



Health
Canada

Santé
Canada

Control of Precursors and Other Substances Frequently Used in the Clandestine Production of Controlled Substances

Discussion Document

Office of Controlled Substances
Drug Strategy and Controlled Substances Programme
Healthy Environments and Consumer Safety Branch
Health Canada

May 2001

TABLE OF CONTENTS

Glossary	i
Executive Summary	iii
Part I Purpose and Background	
Purpose	1
Background	2
Canada's International Obligations	4
Summary of Key Convention Articles	4
Resolutions and International Commitments	7
Canadian Compliance with the 1988 Convention and Other Resolutions: Precursors	8
Current Monitoring and Control of Precursors in Canada	8
Limitations in the Absence of Canadian Regulatory Framework	10
Part II Examples of Regulations in Other Countries	
The European Union	12
The United States	17
CICAD Model Regulations	20
Voluntary Programs	23
Part III Analytical Framework for Monitoring and Control	
Options	27
Discussion and Questions	34
Annex 1 (Text of Article 12)	41

GLOSSARY

CICAD	Inter-American Drug Abuse Commission a branch of the Organization of American States. CICAD has developed Model Regulations for precursors and other chemicals frequently used in the clandestine production of illicit drugs.
CND	Commission on Narcotic Drugs. This is the main drug policy body of the UN.
Controlled Substances	Substances listed in schedules I through V of the <i>Controlled Drugs and Substances Act</i> .
1961 Convention	United Nations Single Convention on Narcotic Drugs, 1961.
1971 Convention	United Nations Convention on Psychotropic Substances, 1971.
1988 Convention	United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.
DEA	Drug Enforcement Agency.
Declaration	A transaction-related report made to the Canadian government by a Canadian operator. (company to government)
ECOSOC	Economic and Social Council of the United Nations
Exempted preparations	Preparations pharmaceutical or otherwise that contain substances in Table I or Table II and are compounded in such a way that the substances cannot be easily or economically recovered (as stated in the 1988 UN Convention Commentary).
HS Code	Harmonized System Code. A code for chemicals as determined by the World Customs Organization.
INCB	International Narcotic Control Board, a quasi-judicial body appointed by ECOSOC and composed of 13 members. INCB is responsible for overseeing the implementation of UN drug conventions, including Article 12 of the 1988 Convention.
License	A legal document issued by the Minister to any individual or company meeting the requirements for holding a license. This gives authority to conduct specific activities with the substances indicated on the license. This can be revoked if the conditions or regulations pertaining to it are not met.
Multilateral Evaluation	An instrument containing 61 indicators adopted by CICAD,

Mechanism	to assess national efforts in drug-abuse control.
Notification	A transaction-related report made to a UN body or foreign authority responsible for national drug control by the Canadian government (country to country).
Non scheduled chemicals	Chemicals frequently used as substitutes in the manufacturing of controlled substances and are not listed Table I or Table II of the 1988 Convention. The list will be determined to accommodate domestic requirements of Canada.
OAS	Organization of American States.
Party	A person or group participating in an action.
Precursor	For the purpose of this discussion paper, the term precursor (or precursor chemical) will be used as a short-hand expression for all the substances listed in Table I and Table II of the 1988 Convention.
Registration	Filing of specific information to the government by operators or organizations participating in specific transactions with precursor chemicals.
Special Surveillance List	List of non-scheduled chemicals used in the clandestine production of controlled substances. This list is determined by the INCB.
State	A political community; nation.
UN	The United Nations.
UNDCP	UN International Drug Control Programme
UNGASS	UN General Assembly Special Session

EXECUTIVE SUMMARY

The diversion of precursor chemicals and other substances frequently used in the clandestine production of illicit drugs is a worldwide problem that requires a global solution. The UN addressed this problem in 1988 by adopting provisions dealing with precursor chemicals within the bounds of the *Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances* (hereafter referred to as the 1988 Convention). It is widely recognized that precursor monitoring and control is one of many complementary supply and demand reduction initiatives in a comprehensive strategy to tackle drug abuse.

Canada acceded to the 1988 Convention in November 1990. At that time, the *Food and Drug Act* and the *Narcotic Control Act* did not include precursors. In 1997, Canada enacted the *Controlled Drugs and Substances Act* with provisions for the control of precursors and the development of regulations over their import, export, production and distribution. With this document, the Government is entering step two of the consultation process in the development of a comprehensive regulatory framework and administrative system which will fulfill Canada's obligations for the control of precursor chemicals.

Interested parties are asked to review the three proposed options for an effective regulatory framework and administrative system. The options are flexible and the elements therein are interchangeable.

- Option 1** Meets the minimum regulatory and administrative requirements under Canada's obligations to the Convention, but does not meet Canada's international commitments or its domestic needs.
- Option 2** Fully meets the regulatory and administrative requirements under Canada's obligations to the Convention, fulfills Canada's international commitments and addresses its domestic needs.
- Option 3** Exceeds the regulatory and administrative requirements, goes beyond Canada's international obligations and commitments and fully addresses Canada's domestic needs.

A detailed discussion of key elements within each option is presented, along with a series of questions which will assist in the formulation of policy and regulations. To provide a point of comparison for the options presented, several examples of compulsory and voluntary initiatives adopted by Canada's major trading partners are described.

PART I: PURPOSE AND BACKGROUND

Purpose

The purpose of this discussion document is to solicit input from private and public-sector stakeholders. It will assist in the development of a regulatory framework and an administrative system, for the control and monitoring of precursors and other substances frequently used in the clandestine production of controlled substances.

The regulatory framework and administrative system will:

1. Enable Canada to fulfill its international obligations:
 - a. As a signatory to the *1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*;
 - b. To related resolutions of the UN CND and the ECOSOC, and to the relevant parts of the Political Declaration adopted by 1998 Resolution of the United Nations General Assembly Special Session in 1998; and
 - c. To commitments made to the G-8 Economic Summit and the OAS.
2. Limit the ability of criminal organizations to legally purchase precursor chemicals in Canada to manufacture illicit drugs. Without precursor regulations, Canada could potentially become a target for clandestine operations in both diverted chemicals and the illicit production of synthetic drugs.
3. Reduce the possible pressure on legitimate businesses from organized crime operators who divert chemicals for illicit use.
4. Provide legislative support for the current voluntary system in place where industry reports suspicious transactions.
5. Provide legislative tools for Canadian law enforcement to monitor and control illicit drug production and traffic, and cooperate with foreign law-enforcement agencies.
6. Increase public safety and decrease environmental hazards by reducing the risks associated with clandestine handling of chemicals and chemical waste.
7. Assist producing countries in the reduction of illicit drug manufacturing by curtailing international diversion of chemicals frequently used in their processing.
8. Create opportunities to enhance cooperation between industry and government and optimize the impact of the precursor regulatory framework.

Background

History

In the early 1980's, after decades of efforts to implement the 1961 and 1971 Conventions, trends in drug abuse and illicit traffic were rapidly escalating worldwide. The UN General Assembly, in its resolution 39/141 of 14 December 1984, voiced concern “at the increasing damage which illicit drug traffic causes to public health, the economic and social development of peoples, and the young people in particular.” Indeed, the international community came to realize that the existing drug-control instruments were inadequate to counter widespread and highly organized clandestine production and illicit traffic in drugs. It was also clear to all concerned that tackling this global phenomenon was beyond the reach of individual States and that a new initiative was required to complement existing Conventions. This new initiative, the 1988 Convention, targeted illicit traffic in all of its dimensions, such as forfeiture of proceeds of drug crimes, extradition procedures, mutual legal assistance, controlled deliveries, drug smuggling in aircraft and vessels, and monitoring and control of chemicals considered essential in the manufacture and processing of illicit drugs. Canada was one of the main instigators of the 1988 Convention, and is widely recognized for its significant contribution throughout its development and adoption of the Convention.

One of the fundamental components of the 1988 Convention is the monitoring and control of precursors. The Chemical Action Task Force¹, in its final report to the *G-7 Economic Summit* in 1992, stated that “The procurement of chemicals necessary to manufacture drugs is one of the few points where . . . drug trafficking intersects with legitimate commerce. Regulation of legitimate commerce to deny traffickers the chemicals they need is one of our most valuable tools in the battle against drug criminals.” Precursor control is viewed by developing and traditional producing countries as a clear indication of countries’ resolve to tackle the global drug phenomenon. Thus, the full implementation of Article 12 of the 1988 Convention is seen by all Parties as critical to the success of the 1988 Convention and the global effort against illicit drugs.

¹The Chemical Action Task Force was initiated by the G7 to promote the regulation of precursors and chemical solvents and reactants internationally.

List of Precursor Chemicals

Table I and Table II of the 1988 Convention, consist of chemicals that are precursors to controlled substances (mostly Table I) and chemicals used mainly as reagents and solvents (mostly Table II). Generally, Table I chemicals are more critical to the production of controlled substances than are those in Table II; as a result, provisions pertaining to these substances are somewhat more rigorous. Table I substances are largely confined to the pharmaceutical industry, while the majority of Table II substances have a broad spectrum of industrial and commercial applications.

