ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

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# FINAL REPORT
# (Preliminary Version)

# GROUP OF EXPERTS ON CHEMICAL SUBSTANCES
# Buenos Aires, Argentina

# ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

**GROUP OF EXPERTS ON**
**CHEMICAL SUBSTANCES**
**August 22 – 24, 2005**
**Buenos Aires, Argentina**

**OEA/Ser.L/XIV.4**
**CICAD/doc.3/05**
**August 29, 2005**
**Original: English**

## FINAL REPORT

**Preliminary Version**

# I. BACKGROUND

The Group of Experts Chemical Substances met in Buenos Aires, Argentina from August 22 to 24, 2005, under the chairmanship of Mr. Gabriel Abboud of Argentina.

During its thirty-sixth Regular Session in Washington, D.C. (December 7-9, 2004), the Commission of the Inter-American Drug Abuse Control Commission (CICAD) received and approved the report of the Group of Experts further to its meeting in Brasilia, Brazil (June 2 to 4, 2004). This report defined the mandate and tasks for the Group that met in Argentina.

# II. PROCEEDINGS

## A. PARTICIPANTS

### 1. MEMBER STATES OF CICAD

Forty-six experts from the following member states participated in this meeting: Argentina, Bahamas, Barbados, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Guatemala, Haiti, Jamaica, Mexico, Panama, Peru, Trinidad and Tobago, United States, Uruguay and Venezuela.

## B. SESSIONS AND ORGANIZATION OF THE MEETING

### 1. OPENING SESSION

The opening session for the meeting of this Group of Experts took place in the Hotel Madero In Buenos Aires on August 22, 2005. This was a joint opening session for this meeting and the meeting of the Group of Experts on Pharmaceutical Products - Dr. José Ramón Granero, Secretario de Programación para la Prevención de la Drogadicción y Lucha contra el Narcotráfico de SEDRONAR, welcomed the participants to the meeting and offered welcoming remarks.

## 2. WORKING SESSIONS

The Group of Experts on Chemical Substances met during five (5) working sessions to consider a variety of issues including pre-export notification (PEN), disposal of chemicals, effective regulatory and administrative controls through inspections and investigations and chemical mixtures. A copy of the schedule of activities is attached.

During the last meeting of the Group of Experts, the Executive Secretariat was asked to undertake consultation and other research related to a number of issues discussed during that meeting. The Executive Secretariat delivered a short report on the status of these assignments. Some of this information was used to facilitate discussions during this meeting and help to define a course of action for the Group.

At the beginning of the meeting, each participant was asked to identify one or two concerns that they had regarding the control of chemical substances. These issues served as the basis for discussions during this meeting or for inclusion in the plan of action for future proposed meetings. The Group identified the following issues:

- Pre-export notifications
- Pharmaceutical products containing Ephedrine and Pseudoephedrine
- Chemical mixtures
- Disposal of chemicals
- Control of chemicals in free trade zones
    - Border controls
    - Training
- Strategies to address differences in controls between countries
- Review and update model regulations
    - Security issues
    - Disposal of chemicals
    - Review of other aspects of the regulations

During the meeting, participants delivered a number of presentations on various issues related to the control of chemicals.

The delegation of Mexico delivered a presentation on the diversion of pharmaceutical products containing ephedrine and pseudoephedrine.

Mr. Wayne Jeffery, a forensic scientist, formerly with the Royal Canadian Mounted Police (RCMP), delivered a presentation on the disposal of chemical substances.

The delegation of Colombia delivered a presentation on the substitution of chemicals used as solvents, oxidants etc. in the manufacture of illicit drugs. This generated a great deal of discussion, as this is a problem shared by many member states where illicit drug production takes place. This presents certain challenges for countries trying to control chemicals and these substitute substances while ensuring their availability for their use for legitimate industrial or manufacturing purposes. Participants noted that differences in the control of chemicals among member states provide narcotraffickers with opportunities for diversion. Colombia offered to share a study that they have undertaken on chemical substitution. The Executive Secretariat will distribute copies of this study to the members of the Group of Experts.

