances;
- that reduce the overall risk to human health and the environment; and
- that are currently or potentially available.[40]

II. EXPORTING DRUGS

A. *EXPORTING REQUIREMENTS GENERALLY*

The export of drugs is regulated by the Food, Drug, and Cosmetic Act (FDCA).[41] Generally, the FDCA prohibits the introduction into interstate commerce--including export--of 'adulterated'[42] or 'misbranded'[43] drugs. However, except for 'new drugs,' which in most cases must be approved for marketing by the FDA before they may be exported (see below) drugs may be exported without meeting FDCA requirements concerning adulteration and misbranding provided they:

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[38]P.L. 101-549 § 611(c).

[39]P.L. 101-549 § 611(b).

[40]P.L. 101-549 § 611(c).

[41]21 U.S.C. §§ 301 *et seq.*

[42]Adulterated drugs are drugs which, *inter alia*, are poisonous, contain unsanitary ingredients, are not made in accordance with good manufacturing procedures, or are not of recognized strength, quality, or purity. 21 U.S.C. § 351.

[43]Drugs are misbranded if, *inter alia*, their labeling is false or misleading, they are not marked as habit forming (if they are so), or they are dangerous when used as prescribed. 21 U.S.C. § 352.

- meet the foreign purchaser's specifications;
- comply with the laws of the importing country;
- are labeled on the outside of the shipping container that they are intended for export; and
- are not sold or offered for sale in domestic commerce.[44]

B. *RECORDS AND REPORTING*

Exporters must comply with FDCA recording and reporting requirements, including:

- registering annually with FDA;
- filing an initial list of all drugs manufactured by the exporter and updating the list semiannually;
- submitting the labeling of all prescription drugs on the lists;
- reporting annually on all drugs subject to approved new drug applications, listing all relevant information obtained during the preceding year.[45]

C. *EXPORTING NEW DRUGS*

'New drugs' are substances which are:

- classified as drugs;
- not generally recognized by qualified scientists as safe and effective; and
- do not have a pre-1938 record of use identical to the use presently intended.[46]

Until they have received FDA approval, new drugs cannot be sold domestically nor, in most cases, can they be exported.[47] To obtain FDA approval, it is necessary to file a new drug application. The filing procedures include:

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[44]21 U.S.C. § 381(e)(1).

[45]21 U.S.C. §§ 355 and 360; 21 C.F.R. § 310.303.

[46]21 U.S.C. 321(p).

[47]21 U.S.C. § 355(a). An exporter wishing to export a new drug can probably avoid U.S. testing and approval requirements by exporting, subject to TSCA regulations, the uncombined chemical constituents of the drug and having them combined to form the new drug abroad. The export of chemical constituents which are not themselves new drugs is not prohibited by FDCA. 21 U.S.C. § 355(a).

- filing an investigational new drug application (IND) in anticipation of initial testing;
- Phase I basic human studies;
- Phase II studies with patients;
- Phase III effectiveness and safety tests;
- Meetings with FDA;
- Review and approval of the new drug application by FDA.[48]

D. *THE DRUG EXPORT AMENDMENTS OF 1986*

Concerned about the sharply diminishing U.S. share of world pharmaceutical production and export, Congress amended the FDCA in 1986. The Amendments created a three-track scheme for the restricted export of unapproved new pharmaceuticals.[49]

1. *Track 1* - Export to Listed Countries

(a) General Requirements

Unapproved new drugs may be exported to twenty-one listed countries[50] provided:

- The drug is approved for sale in the country of import;
- The product has the same active ingredients as a product that has an IND;
- Approval to market the product covered by the IND is being actively pursued;
- FDA has not taken final action refusing to approve the IND product for marketing;
- The product complies with current good manufacturing practice regulations as set out in 21 C.F.R. 210 and 211 and is not adulterated under 21 U.S.C. § 351(a)(1), (a)(2)(A), (a)(3), (c), or (d).
- The outside shipping package label states: "This drug may be sold or offered for sale only in the following countries: (names of countries)"

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[48]*See* J. O'Reilly, Food and Drug Administration, § 13.11 (1990.)