Table I
Acetic anhydride ¹
N-acetylanthranilic acid
Ephedrine
Ergometrine
Ergotamine
Isosafrole
Lysergic Acid
3,4-methylenedioxyphenyl-2-propanone
Norephedrine
1-phenyl-2-propanone
Piperonal
Potassium permanganate ¹
Pseudoephedrine
Safrole
The salts of the substances listed in this Table whenever the existence of such salts is possible

Table II
Acetone
Anthranilic acid
Ethyl ether
Hydrochloric acid
Methyl ethyl ketone
Phenylacetic acid
Piperidine
Sulphuric acid
Toluene
The salts of the substances listed in this Table whenever the existence of such salts is possible (the salts of hydrochloric acid and sulphuric acid are specifically excluded)

¹ Acetic anhydride and potassium permanganate were transferred from Table II to Table I by CND March 2001.

Canada's International Obligations

The majority of Canada's obligations, related to the monitoring and control of precursors and other substances frequently used in the clandestine production of controlled substances are described in Articles 3, 5 and 12 of the 1988 Convention. Canada's remaining precursor commitments relate to resolutions from CND, ECOSOC, UNGASS and OAS.

Summary of Key Convention Articles in the 1988 Convention

Below is a summary of the key obligations under the 1988 Convention; unless otherwise indicated, they are not direct quotes.

Article 12²

Paragraph 1 – Development and Implementation of Regulations and Administrative System

Parties to the Convention “shall take the measures they deem appropriate to prevent diversion of substances listed in Table I and Table II... and shall cooperate with each other to this end.”

While Canada must comply with the intent of this paragraph, there is discretion to develop and implement a regime best suited to Canadian circumstances. There is a clear implication, however, to establish an administrative system, as well as a legal basis for the control and monitoring of those substances in Table I and Table II.

Paragraph 2 – Notification of Substances

Parties to the Convention must notify INCB if they have information that may lead to the inclusion or deletion of a substance in Table I or Table II or the transfer of a substance from one Table to another.

To fulfil this requirement, a national administrative system must include a monitoring feature encompassing all chemicals (Tables I and II and non-scheduled) used in the clandestine production of controlled substances.

²See Annex 1 for the complete version of Article 12.

Paragraph 8 – Monitoring System for Domestic Transactions

“...Parties shall take the measures they deem appropriate to monitor the manufacture and distribution of substances in Table I and Table II which are carried out within their territory.”

This paragraph includes a number of discretionary options for the control of domestic production and distribution, such as: control of persons and enterprises involved in production and distribution; licensing of premises; and issuing authorizations for specific types of transactions.

Paragraph 9 - Mandatory Controls

Parties to the Convention shall:

- Para (a) monitor international trade in substances listed in Table I and Table II in cooperation with manufacturers, importers, exporters, wholesalers and retailers in order to detect suspicious transactions.
- Para (b) Seize any substance in Table I and Table II when there is sufficient evidence that it is used in the clandestine production of narcotic drugs and psychotropic substances.
- Para (c) Notify other Parties regarding suspicious import, export and transit of substances in Table I and Table II. This notification must include information which led to the suspicion.
- Para (d) Require that imports and exports of substances in Tables I and II be properly labelled and documented. Documents must be kept for a period of at least two years and be available for inspection.

Public and private sector cooperation will not only assist in the detection of clandestine activity but will also help facilitate gathering strategic intelligence on the nature and extent of diversion.

In order for Canada to fulfil the notification requirement, it is essential to establish a regulatory duty for industry to report suspicious transactions to competent authorities.

Paragraph 10 – Pre-Export Notification

Exporting countries must provide specified information on every export transaction of substances listed in Table I, prior to such export, when the importing country makes a formal request to the Secretary-General of the United Nations.

INCB identifies all States requiring pre-export notification in its technical report on precursors.

Paragraph 11 - Confidentiality

When requested, Parties must keep confidential any information received about any trade, business, commercial or professional secret or trade process.

Paragraph 12 - Annual Reports

Each Party shall submit annual reports to INCB including the quantity of seized substances in Table I and Table II, substances not in Table I or Table II which have been used significantly in the production of narcotic drugs and psychotropic substances, the methods of diversion and illicit manufacture, and the licit trade in and use of those substances.

This is usually reported on Form D, supplied by the INCB

Paragraph 14 - Exemptions

“....this article shall not apply to pharmaceutical preparation, nor to other preparations containing substances in Table I and Table II that are compounded in such a way that such substances cannot be easily used or recovered by readily applicable means.”

This exemption permits a degree of discretionary options within the regulatory framework to facilitate the legitimate use of single-entity products.

Article 3 - Offences and Sanctions

“Each Party shall adopt measures as may be necessary to establish criminal offences under its domestic law, when committed intentionally.....the manufacture, transport, distribution of equipment, materials or of substances listed in Table I or Table II, knowing they are to be used in or for illicit cultivation, production or manufacture of narcotic drugs and psychotropic substances....the organization, management or financing of these offences.”

This implies that offences under the CDSA are required.

Article 5 - Confiscation

“Each Party shall adopt measures as may be necessary to enable confiscation of.....narcotic drugs and psychotropic substances, materials and equipment or other instrumentalities used in or intended for use in any manner in offences established in accordance with Article 3...”

Other Related Articles

In addition to the Articles listed above, an effective monitoring and control regime for Table I and Table II substances must also consider the provisions of the following Articles:

- Article 9 (cooperation among Parties to the Convention);
- Article 11 (controlled delivery);
- Article 13 (diversion of materials and equipment);
- Article 14 (measures to eradicate illicit crops and to eliminate illicit demand for narcotic drugs and psychotropic substances)
- Article 19 (the use of mail for illicit drug traffic).

Resolutions and International Commitments

Special Surveillance List

Some of precursors listed in Table I and Table II of the 1988 Convention have become difficult for traffickers to obtain as more States implement the provisions of the Convention. As a result, traffickers have found new chemicals and new methods to make the precursor chemical or the final drug.

ECOSOC resolution 1996/29 requested that INCB and UNDCP establish a list of non-scheduled substances used in illicit drug trafficking. In 1998, the limited international special surveillance list of non-scheduled substances was created. Twenty-seven substances were identified from an initial list of 500 substances.

Pre-Export Notification

Resolution S-20/4 B on precursor control, adopted at the UNGASS 1998, requested that States improve their mechanisms and procedures for monitoring trade in precursors. This includes a regular exchange of information between exporting, importing and transit States, in particular sending pre-export notifications to importing countries for all Table I substances, plus acetic anhydride and potassium permanganate. Since using pre-export notifications is an effective mechanism for preventing the diversion of precursor chemicals, it was suggested that States should make the same effort with regard to the remaining substances in Table II.

Canadian Compliance with the 1988 Convention and Other Resolutions: Precursors

Canada acceded to the 1988 Convention in November 1990. At that time, the *Food and Drug Act* and the *Narcotic Control Act*, did not include precursor chemicals. In 1997, Canada enacted the *Controlled Drug and Substances Act* with provisions for the control of precursors and the development of regulations for their import, export, production, and distribution of precursors.

Pending the development of regulations, Canada implemented policies and programs to fulfill some of the precursor related obligations under the Convention.

Current Monitoring and Control of Precursors in Canada

Two federal government departments and two federal agencies oversee the current monitoring and control practices related to precursors.

Health Canada

Many exporting countries require verification by the importing country that the transaction is legitimate; and that the importing company is entitled to receive the specified precursor. In the absence of regulations governing the import of precursor chemicals, Health Canada issues a “No Objection Letter” to the Canadian importer, who sends it to the foreign supplier with a purchase order. There is no legal basis for this letter; it is a courtesy to the industry, enabling the orderly importation of substances required to do business. The data gathered serves as a tracking mechanism for imports of Table I precursors into Canada.

Royal Canadian Mounted Police

The Royal Canadian Mounted Police (RCMP) is able to field reports of suspicious transactions and initiate full investigations when there are clear links to clandestine laboratories. These investigations have resulted in an increasing number of laboratories detected and dismantled yearly in Canada. The RCMP also assists foreign law enforcement to the extent allowable under current legislation.

In 1995, the RCMP established the National Chemical Diversion Reporting Program, where members of large urban RCMP detachments attempted to obtain the cooperation and assistance of chemical companies and related companies. This was accomplished by educational programs addressing the scope of the chemical diversion problem, what constitutes a suspicious transaction, information on the most commonly diverted chemicals, and the magnitude of problems associated with the finished product.

The RCMP is now in the process of re-engineering the National Precursor Chemical Diversion Reporting Program. The new program will include a national coordinator in Ottawa and field coordinators in Vancouver, Toronto, Edmonton and Montreal, who will work closely with other RCMP personnel, domestic and foreign law enforcement agencies, federal government departments (Health Canada, Foreign Affairs and International Trade, and Canada Customs and Revenue Agency) and private industry.