The delegation of Argentina delivered a presentation on the "fee for service" program that they implemented regarding the control of chemicals. This program is based on a fee charged to companies for licensing or registration and other regulatory or administrative activities. The funds received through this program contribute to the funding of Argentina's chemical control program.

Participants were very interested in this issue and proposed that it be included in the plan of action for the Group's next meeting.

## A. Review of Manuals/Guides

**Model Reference Guide for Inspections for the Control of Chemical Substances.**

The delegation of the United States presented a draft of the **Model Reference Guide for Inspections for the Control of Chemical Substances.**

The Group of Experts reviewed, modified and finalized this draft guide (copy attached).

The Group submits this model guide for inspection to the Commission for its consideration. Further to review by the Commission and the inclusion of any changes that it requests, the final version of this model guide will be available for posting to the CICAD web page.

## B. Disposal of chemical substances

The disposal of these substances in a safe, inexpensive and environmentally acceptable way represents a major challenge to all CICAD member states. This problem presents itself when:

- law enforcement officers uncover and dismantle illicit drugs production laboratories,
- when chemicals are seized at the border or in transit
- when seizures take place at chemical firms or other establishments where chemicals are used or manufactured.

Following the last meeting of the Group, the Executive Secretariat initiated consultations with the United Nations Office on Drugs and Crime (UNODC) to determine initiatives that have been implemented with regard to this issue. Coincidentally, the UNODC was just starting to consider this issue and was looking for a consultant to do some preliminary work in this area. The Executive Secretariat recommended Mr. Wayne Jeffrey, a forensic scientist formerly with the Royal Canadian Mounted Police (RCMP), for this assignment.

Mr. Jeffery and his colleague Mr. Jorge Acevedo (formerly of the US Drug Enforcement Administration) have been working on this project. They will present the results of their work to a meeting of experts meeting in Vienna in early September 2005. According to Mr. Jeffery, this will lead to the development of a manual or practical guide on alternatives for the safe disposal of chemicals.

Mr. Jeffrey delivered a presentation on his work on the issue of chemical disposal and his work for the UNODC. He also discussed the basic elements that countries must have in place to allow for the disposal of chemicals and information concerning some of the methods that can be used for this purpose. This presentation served as a point of departure for discussion by a special working group formed to examine this matter further.

The working group, chaired by Colombia, considered the issue of chemical disposal, the work that Mr. Jeffery and Mr. Acevedo have been doing and the manual that they expect to produce. In doing so the group directed their attention to identifying activities that the Group might pursue that would compliment or build on this effort. To this end, the working group proposed a program that would promote continuous training in matters related to the safe handling, investigation and disposal of chemicals by law enforcement, customs and other officials concerned with the control of chemicals. This would include control activities at borders, investigation and dismantling of illicit laboratories and the disposal of seized chemicals. The proposed approach for the program is one of “train the trainers”. In this way, member states could build the capacity for program continuity. The proposed program also includes provisions for periodically providing updated information to trainers. Details of the proposed program are attached.

The Group submits this training program proposal for the consideration of the Commission. It recommends that the Commission directs the Executive Secretariat to study this proposal, refine it as required and then seek funding to implement the program starting with a pilot application to member states in one of the sub-regions of CICAD.

## C. Diversion and Control of Pharmaceutical Products containing Ephedrine and Pseudoephedrine:

The delegation of Mexico delivered a presentation on problems related to the control of raw materials and pharmaceutical products containing ephedrine and pseudoephedrine. These substances are precursors in the production of methamphetamine. This was a presentation that was jointly prepared by the delegations of Canada, Mexico and the United States.

After some discussion, the Group decided that the Group of Experts on Pharmaceutical Products should address this issue. It was therefore deferred to that group's consideration.