[49]The third track deals only with export of partially processed biological products such as blood, serum, and vaccines and is not included in this summary.

[50]The listed countries are: Australia, Austria, Belgium, Canada, Denmark, Germany, Finland, France, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom. 21 U.S.C. § 382(a)(4)(A).

- FDA has not determined that the export of the product is contrary to the public health and safety of the United States; and
- The product complies with the four requirements of 21 U.S.C. § 381(e)(1) (see Part I, above).[51]

(b) Application to Export

Application for export must be filed at least 90 days before the planned export date.[52] Within 10 days of filing the Secretary is to publish a notice of the filing in the Federal Register.[53] The application must:

- Identify the drug to be exported;
- List each country to which the drug is to be exported;
- Contain a certification that:
  - The drug will be exported only to one or more of the twenty-one listed countries that have approved the drug;
  - Only quantities which may be sold in listed countries will be exported;
  - The drug has not been withdrawn from sale in any importing country;
  - Approval for marketing of the drug is actively being sought;
- Identify the establishments in which the drug is being manufactured;
- Include a written agreement from each importer that:
  - The drug will not be exported to a country which is not one of the twenty-one listed countries;
  - The importer will provide notice to the applicant of any knowledge of export to a non-listed country;
  - The importer will maintain records of all wholesalers to which the drug is sold.[54]

The holder of an approved export application must notify FDA within 15 days of:

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[51]21 U.S.C. § 382(b)(1); see also USDHHS, A Review of FDA's Implementation of the Drug Export Amendments of 1986 (1990).

[52]21 U.S.C. § 382(b)(3)(A).

[53]*Id.*

[54]21 U.S.C. § 382(b)(3)(B).

- Withdrawal of approval by the importing country;
- Withdrawal from sale by an importing country;
- Withdrawal of the new drug application for the IND drug;
- Any credible information that the drug may have been exported to a third, non-listed country.[55]

The holder of an approved export application must report annually to the FDA the actions taken during the previous year in pursuit of approval of the IND drug. 21 U.S.C § 382(c)(2).

2. *Track 2* - Drugs for Treatment of a Tropical Disease

An unapproved drug may, upon FDA approval of an export application, be exported to any country in which the FDA has determined, based on credible scientific evidence, that the product is safe and effective for the treatment of a tropical disease.

(a) General Requirements

To be exported under Track 2, a product must also:

- Comply with current good management practices and not be adulterated under 21 U.S.C. § 351(a)(1), (a)(2)(A), (a)(3), (c), or (d),
- Bear on the outside shipping package an appropriate label stating "This drug may be sold or offered for sale only in the following countries: (name of countries)";
- Comply with the four requirements of 21 U.S.C. 381(e)(1) (see Part I supra);
- Not be the subject of a notice by FDA that the export of the drug is contrary to the public health and safety of the United States.[56]

Unlike Track 1, Track 2 does not require that the drug to be exported contain the same active ingredient as a drug covered by an IND and for which approval is being actively sought in the U.S..

(b) Application to Export

An application to export must:

- Describe the drug to be exported;

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[55]21 U.S.C. § 382(c)(1).

[56]21 U.S.C. § 382(f)(1).

- Identify the countries to which export is requested;
- Identify the establishments in which the drug is manufactured;
- Certify that the drug will not be exported to a country for which FDA cannot determine the safe and effective use of the drug; and
- Demonstrate that all other pertinent requirements of the Act have been met.[58]

(c) Reporting Requirements

The holder of an approved Track 2 export application must report to FDA:

- Any information concerning the export of such drug from an approved importing country to a third country;
- Any adverse reactions to the exported drug.[59]

3. NEPA REQUIREMENTS

Under FDA's NEPA regulations, the approval of an application to export an unapproved drug under either Track 1 or Track 2 requires the submission of an environmental assessment (EA).[60] The EA must contain, *inter alia* , the following information:

- Description of the proposed action;
- Identification of the substances that are the subject of the proposed action;
- Substances to be emitted into the environment;
- Predicted levels of concentration and exposure in the air, water, and on land;
- Environmental effects of released substances;
- Use of resources and energy;
- Mitigation measures;
- Alternatives to the proposed action.[61]

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[58]21 U.S.C. § 382(f)(2).