Department of Foreign Affairs and International Trade

Presently, the Department of Foreign Affairs and International Trade is responsible for issuing individual and general export permits through the *Export and Import Permits Act*. In 1992, the precursor chemicals in Table I and Table II of the 1988 Convention were, as an interim measure, placed on Group 8 of the Export Control List, according to the categories defined in the Chemical Action Task Force. Exports of chemicals in Category 8011 require an individual export permit to all destinations other than the U.S. Ephedrine and pseudoephedrine require a permit for all destinations. The export of all Group 8 chemicals, over the indicated thresholds, to Bolivia require an individual export permit; all other exports over the thresholds require a general export permit.

8011	
Names of Substance	Threshold Quantity
Ephedrine (all destinations)	1 kg
Ergometrine	10 g
Ergotamine	10 g
Lysergic acid	10 g
1-phenyl-2-propanone	20 kg
Pseudoephedrine (all destinations)	1 kg
N-Acetylanthranilic acid	40 kg
3, 4-Methylenedioxyphenyl-2-propanone	4 kg

8021	
Names of Substance	Threshold Quantity
Piperidine	0.5 kg
Safrole	4 kg
Isosafrole	4 kg
Piperonal	4 kg
Anthranilic acid	30 kg
Phenylacetic acid	1 kg

8031

Names of Substance	Threshold Quantity
Acetone	2000 l
Ethyl ether	2000 l
Methyl ethyl ketone	2000 l
Toluene	2000 l
Potassium permanganate	500 kg
Sulfuric acid	2000 l
Hydrochloric acid	2000 l

Canada Customs and Revenue Agency

The Canada Customs and Revenue Agency is currently conducting research and gathering information to develop a program related to cross-border movement of precursor chemicals. Once the chemical diversion program within their agency is implemented, CCRA will monitor all imports and exports of the 23 chemicals identified in Table I and Table II of the 1988 Convention. As well, CCRA will investigate suspicious transactions in order to identify high-risk importers and exporters. This information will assist border inspectors in examination and enforcement actions with respect to precursor chemicals being diverted to clandestine laboratories.

In the meantime, cross-border movement of precursors is monitored and controlled as follows:

- CCRA has the authority under the *Customs Act* to seize and/or detain any chemical shipment listed in Group 8 of the *Export and Import Permits Act*, when it exceeds the threshold limit and do not have the appropriate documentation
- Suspicious imports and exports of precursor chemicals are monitored and investigated on an ad hoc basis; usually the investigations are initiated based on intelligence or other information received from law enforcement agencies.

Limitations in the Absence of Canadian Regulatory Framework**Royal Canadian Mounted Police**

Lack of adequate legislation governing precursor chemicals has made it difficult to conduct chemical diversion investigations. Foreign law-enforcement agencies have been exerting an increasing amount of pressure on the RCMP to take action on the sale, movement and seizure of precursor chemicals. Lack of a comprehensive regulatory framework governing the domestic distribution of precursor chemicals, coupled with limited resources, restricts the ability of national and local enforcement agencies to control these transactions.

Presently, the RCMP has to rely on the voluntary National Precursor Chemical Diversion Program to gain information regarding suspicious transactions of precursor chemicals. Private industry is willing to assist the police in the execution of their duties; however, they are reluctant to become too heavily involved without having proper legislation or a specific code of conduct that would cover them in the event of reprisal. It must be remembered that presently there are virtually no restrictions placed on who can distribute and who can purchase.

Canada Customs and Revenue Agency

Increasingly, CCRA is being challenged by domestic and international law enforcement agencies on Canada's lack of controls over precursor chemicals. CCRA is the first line of defense for goods entering the country. Lack of a comprehensive regulatory framework limits CCRA's authority to identify, seize, detain or confiscate suspicious shipments of precursor chemicals imported into Canada, unless they are mislabelled or smuggled in (not declared).

PART II: EXAMPLES OF REGULATIONS IN OTHER COUNTRIES

The following are examples of how other industrialized countries have developed and implemented regulations governing the monitoring and control of precursors and other chemicals frequently used in the clandestine production of controlled substances. These examples provide a point of comparison in the development of the regulatory framework and administrative system.

The European Union

On December 13, 1990, the European Union (EU) adopted Council Regulation (EEC) No. 3677/90, outlining measures member countries must take to discourage the diversion of certain substances for the illicit manufacture of narcotic drugs and psychotropic substances. On December 21, 1992, this regulation was implemented and amended by Community Regulation (EEC) No. 3769/92. While this regulation is directly applicable throughout the EU, implementation by each member country may vary slightly.

The regulations define “scheduled substance” as any substance listed in the Annex to the Regulation.

Imports and Exports

Substance Category	Details
Category 1 (Article 4)	Individual export authorizations must be issued by the competent authority of the member state in which the <i>Customs Export Declaration</i> is to be lodged. A decision on the application shall be taken within 15 working days from the date in which the competent authority considers the file to be complete.
Category 2 (Article 4)	Exports shall be subjected to the provisions of Article 4 whenever they are intended directly or indirectly for any third country which has been identified as a concern, or if they are destined to an operator established in a country listed in Annex 2 (of the regulation). In all other cases, the exportation of Category 2 substances may be authorized on a global basis at the request of the operators concerned by the issue of an open individual authorization.
Category 3 (Article 4)	Exports to non-targeted countries is, in principle, unrestricted; there are circumstances, however, that require open export authorization

Documentation, Records, and Labelling

Item	Details
Documentation	All import, export and transit operations of scheduled substances shall be properly documented to include: 1.The name of the scheduled substance as given ³ . 2.The quantity and weight of the substance; if a mixture, the quantity and weight of the mixture and the weight of percentage of the substance listed; 3.Name and address of the exporter, importer, distributor and ultimate consignee.
Records	Operators must keep detailed records of the above-mentioned activities for three years from the end of the calendar year in which the operation took place.
Labelling	Labels must show the names of the substances as given ⁴ .

Licenses and Registration (Member States will determine the procedures for issuing licenses.)

Substance Category	Details
Category 1 (Licensing)	An operator must obtain a license from the member state for import, export or transit operations. Some exceptions apply.
Category 2 and Category 3 (Registration)	Operators engaged in the import, export or transit of substances in Category 2 , or the export of substances in Category 3, are required to register the addresses of the premises from which they manufacture or trade these substances. The application of the regulation will be exempted if the sum of quantities of substances in Category 3 exported during the preceding calendar year (Jan. 1 to Dec. 31) does not exceed the amounts in the regulation.

Penalties and Final Provisions

Each member State will determine its own penalties, ensuring that they are sufficient to promote compliance with the provisions.

³ In the Annex to the Regulations

⁴ In the Annex to the Regulations

Intra-Community Trade

This directive applies to manufacturing or placing on the market of chemicals in Categories 1 and 2.⁵

Commercial documents must contain sufficient information to identify:

- the name of scheduled substance;
- the quantity and weight of the substance;
- the name and address of the supplier, distributor and consignee; and
- an end user declaration.

Specific European Union Examples

All documentation must be kept for three years from the end of the calendar year in which the operation took place.

Member States of the EU establish regulations that cover both domestic trade and export to third countries outside the EU. Member States, however, may also adopt supplementary measures based on their own legal systems and specific situations.

Germany

In March 1995, the Federal Republic of Germany adopted the *Precursor Control Act*, which enables law enforcement to control the trade, export, import and transit of all the chemicals in all three EU substance categories. The *Precursor Control Act* contains five elements:

- The diversion of precursor chemicals is prohibited by law, violations are subject to prosecution.
- The chemical industry is obliged to take action involving vigilance, identification of operators, notification of suspicious orders.
- There is an obligation to obtain permits and notifications on production, purchase, sale, import, export and transit of precursors.
- There is an obligation to keep records and to specially mark sensitive chemicals.
- There is an obligation to tolerate and to support official requests for providing information.

⁵Category 2 chemicals have prescribed thresholds and there are no controls over intra-community trade in Category 3 chemicals.

The German police have established a trusted working relationship with the chemical/ pharmaceutical industry. It consists of creating an awareness and familiarizing industry with the common goal pursued by police and customs.

Imports and Exports

Exports to non-EU member countries are governed by Council Regulation (EEC) No. 3677/90 and Community Regulation (EEC) No. 3769/92.

Documentation, Records and Labelling

Documentation, record keeping and labelling are governed by EU Council Regulation (EEC) No. 3677/90. Additional requirements are:

Item	Details
Documentation	Customers must make a declaration with data on the specific use of raw material. This does not apply to pharmacy or veterinary pharmacy.
Record Keeping	Records must be kept for six years from the end of the calendar year in which the transaction took place.

Licenses and Registration

Substance Category	Details
Category 1 (Licensing)	<p>Licenses for Category 1 substances are obtained from the Federal Institute for Pharmaceutical and Medicinal Products. The application for a license must include:</p> <ul style="list-style-type: none"> the family name, given name or business name and the address of the applicant; the family name, given name and address of the Precursor Operations Supervisor and a description of his/her position in the operator's enterprise, pursuant to Section 5 of the <i>Precursor Control Act</i>; a description of the location of the places of business, according to their locality, street name and house number; the storage location of the precursors and a description of measures to protect them against unauthorized withdrawal; and the names of the precursors and the type of activity the applicant wants to conduct with the precursors. <p>An application for a new license is required for changes in the license holder, the location of the place of business, an increase in trade of precursors and a change in the type of precursor.</p>
Category 2 (Registration)	Any person who intends to manufacture, dispense or supply to third parties, sell or otherwise market Category 2 precursors, must register with the Federal Institute for Pharmaceutical and Medicinal Products.
Category 3 (Registration)	Registrations for Category 3 substances are required if threshold quantities are exceeded.