## D. Bulletin on Pre-Export Notification (PEN)

A working group, chaired by Peru, considered the issue of pre-export notifications. This has been a recurring topic for discussion by the Group of Experts. It is a simple and effective way to help minimize the diversion of chemical substances. At the same time, member states have been encountering problems with the execution of this mechanism. The problems encountered include failure to send PEN's, sending them late and failure to send no replies, among others.

The Group of Experts proposed to develop an information bulletin that would outline the responsibilities and expectations of countries exporting and importing chemical products as they relate to the PEN mechanism. The working group drafted such a bulletin for the consideration of the Group of Experts. Following some discussion and revisions, the information bulletin (copy attached) was finalized.

The Group of Experts offers this information bulletin for the consideration of the Commission and recommends that it accepts this document and directs the Executive Secretariat to post it on the CICAD web page.

## E. Chemical Mixtures

Chemical mixtures are products that contain varying combinations of chemical substances in different percentages. They include products such as thinners, which are not well defined or standardized in composition. Narcotraffickers wishing to divert chemical mixtures mislabel containers or modify the percentage composition of these substances to circumvent regulations and administrative controls. As such, the control of chemical mixtures presents a particularly difficult challenge for officials in CICAD member states.

Costa Rica chaired a working group to consider alternatives to help member states deal with this problem. One alternative this group discussed related to the 10-digit code used to identify all chemicals. At present, the first 6 digits are used to identify chemicals. Countries have the option to assign the remaining 4 digits as they wish to more precisely identify chemical substances. At present there is no common numbering scheme for these remaining 4 digits.

The working group proposed that the Executive Secretariat communicate with the World Customs Organization (which is responsible for administering the 10-digit code) and the International Narcotics Control Board (INCB) regarding this matter. In doing so, the Executive Secretariat will share the concerns of the CICAD member states regarding chemical mixtures and propose alternatives related to the 10-digit identification code.

The delegation of Costa Rica agreed to prepare a short paper outlining the problem that CICAD member states face regarding chemical mixtures and expanding on a proposal regarding the 10-digit code. The Executive Secretariat will use this paper to prepare letters to the WCO and INCB.

## F. Self assessment matrix for chemical control

During the last meeting of the Group of Experts, the Executive Secretariat reported on increasing requests by member states for technical assistance in the review of national chemical control regulatory and administrative programs. Following this meeting, the Executive Secretariat drafted a matrix of issues and questions that countries should consider when examining their chemical control programs. It is intended as a self-assessment tool that can be used to facilitate a preliminary review to more precisely identify their needs for technical assistance.

The Executive Secretariat distributed the draft matrix (copy attached) prior to the meeting for the consideration of the Group. The Group proposed that the matrix be posted to the web page and modified based on comments from countries as they use it.

The Group offers this self-assessment matrix to the Commission and recommends that the Commission direct the Executive Secretariat to post it on the CICAD web page and modify it based on comments received.

## G. Issues for future consideration by the Group of Experts

Further to the round table discussion of issues of concern and those identified during the course of the meeting, the Group of Experts recommends that it meet during 2006 to consider the following issues as part of its proposed plan of action:

- Synthetic (chemical-based) drugs
- "Fee for service" programs
- Control of chemicals in free trade zones
    - Border controls
    - Training
- Strategies to address differences in controls between countries
- Checklist of questions for use in different types of inspections and investigations
- Review and update model regulations
    - Security issues
    - Disposal of chemicals
    - Review of other aspects of the regulations

## 3. CLOSING SESSION

The Group of Experts concluded its work at 13:00 on August 24. The Chair of the Group closed the meeting and thanked the members for their participation.

## III. CONCLUSIONS AND RECOMMENDATIONS OF THE GROUP OF EXPERTS

**RECOMMENDATIONS TO CICAD IN ITS THIRTY-SEVENTH REGULAR SESSION:**

1. That the Commission consider and accept the following guides or documents and direct the Executive Secretariat to post them to the CICAD web page.
   - "**Model Reference Guide for Inspections for the Control of Chemical Substances"**.
   - Information Bulletin on Pre-Export Notification
   - Self-Assessment Matrix on the Control of Chemical Substance

2. That the Commission direct the Executive Secretariat to study chemical control training proposal, refine it as required and then seek funding to implement the program starting with a pilot application to member states in one of the sub-regions of CICAD.