[59]21 U.S.C. § 382(f)(3).

[60]21 C.F.R. 25.22; A Review of FDA's Implementation of the Drug Export Amendments of 1986 (1990).

[61]21 C.F.R. 25.31(a).

Applicants may be required to submit data in their EA on the consequences of the export of the drug on the importing country's environment. A Review of FDA's Implementation of the Drug Export Amendments of 1980 (1990).

There are no categories of FDA actions which routinely require the preparation of an environmental impact statement (EIS). An EIS is required, however, when:

- evaluation of data in an EA leads to a finding by the FDA that a proposed action may significantly affect the quality of the human environment; or
- initial evaluation of any FDA action establishes that significant environmental effects may be associated with one or more of the probable courses of action being considered.[60]

III. EXPORTING PESTICIDES

Pesticide exports in the U.S. are regulated by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[61]

All producers, including producers of pesticides for export, must register their place of manufacture with EPA and receive an establishment number.[62] They also are required to record their delivery, movement, holding, and disposal of pesticides, and must make these records available for inspection by EPA.[63]

A. *LABELLING REQUIREMENTS*

Every exported pesticide, whether registered or unregistered, must bear a label containing, conspicuously and in English:

- the EPA Establishment Number,
- ingredient statements,
- the name and address of the producer,
- net weight or measure,

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[60]21 C.F.R. 25.21(b).

[61]7 U.S.C §§ 136 to 136y, § 136o(a). Other federal statutes regulate pesticides, but not the export of pesticides, per se. For example, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321) requires EPA to set 'tolerances' of acceptable pesticide residues. While these tolerances apply to imported produce, they do not affect the regulation of pesticide exports.

[62]7 U.S.C. 136(e); 40 C.F.R. § 162.10(f).

[63]7 U.S.C. 136(f).

- if highly toxic, skull and crossbones, the word "poison," and a statement of practical treatment,
- warning and caution statements, and
- in the case of unregistered pesticides, the statement "Not Registered for Use in the United States of America."[64]

All requirements, except the establishment number and producer address, also must be written in the language of the importing country.[65] The label may not contain false representations and the packaging may not imitate any other product.[66]

2. *REQUIREMENTS FOR EXPORTERS OF UNREGISTERED PESTICIDES*

In addition to the labelling requirements set out above, exporters of unregistered pesticides must:

- prepare or package the pesticides according to the directions or specification of the foreign purchaser.[67] EPA has proposed that this be made a requirement for *all* exported pesticides.[68]
- get a written statement from the foreign purchaser acknowledging that he/she understands that the pesticide is not registered in the U.S. and that it cannot be sold in the U.S. This acknowledgment must be received before the product is released for shipment, and must be renewed annually.[69]
- send a copy of the purchaser acknowledgment to EPA, within seven says of receipt, along with a signed certification stating that shipment did not take place before the acknowledgment was received.[70] The EPA is to promptly transmit the acknowledgment statement to the appropriate foreign official through the U.S. Embassy in that country.

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[64]45 Fed. Reg. 50,275.

[65]7 U.S.C. § 136o(a)(1); 40 C.F.R. § 156.10; 45 Fed. Reg. 50,275.

[66]7 U.S.C. §§ 136(q) and 136o(a)(1); 40 C.F.R. § 156.10; 45 Fed. Reg. 50,275.

[67]7 U.S.C. § 136o(a)(1).

[68]55 Fed. Reg. 4,971.

[69]7 U.S.C. § 136o(a)(2); 45 Fed. Reg. 50,276-77.

[70]45 Fed. Reg. 50,276.