Reporting

Reports must be made in writing to the Federal Institute for Pharmaceutical and Medicinal Products within two weeks after the end of each calendar quarter, for the quarter elapsed.

A holder of a license or registration receipt must make a separate report to the Federal Institute for Pharmaceutical and Medicinal Products for each piece of business and for each precursor in Categories 1 and 2 and for each quantity that was:

- imported (broken down by exporting countries);
- exported (broken down by importing countries and export license numbers; and
- dispensed or supplied..

United Kingdom

While the United Kingdom (U.K.) is obliged to implement Council Regulation (EEC) No. 3677/90 and Community Regulation (EEC) No. 3769/92, it is responsible for determining its own penalties.

Imports and Exports

The directive governing trade within the E.U. is enforced and implemented in the U.K. by the 1993 *Controlled Drug Regulations (Substances Used for Manufacture) (Intra-Community Trade)*. Exports outside the E.U. are governed by Council Regulation No. 3677/90.

Documentation, Records and Labelling

Documentation, record keeping and labelling are governed by Council Regulation (EEC) No. 3677/90. Substances in Categories 1 and 2 shall be documented and labelled and documents shall be available for declaration from the customer with specific uses of all substances.

Licenses and Registration

Substance Category	Details
Category 1	Operators who manufacture or place on the market substances in Category 1 shall be licensed by the Home Office and shall only supply these substances to specifically authorized persons.
Category 2	Operators who manufacture or place on the market substances in Category 2 shall be registered with the Home Office.

Offenses and Penalties

An operator who fails to comply with Article 2A of the Community Regulation (Licensing and Registration of Operators) is guilty of an offence and liable:

- on a summary conviction⁶, to a prison term not more than three months, or a fine that is not in excess of the statutory maximum, or both; or
- on conviction on indictment to a prison term not more than two years, or a fine, or both.

United States

The U.S. has adopted *Controlled Substances Regulations*, which are based on the legislation contained in three federal Acts:

- the 1988 *Chemical Diversion and Trafficking Act*;
- the 1993 *Domestic Chemical Diversion Control Act*; and
- the 1996 *Comprehensive Methamphetamine Control Act*).

Some American States have restrictions on distribution practices that are more stringent than those contained in the federal regulations. The activities below relate to regulated transactions⁷

Imports and Exports

Item	Details
Import/Export Declaration	The Import/Export Declaration, DEA form 486, is a three-part form that must be completed by each regulated person for each regulated import, export or international transaction, unless a waiver is issued. Copy one is retained by regulated person, copy two serves as a notification copy to the DEA and copy three is presented to U.S. Customs.
Registration	Importers/exporters of List 1 ⁸ chemicals are required to register with the DEA.
Notification	Importers/exporters must notify the DEA 15 days prior to the date of the transaction.
Regulation	All imports/exports are regulated if they involve a shipment amount of a listed chemical, including a cumulative threshold amount for multiple transactions.

⁶ Summary offences generally have lower maximum penalties and less serious consequences than indictable offences.

⁷ A regulated transaction is defined as a distribution, receipt, sale, importation, exportation or international transaction, involving (1) a threshold quantity of a listed chemical, including a cumulative threshold quantity for multiple transactions (i.e. the amount of all the transaction carried out in a one-month period total the threshold amount); and (2) a tableting machine or an encapsulating machine. Exemptions apply (e.g. domestic sales).

⁸ As listed in the Chemical Handlers Manual

Verification	For export transactions, proof of identity is to be accompanied by a good faith inquiry to verify the existence and validity of the foreign business entity.
Compliance	It is incumbent upon the exporter, broker or trader to assure that each chemical exported complies with the laws and regulations of the destination country.

Documentation, Records and Labelling

Record Keeping	Details
Documentation Domestic	<p>Records must include:</p> <ul style="list-style-type: none"> • the name, address, and, if required, the DEA registration number of each party involved in the regulated transaction; • the date of the transaction; • the name and quantity of the chemical and packaging form; • the method of transfer (e.g. company truck, picked up by customer); • the type of identification; and • the purchaser's unique identification number.
Documentation International	<p>Importers and exporters must complete DEA form 486 for every import, export, or international transaction. The form must be received by the DEA not less than 15 days prior to the transaction date, unless a waiver has been issued. The information required includes:</p> <ul style="list-style-type: none"> • the name, address, telephone number, telex and fax number of the exporter/importer/consignee; • the name and description of the chemical as it appears on the label/container and the name of the chemical as designated in the Code of Federal Regulations 1310.02, the size or weight of the container, the number of containers and the net and gross weights of each chemical in kilograms; and • The proposed date of transaction and U.S. Customs port for exports and foreign port of entry.
Records	<p>Records for all regulated transactions must be kept for two years from the transaction date.</p> <p>Distribution records must be kept if the threshold amount is exceeded during a calendar month.</p>

Licenses and Registration - List 1 Chemicals

<ul style="list-style-type: none"> Annual registration is required for manufacturing for distribution, distribution, importing or exporting.
<ul style="list-style-type: none"> A separate registration is required for each principle place of business, where a List 1 chemical is manufactured for distribution, distributed, imported or exported.
<ul style="list-style-type: none"> The following groups of activities are independent of each other and require separate registration: <ul style="list-style-type: none"> retail distributing of drug products that contain List 1 chemicals; non-retail distributing of List 1 chemicals; and importing/exporting of List 1 chemicals.
<p>Exemptions</p> <p>The following are exempted from registration:</p> <ul style="list-style-type: none"> a manufacturer of a List 1 chemical who uses the chemical solely for internal consumption without subsequent distribution or exportation; a manufacturer already registered with the DEA to import/export a controlled substance that contains a List 1 chemical. However, records must still be kept; anyone who distributes a drug product containing a List 1 chemical, if that person is registered with the DEA to manufacture or dispense controlled substances; and retail distributors whose activities as distributors of non-ordinary over the counter drug products and combination ephedrine drug products are limited exclusively to sales for personal use. Sale for personal use is the sale below the threshold quantities in a single transaction to an individual for legitimate medical use.

Domestic Sales: Non-Regulated Transactions

<p>Normal distribution between agents of a single regulated person, and delivery to a common or contract carrier or by a warehouseman to a storage room.</p>
<p>Any transaction with a listed chemical that may lawfully be distributed under the U.S. federal <i>Food, Drug, and Cosmetic Act</i>, unless:</p> <ul style="list-style-type: none"> the drug contains ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, optical isomers, or salts of their optical isomers; the administration believes that the drug is going to be diverted; and the quantity of the listed chemical exceeds the established thresholds for that particular chemical.
<p>Sales of over-the-counter pseudoephedrine, or phenylpropanolamine products below the threshold levels, by retail distributors in face-to-face transactions to walk-in customers. These include pseudoephedrine/phenylpropanolamine:</p> <ul style="list-style-type: none"> non-liquids sold in packages of not more than 3.0 grams base; and packages in blister packs, with each blister containing not more than two tablets. Where the use of blister packs is not feasible, products are packaged in unit dose packets or pouches.
<p>Any transaction of a product that the U.S. Attorney General has exempted because it is deemed formulated in such a way that it cannot be easily used in the illegal production of illicit substances.</p>

Proof of Identity

Any transaction should be postponed if the regulated person is unable to establish the identity or legitimacy of a customer, until identity is satisfactorily established. This applies to:

- domestic transactions;
- cash sales or sales to individuals;
- electronic orders; and
- export transactions.

Security

Item	Details
Storage	List 1 chemicals must be stored in sealed containers that enable detection of tampering. If this type of storage is not possible, the chemicals must be protected with physical security measures like locks, alarm systems or guards.
	In a retail setting, ephedrine products must be kept behind the counter.
Duty to report	Any suspicious orders must be reported to the DEA.