3. That the Commission consider and accept the plan of action proposed by the Group of Experts and directs that the Group meets in 2006 to consider the issues in the plan as well as other new trends or threats identified in the area of chemical control.

# ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

**MEETING OF THE GROUP OF EXPERTS**
**CONCERNING CHEMICAL SUBSTANCES**
**August 22 - 24, 2005**
**Buenos Aires, Argentina**

## SCHEDULE OF ACTIVITIES
**(***Draft***)**

**Monday, August 22**

| | |
|---|---|
| **08h30 – 09h00** | **Registration** |
| **09h00 – 09h30** | **Opening Remarks** |
| **09h30 – 10h00** | **Introduction and Review**<br>• **Background**<br>• **Objectives and CICAD Commission expectations**<br>• **Schedule of work**<br>• **Proposed work methodology**<br>• **Status report on Recommendations**<br>• **Other issues** |
| **10h00 – 10h45** | **Roundtable introductions and identification of new issues** |
| **10h45 – 11h00** | **Break** |
| **11h00 – 12h00** | **Discussion of new issues** |
| **12h00 – 12h45** | **Review and finalize the draft guide for Inspection** |
| **12h45 – 14h00** | **Lunch** |
| **14h00 – 15h45** | **Review and finalize the draft guide for Inspection (cont.)** |
| **15h45 – 16h00** | **Break** |

| | |
|---|---|
| **16h00 – 17h00** | **Presentation on the diversion of ephedrine and pseudoephedrine (Canada, Mexico, US)** |

**<u>Tuesday, August 23</u>**

| | |
|---|---|
| **09h00 – 10h45** | **Disposal of chemical substances**<br>**Presentation and discussion**<br>**Wayne Jeffrey (Tentative)** |
| **10h45 – 11h00** | **Break** |
| **11h00 – 12h30** | **Working group discussions:**<br>**- Bulletin on Pre-Export Notification (PEN)**<br>**- Self assessment matrix for chemical control**<br>**- Drugs codes for mixtures**<br>**- Diversion of medications that contain pseudoephedrine**<br>**- amendments to the CICAD model regulations**<br>**- Disposal of chemicals**<br>**– elements to consider in updating the model regulations**<br>**- identification of other issues related to the disposal of chemicals**<br>**- Other issues** |
| **12h30 – 14h00** | **Lunch** |
| **14h00 – 15h45** | **Working group discussions (con't)** |
| **15h45 – 16h00** | **Break** |
| **16h00 – 17h30** | **Working group discussions (con't)** |

**Wednesday, August 24**

| | |
|---|---|
| **09h00 – 10h45** | **Working group discussion regarding new issues identified** |
| **10h45 – 11h00** | **Break** |
| **11h00 – 12h00** | **Conclusions, commitments and recommendations for action by the Expert Group** |
| **12h00** | **Closing** |

ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

# Best Practices Guideline for Investigations of Chemical Substances

# ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

**Best Practices Guideline for Investigations of**

**Chemical Substances**

## TABLE OF CONTENTS

## I. Introduction

### A. Background

The diversion of chemical substances from legitimate commerce to the illicit production of controlled substances is a major international challenge. The business of manufacturing, international trade (import, export, transit, and brokerage), and distribution of chemicals has traditionally been less tightly regulated than pharmaceutical controlled substances. The chemical distribution system lacks the involvement of health care professionals who, for example, prescribe and dispense controlled substances to patients. Perhaps for these reasons, some countries have observed that the percentage of firms engaged in questionable practices is higher in the area of regulated chemicals than in the pharmaceutical sector.