3. *EXPORT REQUIREMENTS FOR SUSPENDED OR CANCELED PESTICIDES*

If a pesticide registration is canceled, suspended, or otherwise ceases to be effective, EPA must notify, through the State Department, other countries and appropriate international agencies of the change. Such notice must contain, upon request, information concerning other registered pesticides which could be used in place of the deregistered pesticide.[71]

4. *CONFIDENTIALITY*

EPA has recently modified its policy regarding the confidentiality of information reported to EPA by pesticide producers. EPA has given notice that it now treats as public information the name and location of production facilities, the names of pesticides produced, sold or distributed, and the active ingredients used. In addition, it will make public the fact that an exporter has notified EPA that it intends to export an unregistered pesticide,[72] and will release the names of countries to which unregistered pesticides are exported.[73]

5. *PROPOSED EPA POLICY*

EPA has proposed changes to its pesticide exports procedures and export labeling requirements.[74] The review is being undertaken, in part, to bring the U.S. into conformity with the joint FAO/UNEP Prior Informed Consent program (PIC), which provides uniform country notification procedures for banned or severely restricted pesticides and industrial chemicals. EPA is considering requiring purchaser acknowledgments for products which are identical or substantially similar to registered chemicals, while not requiring them for unregistered products which are exported only for research and development purposes. It also is considering multilingual requirements for acknowledgment statements and labels, and is proposing to expand the number of countries to be notified under 7 U.S.C § 136o(a)(2).

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[71] 7 U.S.C. § 136o(b).

[72] 55 Fed. Reg. 1261.

[73] EPA Class Determination 1-91.

[74] 55 Fed. Reg. 4,956 (Feb. 12, 1990).

IV. EXPORTING HAZARDOUS WASTE

A. *RESOURCE CONSERVATION AND RECOVERY ACT*

Hazardous waste is regulated by the Resource Conservation and Recovery Act (RCRA).[75] Under RCRA, 'hazardous waste' means 'solid waste' or a combination of solid wastes which may (1) cause or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness or (2) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.[76] 'Solid waste' includes solids, liquids, and contained gases resulting from commercial and community activities, but excludes source, special nuclear, or byproduct material regulated by the Atomic Energy Act of 1954, as amended.[77] (See below).

1. EXPORTING REQUIREMENTS

Export of hazardous waste is prohibited unless

- EPA has received prior notification,
- the receiving country has consented to accept the hazardous waste,
- a copy of the EPA Acknowledgement of Consent (the receiving country's consent) accompanies the shipment, and
- the shipment conforms to the terms of the receiving country.[78]

2. NOTIFICATION REQUIREMENTS

An exporter of hazardous waste must notify EPA 60 days before shipment abroad and may cover activities for twelve months or less. Notification must be in writing, signed by the exporter, and include

- the exporter's name, address, telephone number, and EPA ID number,
- the waste type,
- frequency and length of time of exports,
- quantity of waste to be exported,

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[75]42 U.S.C. §§ 6901 *et seq.*

[76]42 U.S.C. § 6903(5).

[77]42 U.S.C. § 2011). 42 U.S.C. § 6903(27).

[78]42 U.S.C. § 6938; 40 C.F.R. § 262.52.

- all entry and departure points for each country through which the waste will pass,
- description of mode of transport,
- method of treatment, storage, and disposal in receiving country,
- name and address of consignee, and
- length of time and manner of handling in transit countries.[79]

3. OTHER EXPORT REQUIREMENTS

The State Department and EPA must provide a complete notification to the receiving country and any transit countries.[80] EPA will inform the exporter as to whether the receiving country consents to the shipment.[81]

No later than March 1 of each year, primary exporters must file an annual report with the EPA, summarizing the types, quantities, frequency, and ultimate destination of all hazardous waste exported during the previous year.[82]

Exporters must record the location of the hazardous waste from "cradle to grave." In addition, they must keep for a period of three years copies of (1) notification of intent to export, (2) each EPA Acknowledgement of Consent, (3) each confirmation of delivery, and (4) each annual report.[83]

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[79]40 C.F.R. § 262.53(a).

[80]40 C.F.R. § 262.53(e).

[81]40 C.F.R. § 262.53(f).

[82]40 CFR § 262.56(a).

[83]40 C.F.R. § 262.57(a).