Offences and Penalties

Item	Details
Unlawful distribution	It is unlawful for any person to distribute a listed chemical to a person who intends to use the substance in an unlawful manner. Such distribution is subject to fines up to \$25,000 for individuals, and up to \$250,000 for organizations.
Violation of foreign law	Exports that are in violation with the destination country's laws are subject to a prison term not exceeding 10 years. Fines are: <ul style="list-style-type: none"> • up to \$250,000 for individuals • up to \$500,000 for organizations

Model Regulations to Control Chemical Precursors and Chemical Substances, Machines and Materials of the Inter-American Drug Abuse Control Commission (CICAD Model Regulations)

The Inter-American Drug Abuse Control Commission (under the Organization of American States) has adopted *Model Regulations to Control Chemical Precursors and Chemical Substances, Machines and Materials* (CICAD Model Regulations). They include three tables of chemicals similar to 1988 Convention Tables I and II and the special surveillance list. Below are relevant sections of the regulations:

Licenses and Registration

Item	Details
Table I (Licensing)	A permit and a license are required by an operator who produces, manufactures, prepares, transforms, stores, imports, exports, markets, uses or engages in any other type of transaction involving Table I substances.
Table II (Registration)	An operator who produces, manufactures, prepares, transforms, stores, imports, exports, markets, uses or engages in any other type of transaction involving Table II substances shall register with the competent authorities.
Table II and Table III (Notification)	A notification may be required for any Table II or Table III chemical, as determined by the competent authority.
Time limitations	All permits, and notifications, must be obtained not less than 15 days prior to the expected transaction date.
Permit Use	Any permit that is issued can be used only once, for the transaction that it was obtained for, and expires 180 days after it was issued, regardless of whether the transaction has been completed.
Permit/ Notification Application Requirements	<p>All applications for permits or notifications must contain*:</p> <ul style="list-style-type: none"> • the importer's/exporter's name, address, license or registration, telephone, telex, fax numbers and e-mail address, where applicable; • the name, address, telephone, telex, fax and e-mail of the agent or importer and forwarder, if any; • the name and number of the chemicals as they appear in the commodity description. This information must appear on the containers they are being shipped in; • net weight or volume of the chemical, quantity and net weight of the containers; • schedule, shipping, and import/export date. Place of origin, and points of shipments, stopover ports, place of entry into the country, and final destination; • means of transportation, and identification of the carrier; • names, addresses, telephone, telex, fax and email addresses of the supplier and purchaser; and • names, addresses, telephone, telex, fax and email addresses of the end-user or consignee, if known, or ascertainable through reasonable inquiry. <p>The competent authorities must maintain a record of all authorizations, licenses, and the like, either granted, denied or revoked.</p> <p>* this list is not exhaustive.</p>

Documentation, Records and Labelling

All records must be kept for a period not less than two years.

All records regarding chemicals listed in Table I or Table II must include:

- amounts received, imported; and/or exported;
- amounts produced, manufactured, prepared, or extracted; amounts used to manufacture, or prepare other products;
- amounts marketed domestically;
- existing stocks; and
- amounts lost, destroyed or reduced by effects, such as shrinking, and other causes, like accidents and pilferage.

Records for various transactions, must include:

- date of transaction;
- name, address, telephone, fax and e-mail address, as well as the license or registration number of every party involved;
- name, amount, unit of measurement and form of presentation and packaging of the precursor and other chemical substances, if any; and
- means of transportation and identification of the transport company.

Mixtures

Substances	Details
Table I	A mixture that contains a Table I substance in any concentration is subject to the controls of Table I.
Table II	A mixture that contains a Table II substance in concentrations greater than 30 percent is subject to the controls of Table II.
	If there is more than one Table II substance in the mixture, and the percentage concentration of each substance added together exceeds the percentage that has been set by each country, then the mixture is subject to the controls of Table II.
Table III	If a mixture contains one or more Table III chemicals and the concentration of one chemical or the combination of one chemical with the others exceeds the established acceptable levels, the mixture is subject to control under Table III.
Exemptions	Mixtures containing chemicals included in Table I, II, or III are not subject to the above-mentioned controls if they are not likely to be used in the production of narcotics, psychotropic substances, or other substances with similar effects.

Offenses

Any transaction involving a Table I or II chemical, with the knowledge that it is going to be used in the production of a narcotic drug, or psychotropic substance in any manner is prohibited.

It is an offence to organize, manage, or finance any such transaction, whether it is occurring at home or abroad..

The abovementioned offences are extraditable, in accordance with the guidelines of the member States.

General

The competent authorities may request that a chemical be added, deleted, or relocated from the tables. This is done by submitting the request and the reason for it to the Secretary General of the OAS.

Any member state can stipulate exceptions to licensing, permits or registration in accordance with national needs, provided those needs do not put the country in conflict with the regulations.

Any person involved in any way with a substance listed in Tables I, II or III must notify the competent authorities if they suspect that the chemical is going to be used in any way in the production of an illicit drug.

Every member state must designate their competent authority to the Secretary General of the OAS, and to the UN Secretary General.

Voluntary Programs

Many countries have implemented a voluntary program designed to :

- protect against the diversion of chemicals for the illicit production of drugs;
- facilitate cooperation with government and police authorities in the controlled delivery of chemicals destined for use in the illicit production of drugs, and
- educate and train staff and end users of precursor chemicals as to the issues involved and procedures to be adopted.

Generally, organizations that have adopted a code of conduct or Responsible Care program agree to:

- protect against the diversion of chemicals to the illicit production of drugs; and
- facilitate cooperation with the government and police authorities in the controlled delivery of chemicals destined for use in the illicit manufacturing of drugs.

European Community

The European Commission has developed guidelines on legislative obligations as well as voluntary controls in a document called “Chemical Control in the European Community - Guidelines for the Chemical Trade.” It identifies indicators of suspicious transactions to help suppliers recognize suspect orders or requests for information relating to chemicals that might be used for the illicit manufacture of narcotic drugs, and suggests appointing someone to be responsible as the main contact between the company and competent authorities.

Annexes to the guidelines include:

- a voluntary monitoring list;
- the UN Special Surveillance List and its associated guidelines;
- recommended actions to be taken by National Competent Authorities in approaching industry about preventing the diversion of substances included on the Limited International Special Surveillance List; and
- recommended actions to be taken by the chemical industry with regard to implementation of the Limited International Special Surveillance List.

United Kingdom

Below are the relevant elements included in the U.K.'s voluntary code of conduct.

The operator shall notify the National Criminal Intelligence Service of any suspicious inquiry or order the operator may receive as soon as it is practicable and in any case prior to dispatch.

Each association member shall nominate one or more liaison officers whose specific duty will be to promote best practices throughout the company and ensure that suspicious orders or inquiries are reported to the relevant authorities. Each liaison officer will be responsible for assigned scheduled substances.

There is a list of additional chemicals monitored by industry which are not scheduled, similar to the Special Surveillance List

Germany

Below are the relevant elements included in Germany's code of conduct.

There is an agreement signed by the Association of Chemical Companies and the German Government, which commits all members to fully co-operate with police, customs and other law enforcement agencies in order to prevent the misuse of their products for illegal drug production.

There is also a close working relationship between the police and customs called the Joint Police /Customs Precursor Control Unit, which is responsible for all measures within a voluntary monitoring system which covers 52 chemicals.

Australia

Australia's national code of conduct establishes a common system of practice for Australian chemical manufacturers, importers and distributors. Participating companies or organizations have agreed to closely monitor all sales of goods listed in substance Categories I, II and III and comply with their respective regulations:

Category I	<ul style="list-style-type: none"> require an end user declaration, are sold to the account holder only; supply must be delayed not less than 24 hours. <p>Record keeping shall be maintained a minimum of two years. Locked storage must be provided at all times; access should be restricted or controlled.</p>
Category II	<ul style="list-style-type: none"> require an end user declaration only when they are sold to non-account holders.
Category III	<p>This list alerts companies and organizations to suspicious orders or inquiries. No official reporting is required unless warranted.</p>

Particulars on record keeping, notification of suspicious orders and enquiries, storage, education and training, liaison officers and updating the code are included in the Code of Conduct document.

United States

The chemical industry in the U.S. has developed voluntary initiatives to minimize diversion from legitimate industry to illicit manufacturing.

Retail Initiatives:

<ul style="list-style-type: none"> Adopt sales quantity limits i.e. discontinue selling large pack sizes.
<ul style="list-style-type: none"> Point of sale messages that inform the sales clerk when a person is trying to buy more than a threshold amount of a listed chemical.
<ul style="list-style-type: none"> Sign postings notifying their customers about their policy restricting the sale of products.
<ul style="list-style-type: none"> Limiting shelf stock so that a consumer has to ask to obtain excessive quantities of certain substances. Limiting in store stock as well.
<ul style="list-style-type: none"> Educate employees
<ul style="list-style-type: none"> Place selected products behind the counter

Manufacturers' and Distributors' Initiatives

- | |
|---|
| • Selling smaller sizes in blister packs. |
| • Discontinue large sizes (>100 units/package). |
| • Review sales and trend data. |

PART III ANALYTICAL FRAMEWORK FOR MONITORING AND CONTROL

Options

As outlined in Part I, three options, covering the full range of potential responses, are proposed for the development of a regulatory framework and administrative system. These options do not have borders; the resulting policy and regulations may consist of permutations of the options proposed. When reviewing the options, it is important to take the following issues into consideration:

- **Risk Management** – with the increasing prevalence of abuse of synthetic drugs since the 1980's and the likelihood of further growth, chemical precursor control and monitoring has become a key risk management tool.
- **Focus** – there are large variations in the methods of synthesis of drugs and an enormous choice of chemicals available; therefore, all options must focus on those chemicals that are most critical or most frequently used for clandestine purposes.
- **Industrial Usefulness** – precursor control must not place undue restrictions on internal commerce or put Canadian exporters at a commercial disadvantage vis-a-vis foreign competitors. It should be recognized that a number of chemicals frequently used in the clandestine production of drugs have legitimate uses (particularly chemicals listed in Table II of the 1988 Convention) and are subject to a large volume of domestic and international transactions.
- **Close Cooperation** – a close cooperative effort among national authorities, legitimate producers and distributors of chemicals is critical to the success of precursor control and monitoring.
- **Industry Codes of Good Practice** – these codes can contribute significantly to the minimization of chemical diversion domestically, particularly when supported by an effective regulatory framework. This framework is necessary to ensure compliance by the small proportion of firms that currently neither belong to associations nor implement codes of practice.
- **Flexible Framework** – both the regulatory framework and administrative system for precursor chemicals must be flexible to accommodate a dynamic response to a rapidly changing illicit drug environment.
- **Compatibility with International Trade Practices** – in order to ensure optimum success and minimal trade disruption, Canada's framework should, to the extent feasible, be consistent and compatible with precursor interventions launched by our major trading partners.