In 1999, CICAD approved a revised "model regulation" with respect to chemical control.[1] Many countries in the hemisphere have used this model as a reference in drafting national laws. But in order for chemical control systems to function effectively, states need more than strong laws and regulations. They need sufficient administrative and enforcement structures to monitor trade, scrutinize license applications and regulate businesses after licensure, receive and respond to pre-notifications of shipments, review requests for import and export permits, and investigate possible wrongdoing by licensed persons and firms. The key to the integrity of such a system is focused, professional inspections and investigations.

At its meeting in Brasilia in June 2004, the Group of Experts on Pharmaceutical Products requested a guide of best practices for inspections and investigations relating to the handling of pharmaceutical products. Following the drafting of that guide, this document was prepared because the Group of Experts believe that countries may find it just as useful to have a "best practices" guide for inspections and investigations in the area of regulated chemical substances as for pharmaceutical products.

[1] Model Regulations to Control Chemical Substances Used in the Illicit Production of Narcotic Drugs and Psychotropic Substances (May 1999).

B. Purpose

Inspections and investigations of handlers of chemical substances are conducted to prevent and detect their diversion from legitimate to illicit channels. Additional objectives are to prevent the illicit manufacture of controlled substances, to identify and take administrative or criminal action against violators, and to identify, seize and forfeit illicit assets. These inspections and investigations should be part of a national system that, at the same time, ensures an adequate and uninterrupted supply of chemical substances required to meet legitimate medical, commercial, and scientific needs.

## II. Profile of an Inspector/Investigator

The investigative team must be constituted by personnel specialized in the different areas related to the administrative, technical and investigative control of the chemical substances.

At the minimum, the team should be made up of one chemical specialist (chemical technician, chemist, chemical engineer, chemical pharmacist, licensed chemist) with knowledge in evidence gathering, and a specialist in accounting, with emphasis in documentation analysis and bookkeeping (control books, raw material logs, import, export, etc.). (

Additionally, control institutions should propose and implement training programs for investigators on the different analytical and auditing methodologies, as well as the information exchange related to the diversion of chemical substances.

## III. Common Elements of an On-Site Inspection

**Scope.** An on-site inspection is central to any investigation of an applicant for licensure or a licensee. All on-site visits should include certain common elements and practices. This part discusses those common elements. Later parts will address additional aspects of the on-site inspection that relate to a particular type or stage of investigation.

A. Preparing

Before conducting the on-site inspection, the Inspector should check all available criminal information records and other appropriate information systems concerning the applicant. These should include a search of all required business licenses.

B. Staffing

At least two Inspectors should participate in all aspects of the on-site portion of the inspection.

C. Notice Prior to Inspection

Except in the case of a pre-registration inspection, no advance notice should be required by law or given by the competent authority. In fact, advance notice may hamper the integrity of a scheduled or complaint investigation.

D. Introduction of Inspector

To initiate the on-site inspection, the Inspectors should present their identification to a representative of the business and state the purpose of the visit.

E. Obtaining Lawful Access

As a condition of application for licensure and for retaining a license, national laws and regulations should provide for the licensee's consent to inspection by regulatory and law enforcement authorities at reasonable times to ensure compliance or to investigate complaints. Nonetheless, access in each particular case should be through established, lawful means.

The process is simplest in the case of a pre-registration inspection (where applicable, *i.e.*, where the activities and/or chemicals require registration), where the applicant should view the visit as a pre-condition to licensure. If an applicant denies access, then the competent authority should deny the license. In other cases, including scheduled inspection and complaint investigations, the bases for gaining lawful access will vary by national law.

A reasonable series of options for obtaining lawful access is described below.

1. A Notice of Inspection, prepared on a form by the investigating entity, is the simplest means of gaining access. The Notice should contain a statement of rights and an acknowledgement of consent to inspection.

2. The representative of the business at the premises should sign the Notice form as evidence of consent. In some cases, a firm will give only verbal consent. In such cases, the Inspector should so indicate on the form. Both Inspectors should sign. In either case, a copy of the form should be given to a responsible representative at the firm.

3. If the Notice is not effective to gain consent to enter, the Inspector may seek an Administrative Inspection Warrant (AIW) signed by a judge. The AIW allows no greater right of inspection, but the judicial backing affirms that the inspection is in fact legally authorized.