V. RADIOACTIVE MATERIALS[84]

U.S. law, for purposes of export, does not distinguish radioactive waste from other radioactive materials.[85] The export of radioactive materials, including source material,[86] special material,[87] and byproduct material,[88] is regulated under the Atomic Energy Act.[89]

A. *LICENSING REQUIREMENTS*

The export of radioactive materials requires a general or specific license issued by the Nuclear Regulatory Commission.[90] Information provided by the applicant, and all other information required by the Commission, must be complete and accurate in all material respects.[91]

Every applicant and licensee must notify the Commission of any information having a significant implication for public health and safety or common defense and security, within two working days of identifying the information.[92]

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[84]This section analyzes provisions contained in 10 C.F.R. §§110.1-.135. as authorized by the Atomic Energy Act (42 U.S.C. §§ 2011 *et seq.*). It does not cover any material contained in the Guidelines of the International Atomic Energy Agency (IAEA) or the Treaty on the Non-Proliferation of Nuclear Weapons (T.I.A.S. 6839).

[85]The Nuclear Regulatory Commission is contemplating developing a legal regime specifically to address the export of radioactive wastes but, to date, has published no proposals.

[86]'Source material' means (1) uranium or thorium, other than special nuclear material, or (2) ores which contain by weight 0.05% or more of uranium or thorium, or any combination of these. 10 C.F.R. § 110.2.

[87]'Special nuclear material' means plutonium, uranium-233 or uranium enriched above 0.711% by weight in the isotope uranium-235. *Id.*

[88]'Byproduct material' means radioactive material (except special nuclear material) produced by the exposure to the radiation incident to the process of producing or using special nuclear material. *Id.*

[89]42 U.S.C. §§ 2011 *et seq.*

[90]10 C.F.R. § 110.5.

[91]10 C.F.R. § 110.7a(a).

[92]10 C.F.R. § 110.7a(b).

B. *GENERAL LICENSE*

A general license may be issued for certain categories of source material,[93] special material,[94] and byproduct material,[95] if the Commission determines that any exports or imports made under the general license will not be inimical to the common defense and security or constitute an unreasonable risk to the public health and safety and otherwise meet applicable statutory requirements.[96]

A general license for export may not be used if the exporter knows or has reason to believe that the material will be used in any activity related to isotope separation, chemical reprocessing, heavy water production, or the fabrication of nuclear fuel containing plutonium, unless those activities are authorized under an agreement for cooperation.[97]

For security reasons, source material, special material, byproduct material, and equipment may not be shipped to Cuba, Kampuchea, North Korea, or Viet Nam under an NRC general license.[98] Any other country may lose its general license eligibility in response to "significant adverse developments" in that country.[99]

C. *SPECIFIC LICENSE*

A person may apply for a specific license to export materials which cannot be exported under a general license. An application for a specific license must include

- the name and address of the applicant,
- the name and address of the supplier of the material,
- the country of origin of the material, if known,
- the names and addresses of all intermediate and ultimate consignees, other than intermediate consignees performing shipping services only,
- the dates of proposed first and last shipment,

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[93]*See* 10 C.F.R. § 110.22.

[94]*See* 10 C.F.R. § 110.21.

[95]*See* 10 C.F.R. § 110.23.

[96]10 C.F.R. § 110.20(a). The NRC interprets this provision to pertain to health and safety risks in the U.S. only.

[97]10 C.F.R. § 110.20(d).

[98]10 C.F.R. §§ 110.21-.23, and .28.

[99]10 C.F.R. § 110.20(e).

- a description of the material.[100]

1. LICENSING CRITERIA

The following criteria govern the review of licensing applications:

- IAEA safeguards as required by Article III (2) of the Treaty on the Non-Proliferation of Nuclear Weapons[101]
- the material exported may not be used for any nuclear explosive device or for research and development of such a device,
- adequate security measures, as set forth in 10 C.F.R. § 110.43, must be taken,
- material may not be retransferred to the jurisdiction of any other country without prior approval of the U.S.,
- material may not be reprocessed or otherwise altered without prior approval of the U.S.
- IAEA safeguards must be maintained by non-nuclear weapon importing countries,[102]
- the export must not be inimical to the common defense and security.[103]

No license to export material, other than byproduct material, will be issued for any non-nuclear weapon state which the President determines has

- detonated a nuclear explosive device,
- terminated or abrogated IAEA safeguards,
- materially violated an IAEA safeguard agreement,

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[100]10 C.F.R. § 110.31.