Option 1

This option meets the minimum regulatory and administrative requirements under Canada's obligations to the Convention, but does not meet its international commitments or domestic needs.

	Category A ⁹ (Table I)	Category B (Table II)	Category C (non-scheduled chemicals)
Imports and Exports	Pre-export declaration and notification for all substances, either to all countries or to selected high risk destinations	none	none
Licenses and Registration	License required for import, export, production and large scale distribution Renewal period may vary	none	none
Documentation, Records and Labelling	1988 Convention requirement: Article 12, para 9(d) ¹⁰ Records maintained for a minimum of two years ¹¹	1988 Convention requirement: Article 12, para 9(d) ¹⁰ Records maintained for a minimum of two years ¹¹	none

⁹ Categories A, B and C mimic Tables I, II and non scheduled precursor chemicals respectively. The term Category has been used to differentiate between the term Table as used in the 1988 Convention. This gives flexibility when adding or deleting chemicals from a Category.

¹⁰Para 9 (d) Imports and exports must be properly labelled and documented. Commercial documents such as invoices, cargo manifests, customs, transport and other shipping documents shall include the names as stated in Table I or Table II, of the substances being imported or exported, the quantity being imported or exported, and the name and address of the exporter, the importer and when available the consignee.

¹¹ Customs records must be kept for six years in accordance with the Customs Act.

Option 1 continued	Category A (Table I)	Category B (Table II)	Category C (non-scheduled chemicals)
Offense ¹²	Criminal offense for the manufacture, import/export, transport or distribution of precursor chemicals with knowledge of use in or for the clandestine production of narcotic and psychotropic substances	Criminal offense for the manufacture, import/export, transport or distribution of precursor chemicals with knowledge of use in or for the clandestine production of narcotic and psychotropic substances	none
Seizure and Confiscation	Seizure for products involved in activities where there is probable cause of a violation Confiscation upon a court order	Seizure for products involved in activities where there is probable cause of a violation Confiscation upon a court order	none
Reporting by Industry	Regulatory requirements to report suspicious transactions	Regulatory requirements to report suspicious transactions	none
Reporting by Government ¹³	Suspicious transactions Amount of seized substances and method of diversion Patterns and trends	Suspicious transactions Amount of seized substances and method of diversion Patterns and trends	Suspicious transactions Amount of seized substances and method of diversion Patterns and trends
Security	none	none	none
Monitoring	Compliance and to meet reporting requirements	To meet reporting requirements	To meet reporting requirements

¹²Administrative penalty can be assessed under the Customs Act for regulatory violations of imports and exports

¹³Reporting to trading partners and INCB

Option 2

This option fully meets the regulatory and administrative requirements under Canada's obligations to the Convention, fulfils its international commitments and addresses domestic needs.

	Category A (Table I)	Category B (Table II)	Category C (non-scheduled chemicals)
Imports and Exports	Pre-import authorization: individual permit for each transaction or a general authorization permit. Pre-export authorization for each transaction for all substances: for all destinations or selected high risk destinations	Pre-export declaration and notification for: selected high risk destinations with or without a threshold	none
Licenses and Registration	License required for import, export, production and large scale distribution. Renewal period may vary	License or registration for specific transactions: for some or all substances; with or without thresholds	none
Documentation Records and Labelling	Proper documentation and labelling for all licensed transactions in addition to Article 12 para 9(d) ¹⁴ End user declaration for all licensed transactions Records maintained for a minimum of two years ¹⁵	1988 Convention requirement: Article 12, para 9(d) ¹⁴ Records maintained for a minimum of two years ¹⁵	none

¹⁴Para 9 (d) Imports and exports must be properly labelled and documented. Commercial documents such as invoices, cargo manifests, customs, transport and other shipping documents shall include the names as stated in Table I or Table II, of the substances being imported or exported, the quantity being imported or exported, and the name and address of the exporter, the importer and when available the consignee.

¹⁵Customs records must be kept for six years in accordance with the Customs Act.

Option 2 continued	Category A (Table I)	Category B (Table II)	Category C (non-scheduled chemicals)
Offense ¹⁶	Criminal offense for the manufacture, import/ export, transport or distribution of precursor chemicals with knowledge of use in or for the clandestine production of narcotic and psychotropic substances Violation of regulatory requirements	Criminal offense for the manufacture, import/export, transport or distribution of precursor chemicals with knowledge of use in or for the clandestine production of narcotic and psychotropic substances Violation of regulatory requirements	none
Seizure and Confiscation	Seizure for products involved in activities where there is probable cause of a violation Confiscation upon a court order	Seizure for products involved in activities where there is probable cause of a violation Confiscation upon a court order	none
Reporting by Industry	Regulatory requirements to report: suspicious transactions; significant losses; disappearance and thefts; damage to containers.	Regulatory requirements to report: suspicious transactions; significant losses; disappearance and thefts; damage to containers.	Voluntary reporting of suspicious transactions
Reporting by Government ¹⁷	Suspicious transactions Amount of seized substances and method of diversion Patterns and trends	Suspicious transactions Amount of seized substances and method of diversion Patterns and trends	Suspicious transactions Amount of seized substances and method of diversion Patterns and trends
Security	Voluntary Standards by Industry	Voluntary standards by Industry	none
Monitoring	Compliance and to meet reporting requirements.	Compliance and to meet reporting requirements	To meet reporting requirements.

¹⁶ Administrative penalty can be assessed under the *Customs Act* for regulatory violations of imports and exports

¹⁷ Reporting to Trading partners and INCB

Option 3

This option exceeds the regulatory and administrative requirements, goes beyond Canada's international obligations and commitments and fully addresses Canada's domestic needs.

	Category A (Table I)	Category B (Table II)	Category C (non-scheduled chemicals)
Imports and Exports	Individual permits for each import/export transaction	Individual permit to export to selected high risk destinations	Pre-export declaration and notification for: selected high risk destinations with or without threshold.
Licenses and Registration	License required for all transactions	License or registration for all transactions: with or without thresholds Exemptions for strong compliance record	none
Documentation, Records and Labelling	Proper documentation and labelling for all licensed transactions in addition to Article 12 para 9(d) ¹⁸ End user declaration for all licensed transactions Records maintained for a minimum of two years ¹⁹	Proper documentation and labelling for all licensed transactions in addition to Article 12 para 9(d) ¹⁸ End user declaration for all licensed transactions Records maintained for a minimum of two years ¹⁹	1988 Convention requirement: Article 12, para 9(d) ¹⁸ Records maintained for a minimum of two years ¹⁹

¹⁸Para 9 (d) Imports and exports must be properly labelled and documented. Commercial documents such as invoices, cargo manifests, customs, transport and other shipping documents shall include the names as stated in Table I or Table II, of the substances being imported or exported, the quantity being imported or exported, and the name and address of the exporter, the importer and when available the consignee.

¹⁹Customs records must be kept for six years in accordance with the Customs Act.

Option3 continued	Category A (Table I)	Category B (Table II)	Category C (non-scheduled chemicals)
Offense²⁰	Criminal offense for the manufacture, import/ export, transport or distribution of precursor chemicals with knowledge of use in or for the clandestine production of narcotic and psychotropic substances Violation of regulatory requirements	Criminal offense for the manufacture, import/export, transport or distribution of precursor chemicals with knowledge of use in or for the clandestine production of narcotic and psychotropic substances Violation of regulatory requirements	none
Seizure and Confiscation	Seizure for products involved in activities where there is probable cause of a violation Confiscation upon a court order	Seizure for products involved in activities where there is probable cause of a violation Confiscation upon a court order	none
Reporting by Industry	Regulatory requirements to report: suspicious transactions; significant losses; disappearance and thefts; damage to containers.	Regulatory requirements to report: suspicious transactions; significant losses; disappearance and thefts; damage to containers.	Voluntary reporting of suspicious transactions
Reporting by Government²¹	Suspicious transactions Amount of seized substances and method of diversion Patterns and trends	Suspicious transactions Amount of seized substances and method of diversion Patterns and trends	Suspicious transactions Amount of seized substances and method of diversion Patterns and trends
Security	Prescribed Standards	Voluntary standards by Industry	none
Monitoring	Compliance and to meet reporting requirements	Compliance and to meet reporting requirements	Compliance and to meet reporting requirements

²⁰ Administrative penalty can be assessed under the *Customs Act* for regulatory violations of imports and exports

²¹ Reporting to Trading partners and INCB

Discussion and Questions

The following questions are designed to facilitate discussion and gather comments for the development of a new regulatory framework and administrative system. We ask that you examine the analytical framework containing options 1, 2 and 3, with these questions in mind. The questions vary in scope to accommodate the wide interests of the stakeholders.