Note: A judicial order of this kind should be obtained at the outset, if the Inspectors suspect non-compliance, and especially criminal activity, at the premises. The basis for such warrants does not need to be suspicion or wrongdoing, but merely a valid public interest in the effective enforcement of laws and regulations. (This is called "administrative probable cause.")

## IV. Pre-Registration Inspections

**Scope.** A pre-registration inspection is more than a pre-condition for licensure – although that is its central legal function. It should also try to set the applicant on a course towards full compliance with the letter and spirit of applicable laws and regulations. A good corps of licensees can even assist regulatory and law enforcement officials in doing their job to assure compliance and protect the public.

In terms of the applicable law and regulatory scheme, the fundamental purpose of the pre-registration inspection is to determine the fitness and suitability of the applicant to engage in the activities for which registration is requested. To this end, the Inspectors should examine the following areas during the on-site pre-registration inspection.

### A. Accuracy and Completeness of Application

The Inspections should review the application with the firm's management to determine that all information regarding the proposed activity has been accurately presented. They should explain that only those activities stated on the application may be conducted, only at the business address in the application, and only with the chemicals for which codes were presented on the application.

### B. Identification of Responsible Individuals

The Investigators should identify the owner and manager of the corporation, any legal representative, and the person(s) responsible for record keeping, security and handling of chemical substances at the location that is applying for registration. Sufficient information (name, address, date/place of birth, driver's license number, and citizenship) should be solicited to permit a follow-up review of law enforcement records.

### C. Interviews

A team of at least two Inspectors should conduct the interviews. The collective team should possess the skills and expertise in the various areas noted above. The Inspectors should conduct interviews to gather information regarding the capacity of the

company to operate within the relevant laws, regulations or administrative requirements of a licensed company. They should interview the individuals who are responsible for compliance, as well as those persons who will be directly maintaining records, handling chemical substances and others, as required. D. Familiarization with Regulatory System

The Inspectors should ensure that the applicant is aware of and is able to comply with all provisions of the country's applicable laws and regulations. They should clarify common errors and misunderstandings of the law, and may explain any national and regional trends in diversion. For example, an applicant should be advised to take a complete and accurate count of chemical substances on the date of licensure (even if zero). Requirements of other types of transaction records, and the duty to maintain and retain such records available for inspection, should be discussed. Inspectors should stress the duty to report to the competent authorities any losses or apparent thefts of chemicals, and any transaction or proposed transaction that gives rise to a reasonable suspicion that the product may be diverted.

E. Review of Other Relevant Licenses

The Inspectors should examine any licenses or permits otherwise required for the applicant to conduct its pre-registration activities as well as the proposed activity (*e.g.*, licenses or permits for handling or storing toxic or hazardous substances, pharmacy or hospital registration, as well as general business licenses). Documents at the firm should be cross-checked with those obtained – preferably in advance -- from official public records.

F. Security

Unlike with pharmaceutical controlled substances, chemical substances are not subject to prescribed security requirements. However, firms are required to report to the competent authorities any loss or unusual or significant disappearances of substances under the firm's control. (See Article 30 of the Model Regulations.) Implicit in this obligation to report is the responsibility of firms to have effective systems to prevent and detect thefts or losses.

## V. Scheduled Inspectors

**Scope.** This section covers inspections that are not for initial licensure (see Part III) or as part of a complaint investigation (see Part V). All licensed manufacturers, distributors, importers, and exporters should be subject to scheduled on-site inspection to ensure compliance with laws and regulations. A satisfactory inspection entitles the licensee to continued licensure. An unsatisfactory inspection may lead to further action, including sanctions. This section will first review the types of scheduled inspections and then discuss how the inspections are conducted.

A. Types of Scheduled Inspections

1. New Licensee Re- Inspection

Licensees should be inspected within one year of initial licensure to ensure they have established good systems and patterns for compliance with the law and preventing diversion of chemical substances.