[101]T.I.A.S. 6839.

[102]This criterion will not be applied if the President notifies the Commission that failure to approve an export because this criterion has not been met would be seriously prejudicial to the achievement of U.S. nonproliferation objectives or otherwise jeopardize the common defense and security. 10 C.F.R. § 110.42(6).

[103]10 C.F.R. § 110.42.

- engaged in activities involving source or special materials and having direct significance for the manufacture or acquisition of nuclear explosive devices, and failed to take sufficient steps toward terminating such activities.[104]

No license to export material, other than byproduct material, to any country which the President determines has

- materially violated an agreement for cooperation with the U.S. or the terms of any other agreement under which nuclear equipment or material has been exported,
- assisted, encouraged, or induced any non-nuclear weapon state to engage in activities involving source or special material and having direct significance for the manufacture or acquisition of nuclear explosive devices, and failed to take sufficient steps to terminate such activity,
- entered into an agreement for the transfer of reprocessing equipment, materials, or technology to the control of a non-nuclear weapon state.[105]

[104]10 C.F.R. § 110.45(A).

[105]10 U.S.C. § 110.45(b). The President may waive these requirements after determining that the cessation of exports to an implicated country would seriously prejudice the achievement of U.S. nonproliferation objectives or otherwise jeopardize the common defense and security.

EXPORTING REQUIREMENTS OF CONTROLLED AND HAZARDOUS SUBSTANCES IN THE UNITED STATES

	FIFRA	TSCA	CPSA/ FHSA	Title VI	RCRA	FDCA	AEA
Consent from importer	A						
Consent from importing country					A		A
Consent from transit countries							
Notification to importing country by exporters							
Notification to importing country by U.S. government	A	A	A		A		
Notification to transit countries	S				A		
Notif. to U.S. of intent to ship		S	S		A		S
Notification to import country of substance's deregistration	A						
Labelling requirements	A		A	A		A	
Bilingual/Multilingual labelling	S						
Packaging and preparation requirements	A					A	
License to ship					A		A
Registration of manufacturing facility	A					A	
Registration of substance					A?	A	
Records of exporter to U.S. agency		A				A	
Safety, health, environmental information to U.S. agency		A				A	
"Unreasonable risk" standard - importing country							
"Unreasonable risk" standard - U.S.		S	S			A	A
Restrictions on importer practices							A
Restrictions on retransfer						S	A
Substances banned for export			S			S	A
Must meet for purchaser's specs						A	
Must comply with importing					A	A	
Cradle-to-grave recording					A		
Reporting to regulatory agency				A	A		

A - Always S - Sometimes

APPENDIX

BASEL CONVENTION

The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (Basel Convention)[106] creates an international regime for regulation of and reporting on the transboundary shipment of hazardous wastes.[107]

A. *GENERAL OBLIGATIONS*

Parties to the Convention are obligated

- to ensure that generation of waste is reduced to a minimum,
- to ensure that domestic disposal facilities are adequate,
- to prevent pollution due to hazardous waste,
- to ensure that transboundary movement of wastes is reduced to a minimum,
- to not allow the export of wastes to Parties that prohibit import of such wastes, or if the exporting State believes the wastes will not be handled in an environmentally sound manner,
- to provide information on exported wastes to importing Parties,
- to prevent the importation of wastes if it has reason to believe they will not be handled in an environmentally sound manner, and
- to cooperate with other Parties and interested organizations to ensure the environmentally sound management of wastes and the prevention of illegal traffic in wastes.[108]

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[106]*Done*, March 22, 1989 at Basel, 28 ILM 649, 657 (1989).

[107]The Basel Convention will enter into force on the ninetieth day after the date of deposit of the twentieth instrument of ratification, acceptance, formal confirmation, approval, or acceptance. To date, ten instruments have been received. The U.S. is a signatory, but has not yet ratified the Convention.