The information provided will be instrumental in the development of the most appropriate regulatory and administrative framework. Your comments will also enable us to assess the impact of the various options, both on your organization and on the industry. All comments will be kept confidential and will be used only for the purposes stated in this document.

There will also be an opportunity to comment once the regulations are drafted and published in *Canada Gazette Part I*.

General Questions

1. What is the nature and extent of your organization's involvement with precursor chemicals? (This could range from using a small amount of a Table II chemical for a manufacturing process to numerous transaction in all of the substances)
2. If your organization is engaged in international trade of precursor chemicals, which country (ies) is/are your major trading partner(s)?
3. How significant are the transactions involving the precursor chemicals in your organization?
4. What are examples of the costs of compliance associated with the options?
5. Describe examples of the changes you would have to implement in your organization for the different options.
6. Does your organization believe that there are production and/or trade considerations unique to Canadian firms? If yes, please explain.
7. What are examples of the economic impacts associated with the options, for example trade, competitiveness and employment?
8. Please provide any information from your organization's foreign affiliate operations (if applicable) that could assist in the development of a Canadian monitoring and control framework.

9. To what extent do you implement the concept of “life-cycle“ product stewardship” through the distribution chain? More specifically, do you require a verbal or written end user declaration or do you use other means of verifying the legitimacy of transactions and identity of operators?
10. The following question addresses safety. Do your organization’s members have any personal concerns regarding the monitoring of legitimate chemical transactions to determine possible diversion? If yes, please explain.
11. Are there any important issues or concerns that have been insufficiently covered or missed in this discussion document and the three options?

Import/Export

As mentioned Part I, Article 12, Paragraph 10 of the 1988 Convention requires exporting countries to provide specific information for each export transaction of Table I substances, prior to export, when importing countries have formally made such a request to the Secretary General of the UN. Numerous countries have invoked this provision for Table I substances and some have even extended the provision to selected Table II substances. To provide this information to importing countries, Canada must, at a minimum (Option 1), require exporting firms to file a declaration for Table I substances prior to export. This export declaration, however, would neither enable Canada to stop exports intended for clandestine production nor would it address other concerns related to imports of precursor chemicals destined for clandestine manufacturing. Option 2 was designed to address these issues with prior authorization for both import and export of Table I substances and pre-export declaration for Table II substances in the case of selected high risk destinations. More rigorous provisions are foreseen in Option 3 calling for an extension of the permit system used for Controlled Substances to each import and export transaction of Table I substances, individual authorizations for export of Table II substances to selected high risk destinations and pre-export declaration for export of chemicals on the special surveillance list to selected high risk destinations.

When providing feedback on the import/export options consider the following questions as they apply to your organization.

1. Where do you see the point of equilibrium between regulatory provisions for import/ export control of precursor chemicals and burden on legitimate trade?
2. Can you provide estimates on the range of incremental costs to your organization or members associated with the options identified, if any?
3. What are your views on the merits and feasibility of a system where general authorizations for imports are issued with provisions for reporting transactions, compared to one where individual permits are required? (See Option 2 Category A,)

4. Looking at Options 2 and 3, are individual thresholds for Categories B and C more cumbersome to implement than no thresholds? From your perspective what are the advantages and disadvantages?
5. Do you see major impediments in implementing end user declarations for Table I chemicals?
6. Under what circumstances, if any, would you foresee a need for exemptions for specific products or mixtures containing precursor chemicals?
7. Do you have any additional suggestions or comments to make in regard to the import/export of precursor chemicals?

License /Registration

Article 12, Paragraph 8, describes the type of controls that Parties to the 1988 Convention may implement over persons and enterprises engaged in the production and distribution of precursor chemicals, including controls over the premises where such production and distribution may take place. While signatories to the Convention have discretion in implementing these controls, most jurisdictions have found it necessary to enact varying licensing and registration schemes as a means of discharging their responsibilities under the Convention. In Canada, establishing regulatory provisions for licensing and registration of legitimate producers and operators is a necessary step to implement, inter alia, a criminal offence for unlawful transactions in precursor chemicals as required under Article 3, Paragraph 1, of the Convention. Moreover, Article 12, Paragraph 9(a) requires operators to report suspicious transactions to competent authorities. Thus, licensing operators and premises engaged in the production, import, export and large scale distribution of Category A chemicals, and registration for similar activities in Category B chemicals, along with a regulatory obligation to report suspicious transactions, are a means of control and is considered a minimum step in Option 1. Licensing requirements are expanded in options 2 and 3.

1. Here again the notion of balance between monitoring/control and burden on trade applies. Where do you see the point of equilibrium in this case?
2. Can you provide estimates on the range of incremental costs to your organization or members associated with the licensing and registrations options identified?
3. Licenses issued under the *Controlled Drugs and Substances Act* are renewable on an annual basis. Would you see benefits for longer renewal periods for licensing/registration? Under what conditions?
4. Other jurisdictions have attached licensing and registration thresholds to Category B and category C chemicals. Do you favour a similar approach in Canada?

5. Other jurisdictions have provided exemptions under certain circumstances and/or for specific products or mixtures where the precursor chemicals are not readily extractable. Can you provide information on circumstances necessitating exemptions? What do you consider as potential criteria for exempting certain products or mixtures of precursors? Please provide examples.
6. Do you have any relevant information to share on licensing/registration from experience gained by an affiliate (s) in other jurisdictions?
7. Do you have any additional suggestions to make in regards to the licensing/registration of persons and premises?

Documentation, Records and Labelling

Article 12, Paragraph 9(d) of the Convention states that imports and exports are required to be properly labelled and documented. Commercial documents such as invoices, cargo manifests, customs, transport and other shipping documents should contain the following essential information: name(s) of the substance(s) as stated in Table I or Table II, the quantity of the substance, the name and address of the exporter, the importer and when available the consignee, and other information as required by the State. In Canada, CCRA requires the HS code and a list of ingredients.

The Convention requires documents to be kept and made available for inspection for two years. This time frame is consistent with Regulations to the CDSA, such as the Narcotic Control Regulations. The exception will be for CCRA documents -- the *Customs Act* requires that documents be kept for six years.

1. What are your current practices for labelling? Do you use the HS code or another standard for the identification of chemicals?
2. What documentation do you use for domestic distribution? Would it be beneficial to use HS codes or another standard for all transportation documents.
3. Do you have any suggestions which will facilitate the implementation of the regulations regarding documentation, records and labelling?

Offences

Canada is bound to establish as criminal offences the production, transport and distribution of Category A and Category B chemicals, knowing that they are to be used in the production of controlled substances.

1. Criminal offences and sanctions would clearly target diversion behaviour and every effort would be made to focus enforcement on clandestine activities. With this in mind, can you foresee any circumstances or issues which should be brought forward to sharpen the focus of the regulatory framework?
2. Do you have any other comments or suggestions to make regarding offences?

Security

The 1988 Convention does not address security, other than through a general requirement to take measures deemed appropriate to prevent diversion of precursor chemicals. While some jurisdictions have enacted security requirements, others rely on voluntary codes of good practices. As a result, Option 1 does not address security issues; Option 2 is designed around voluntary industry standards; and Option 3 proposes regulatory standards for chemical precursors of category A. Based on the experience gained in the control of psychoactive pharmaceuticals is any indication, once controls are implemented, the street price for precursor chemicals is likely to exceed the commercial price by a large margin; then commercial storage facilities could become a target for criminal acts.

1. What security measures does your organization or member firms have in place or be willing to implement regarding the storage, handling and transport of precursor chemicals, particularly those in Category A?
2. Can you foresee what incremental costs and or burden to business practices might be associated with security measures?
3. Can you foresee opportunities to reduce diversion risks while maintaining cost effectiveness through process re-engineering and reduced inventories throughout the distribution chain?
4. Do you have any suggestions related to physical and procedural security?

Monitoring

Article 12, paragraphs 8 and 9 call on Parties to the 1988 Convention to implement measures for the monitoring of production and trade in precursor chemicals in cooperation with producers and distributors. Many jurisdictions have acknowledged the importance and synergy of voluntary monitoring programs working hand-in-hand with effective regulatory frameworks. In 1994, the International Council of Chemicals Associations and the World Customs Organization signed a Memorandum of Understanding calling on countries to exercise vigilance through cooperation between competent authorities and commercial operators. In Canada, the chemical industry has

implemented the voluntary program Responsible Care®. While this program focuses on product stewardship, the main emphasis appears to be on environmental concerns.