2. Scheduled Chemical Inspection

A full inspection should occur on a cyclical basis, but not less than once every five years, for all licensees, *i.e.*, importers, exporters, manufacturers, distributors, and, if applicable in the national system, transporters. The inspection should include a review of the record keeping and security controls for listed the chemical products or substances.

The Inspectors, accompanied by a company representative, should conduct a physical inventory of all listed chemicals on site or in the possession of the firm at the time of the inspection and verify its accuracy. The inventory should be recorded and signed by the Inspector and the company representative. The Inspector should review all logbooks or records of receipts, sales, thefts, losses and any other records required to be maintained by law.

Once the verification and audit are complete, any deviation in the accountability such as shortages or overages must be addressed by the company. The Inspector should document all findings during the inspection as well as the explanations for any discrepancies provided by the company in order to prepare a report for the appropriate entity making decisions regarding further action.

3. Secondary/Follow-up Inspection

A secondary or follow-up inspection investigation occurs when an Inspector documents actionable items, (*e.g.*, by a citation or administrative action) against a licensee as a result of findings from the firm's scheduled inspection. Secondary inspections are also appropriate when another inspection results in administrative action other than a resolution fully in favor of the licensee.

B. <u>Elements of a Scheduled Inspection</u>

A scheduled inspection should be divided into three phases: preparation, on-site visit and follow-up.

1. Preparation

The Inspectors should examine all available information pertinent to the licensee to determine past history and complaints submitted concerning the licensee or its products.

2. Walk-Through Visit

Immediately after obtaining lawful access, the Inspectors should conduct a walk-through inspection of the firm's facility, gaining an initial familiarity with the firm's general procedures for handling chemical substances. Also during the walk-through inspection, the Inspector should take note of storage areas and any security practices with respect to chemical substances.

3. Interviews

In addition to a general review of compliance practices, the interviewing Inspector should ask the licensee about any known or suspected diversion of chemical substances.

4. Additional Background Information

Inspectors should obtain on-site, or verify information from advance off-site research, the following information:

- Names, addresses, dates of birth, etc. of corporate owners and officers of the firm, as well as persons responsible for record keeping and security.
- Information concerning the location(s) of the firm, length of time in business, and length of time at the current location.
- Percentage of the firm's business in chemical substances.
- Number of employees and the type of work they perform.
- Whether the firm has had any losses or thefts of chemical substances since the last investigation (if any) or since they began business, if a new firm.
- The firm's procedures and systems for:

  **--** pre-employment checks, background checks, and drug screenings;

  -- verification that customers are properly licensed or registered, and for obtaining customers' license numbers; and

  -- identifying suspicious and excessive orders.

## VI. Investigations of Complaints and Suspicious Activities

**Scope.** A "complaint investigation" is any targeted investigation of a licensee or non-licensee other than a pre-registration or scheduled inspection. A complaint investigation may be triggered by a tip from law enforcement (*e.g.*, based on an investigation of a known chemical diverting organization), a complaint by a citizen or customer, a result of "flags" from a database that tracks chemical substances, and

complaints from legitimate industry and chemical associations, or from information found during a scheduled inspection.

A. Objective

A complaint investigation program should focus limited national resources on priority targets. The complaint investigation should seek to determine whether the target has violated the law. In appropriate cases, the investigation may also assist other countries.

B. Setting Priorities for Complaint Investigations

1. The government should focus efforts on chemical substance diversion for profit. Different components may concentrate on various types of targets depending on their capabilities and jurisdiction. It is for this reason that it is of the utmost importance that agencies share and exchange information regarding diversion cases. Countries should consider designating a central point of contact to monitor investigations and prosecutions of chemical diversion cases.

2. The greatest emphasis should be placed on licensees who, through the veil of legitimacy or their position in an organization, are suspected of diverting large quantities of chemical substances.