[108]Art. 4 §§ 1, 2.

In addition, Parties may not permit wastes to be exported to, or imported from, a non-Party.[109] Nor may Parties permit wastes to be exported for disposal within the area south of 60° South latitude.[110]

Parties must also

- prohibit unauthorized persons under their jurisdiction from transporting or disposing of wastes,
- ensure that waste subject to transboundary movement are packaged, labelled, and transported in conformity with generally accepted and recognized rules and standards, and
- require a movement document to accompany wastes from the commencement of movement to disposal.[111]

Parties must take appropriate measures to ensure that the transboundary movement of wastes will be allowed only if

- the State of export does not have the technical capacity and the necessary facilities to dispose of those wastes in an environmentally sound manner,
- the wastes are required as a raw material for recycling or recovery industries in the State of import, or
- the transboundary movement is in accordance with other criteria to be decided upon by the Parties.[112]

B. *TRANSBOUNDARY SHIPMENTS*

Parties are required to designate one or more competent authorities and a focal point to receive notification.[113] Parties must notify, or require the exporter to notify, in writing and through the competent authority of the State of export the competent authority of concerned States of any transboundary movement of wastes. The State of export may not permit shipment until notice of consent has been received in writing from the receiving

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[109]Art. 4 § 5.

[110]Art. 4 § 6.

[111]Art. 4 § 7.

[112]Art. 4 § 9.

[113]Art. 5.

State. This notice must confirm the existence of a contract between the exporter and the disposer specifying environmentally sound management of the waste.[114]

Notice must also be sent to every State through which the shipment will pass (transit States). The shipment may not proceed unless all transit States consent.[115] Upon receipt of the shipment, the disposer must inform both the exporter and the competent authority of the exporting State that he has the wastes and, in due course, that he has completed disposal.[116] All transboundary movements of waste must be covered by insurance, as required by the States of import and transit.[117]

If a transboundary shipment cannot be completed, the exporter and State of export must take the waste back, unless alternative arrangements can be made for environmentally sound disposal within 90 days.[118]

C. *ILLEGAL TRAFFIC*

Illegal traffic includes the transboundary movement of wastes

- without proper notification or consent,
- with consent obtained by misrepresentation or fraud,
- that does not conform in a material way to the documents,
- that results in disposal in contravention of the Convention or international law.[119]

The Exporting State must within 30 days take back the wastes or otherwise properly dispose of them if it is the exporter's or the generator's conduct which is deemed illegal.[120] The importing State has similar obligations if the illegality is on the part of the importer or

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[114]Art. 6. § 3(b).

[115]Art. 6 § 4.

[116]Art 6 § 9.

[117]Art. 6 § 11.

[118]Art. 8.

[119]Art. 9 § 1.

[120]Art. 9 § 2.

disposer.[121] If the illegality cannot be assigned to persons in either the importing or the exporting State, then both States must cooperate to ensure proper disposal.[122]

D. *TRANSMISSION OF INFORMATION*

Before the end of the year the Parties must transmit to the Secretariat the following information:

- their designated competent authorities and focal point,
- the amount of hazardous and other wastes exported, their category, characteristics, destination, transit countries, and disposal method;
- the amount of hazardous and other wastes imported, their category, characteristics, origin, and disposal method,
- disposals that did not proceed as intended,
- efforts to achieve a reduction in the amount of wastes subject to transboundary movement,
- the measure adopted to implement the Convention,
- statistics on human health and the environment relating to generation, shipment, and disposal of wastes,
- information on bilateral, regional, and multilateral agreements for transboundary shipments of waste,
- information on accidents and measures to deal with them,
- information on local disposal options,
- information on measures taken to develop technology to reduce or eliminate production of wastes, and
- any other information deemed relevant by the Parties.[123]

In addition, the Parties must notify all concerned states of any accident occurring in the transboundary shipment of wastes which are likely to present risks to human health and the environment in other states.[124]

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[121]Art. 9 § 3.

[122]Art. 9 § 4.

[123] Art. 13 § 3.

[124]Art. 13 § 1.