1. What role do you see for voluntary initiatives in reducing precursor diversion?
2. Can you describe where you see “ the efficient frontier” in the mix of regulatory requirements and voluntary measures?
3. To what extent is your firm/association prepared to go beyond regulations to monitor transactions and prevent diversion of precursors?
4. Does your company implement the “know your client” concept? What quality- assurance measures do you have in place to verify the legitimacy of the client?
5. Do you have additional comments or suggestions in regards to regulatory and voluntary monitoring options?

Reporting

Article 12, Paragraph 9(a) in the 1988 Convention requires that manufacturers, importers, exporters, wholesalers and retailers inform competent authorities of suspicious transaction and orders. Throughout the Convention and in Resolutions from CND the implementation of an effective and efficient reporting regime is stressed repeatedly. Open channels of communication between the industry and authorities (government or law enforcement) are instrumental in ensuring that all suspicious transactions and trends are monitored. Regulations governing the reporting of suspicious transactions would be a minimum requirement (Option 1). Regulations governing the reporting of thefts, losses and damage to containers are featured in options 2 and 3.

Article 12, Paragraph 12 of the 1988 Convention addresses reporting to INCB by the State. The annual reports should include:

“Amounts of seized substances in Table I and Table II and, when known their origin;
Any substance not included in Table I and Table II which is identified as having been used in illicit manufacturing of narcotic and psychotropic substances, and which is deemed by the Party to be sufficiently significant to be brought to the attention of the Board; and
methods of diversion and illicit manufacture.”

1. The RCMP has distributed guidelines on the reporting of “suspicious” transactions for precursor chemicals to enforcement authorities. Do you have any comments to make on your experience with these guidelines, or any suggestions to make toward their improvement?
2. Would your organization benefit from an information package or a training program on the identification and reporting of suspicious transactions?

3. Do you feel that there is a safety risks to your organization or its members with a voluntary reporting program? Do you believe they would be minimized using a regulated program, which would provide coverage in the event of reprisal?
4. Do you have any additional suggestions to make in regards to reporting, voluntary or regulated?

Please provide your response in writing by June 20, 2001 to: Theresa Schopf , Policy and Regulatory Affairs Division, Office of Controlled Substances, Health Canada. Address Locator 3503D Ottawa, Ontario. K1A 1B9; tel: (613) 946-6435; fax:(613) 946-4224; email: theresa_schopf@hc-sc.gc.ca . Your comments will assist us to focus our discussions at the consultation workshop in Ottawa, June 27 and 28, 2001. **Please let us know by June 6, 2001 if you would like to participate in this workshop.**

**UNITED NATIONS CONVENTION AGAINST ILLICIT TRAFFIC IN
NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES**

Article 12

**SUBSTANCES FREQUENTLY USED IN THE ILLICIT
MANUFACTURE OF NARCOTIC DRUGS OR PSYCHOTROPIC SUBSTANCES**

1. The Parties shall take the measures they deem appropriate to prevent diversion of substances in Table I and Table II used for the purpose of illicit manufacture of narcotic drugs or psychotropic substances, and shall co-operate with one another to this end.
2. If a Party or the Board has information which in its opinion may require the inclusion of a substance in Table I or Table II, it shall notify the Secretary-General and furnish him with the information in support of that notification. The procedure described in paragraphs 2 to 7 of this article shall also apply when a Party or the Board has information justifying the deletion of a substance from Table I or Table II, or the transfer of a substance from one Table to the other.
3. The Secretary-General shall transmit such notification, and any information which he considers relevant, to the Parties, to the Commission, and, where notification is made by a Party, to the Board. The Parties shall communicate their comments concerning the notification to the Secretary-General, together with all supplementary information which may assist the Board in establishing an assessment and the Commission in reaching a decision.
4. If the Board, taking into account the extent, importance and diversity of the licit use of the substance, and the possibility and ease of using alternate substances both for licit purposes and for the illicit manufacture of narcotic drugs or psychotropic substances, finds:
 - (a) That the substance is frequently used in the illicit manufacture of a narcotic drug or psychotropic substance;
 - (b) That the volume and extent of the illicit manufacture of a narcotic drug or psychotropic substance creates serious public health or social problems, so as to warrant international action, it shall communicate to the Commission an assessment of the substance, including the likely effect of adding the substance to either Table I or Table II on both licit use and illicit manufacture, together with recommendations of monitoring measures, if any, that would be appropriate in the light of its assessment.
5. The Commission, taking into account the comments submitted by the Parties and the comments and recommendations of the Board, whose assessment shall be determinative as to scientific matters, and also taking into due consideration any other relevant factors, may decide by a two-thirds majority of its members to place a substance in Table I or Table II.
6. Any decision of the Commission taken pursuant to this article shall be communicated by the Secretary-General to all States and other entities which are, or which are entitled to become,

Parties to this Convention, and to the Board. Such decision shall become fully effective with respect to each Party one hundred and eighty days after the date of such communication.

7. (a) The decisions of the Commission taken under this article shall be subject to review by the Council upon the request of any Party filed within one hundred and eighty days after the date of notification of the decision. The request for review shall be sent to the Secretary-General, together with all relevant information upon which the request for review is based.

(b) The Secretary-General shall transmit copies of the request for review and the relevant information to the Commission, to the Board and to all the Parties, inviting them to submit their comments within ninety days. All comments received shall be submitted to the Council for consideration.

(c) The Council may confirm or reverse the decision of the Commission. Notification of the Council's decision shall be transmitted to all States and other entities which are, or which are entitled to become, Parties to this Convention, to the Commission and to the Board.

8. (a) Without prejudice to the generality of the provisions contained in paragraph 1 of this article and the provisions of the 1961 Convention, the 1961 Convention as amended and the 1971 Convention, the Parties shall take the measures they deem appropriate to monitor the manufacture and distribution of substances in Table I and Table II which are carried out within their territory.

(b) To this end, the Parties may:

(i) Control all persons and enterprises engaged in the manufacture and distribution of such substances;

(ii) Control under licence the establishment and premises in which such manufacture or distribution may take place;

(iii) Require that licensees obtain a permit for conducting the aforesaid operations

(iv) Prevent the accumulation of such substances in the possession of manufacturers and distributors, in excess of the quantities required for the normal conduct of business and the prevailing market conditions.

9. Each Party shall, with respect to substances in Table I and Table II, take the following measures:

(a) Establish and maintain a system to monitor international trade in substances in Table I and Table II in order to facilitate the identification of suspicious transactions. Such monitoring systems shall be applied in close co-operation with manufacturers, importers, exporters, wholesalers and retailers, who shall inform the competent authorities of suspicious orders and transactions.

(b) Provide for the seizure of any substance in Table I or Table II if there is sufficient evidence that it is for use in the illicit manufacture of a narcotic drug or psychotropic substance.

(c) Notify, as soon as possible, the competent authorities and services of the Parties concerned if there is reason to believe that the import, export or transit of a substance in Table I or Table II is destined for the illicit manufacture of narcotic drugs or psychotropic substances, including in particular information about the means of payment and any other essential elements which led to that belief.

(d) Require that imports and exports be properly labelled and documented. Commercial documents such as invoices, cargo manifests, customs, transport and other shipping documents shall include the names, as stated in Table I or Table II, of the substances being imported or exported, the quantity being imported or exported, and the name and address of the exporter, the importer and, when available, the consignee.

(e) Ensure that documents referred to in subparagraph (d) of this paragraph are maintained for a period of not less than two years and may be made available for inspection by the competent authorities.

10. (a) In addition to the provisions of paragraph 9, and upon request to the Secretary-General by the interested Party, each Party from whose territory a substance in Table I is to be exported shall ensure that, prior to such export, the following information is supplied by its competent authorities of the competent authorities of the importing country:

(i) Name and address of the exporter and importer and, when available, the consignee;

(ii) Name of the substance in Table I;

(iii) Quantity of the substance to be exported;

(iv) Expected point of entry and expected date of dispatch;

(v) Any other information which is mutually agreed upon by the Parties.

(b) A Party may adopt more strict or severe measures of control than those provided by this paragraph if, in its opinion, such measures are desirable or necessary.

11. Where a Party furnishes information to another Party in accordance with paragraphs 9 and 10 of this article, the Party furnishing such information may require that the Party receiving it keep confidential any trade, business, commercial or professional secret or trade process.

12. Each Party shall furnish annually to the Board, in the form and manner provided for by it and on forms made available by it, information on:

(a) The amounts seized of substances in Table I and Table II and, when known, their origin;

(b) Any substance not included in Table I or Table II which is identified as having been used in illicit manufacture of narcotic drugs or psychotropic substances, and which is deemed by the Party to be sufficiently significant to be brought to the attention of the Board;

(c) Methods of diversion and illicit manufacture.

13. The Board shall report annually to the Commission on the implementation of this article and the Commission shall periodically review the adequacy and propriety of Table I and Table II.

14. The provisions of this article shall not apply to pharmaceutical preparations, nor to other preparations containing substances in Table I or Table II that are compounded in such a way that such substances cannot be easily used or recovered by readily applicable means.