C. Inter-Agency and International Cooperation and Flexibility

1. Chemical cases tend to cross national borders, so investigators need to think and work on an international scale. This requires a level and spirit of outreach, information-sharing, and case cooperation that may stretch and challenge established national procedures. Investigators should make full use of informal ("cop to cop") contacts and, as necessary, international cooperation mechanisms as provided in Article 9 of the 1998 United Nations Convention Against Trafficking in Narcotic Drugs and Psychotropic Substances.

2. It is not uncommon for countries to divide responsibilities among several ministries or components for, *e.g.*, (1) the regulation of chemical substances and chemical handlers (*e.g.*, issuance of licenses to import, export, manufacture, or distribute), (2) border and customs control, and (3) criminal enforcement. For example, the health ministry might have primary responsibility in the first area, border and customs agencies in the second, and the national police might have the lead on the third. In such countries, a highly integrated inter-agency mechanism should be developed that, for example, allows the regulatory authority to refer individuals suspected of criminal conduct to the criminal enforcement authority and permits all components to communicate with the agencies responsible for monitoring national ports of entry and the border. Shared databases, cooperative investigations, co-location of personnel, and other arrangements that foster the greatest permissible communication and coordination will help avoid gaps, duplication of effort, and inter-agency rivalry.

3. Chemical diversion cases tend to be complex because of the extensive paperwork necessary to prove certain violations. This tendency makes it important that countries adopt a flexible approach and develop an organization that avoids unnecessary institutional barriers or diversions of investigative responsibility or "turf."

D. Investigative Techniques

The type of investigation and the desired action may dictate the techniques to be used, which may include:

- Searches of the controlled premises and other places where records and evidence may be located;
- Accountability audits of chemical substances;
- Interviewing employees, including managers and owners;
- Undercover purchases;
- Controlled deliveries;
- Video, audio and wiretap surveillance; and
- Use of informants.

4. A critical element of chemical investigations is to "backtrack" from known information to determine all persons, firms, and activities further up and down the chain of distribution. For example, a drum of acetone or potassium permanganate found in a truck crossing a border or in a clandestine laboratory should be carefully scrutinized for company name, label, or any other traceable information. The Investigator should pursue any and all leads to the source to determine purchasers and other handlers and any potentially culpable persons anywhere in the chain of distribution. The "backtracking" need not – and should not – stop at the national border; investigators should contact and seek assistance from the competent authorities of other governments as needed.

5. If the investigation appears to be in support of a criminal case, it will be necessary to develop evidence that a person or firm had the requisite knowledge or intent that the chemicals it handled would be diverted to illicit uses. Illegal laboratory and storage facilities should be identified and seized.

6. Investigators also need to identify money laundering schemes used by traffickers and to identify and seize the traffickers' money and other assets using all available laws.

E. Preparing a Report of Investigation

The Investigator should prepare a detailed report documenting all areas of non-compliance and/or criminal conduct. A good format for the report would include both an organized analysis of findings by subject-area and a listing of which applicable laws and regulations were violated, together with a summary of the evidence to prove each violation. Further documentation may include any history of past violations. If relevant, and to the extent the Investigator has been able to ascertain, the investigative report should discuss the subject's compliance with or violation of foreign laws. This is especially important in countries where, for example, it is illegal to export a chemical in violation of the law of the receiving country.

## VII. Actions against Licensees

**Scope.** This part discusses the handling of a case after the complaint investigation is completed – at least in its initial phase. It reviews the legal bases for sanctions and the choice of appropriate sanctions with specific examples of possible options.

A. Moving from Investigation to Sanctions or Referral for Action

The Investigator should discuss his report with his supervisors and determine the most appropriate type of action or actions; this will dictate whether and how the case is referred. A combination of referrals may be best, *e.g.*, to the health ministry or other licensing authority for action against the license of a chemical handler and/or for civil money penalties, and to police authorities for investigation of an individual employee who, without the company's knowledge or participation, intentionally diverted chemicals. Upon determining the course of action, the Investigator is responsible for preparing the referral documents.

If the Investigator believes that significant violations have occurred warranting criminal prosecution, a prosecuting attorney should be contacted and apprised of the findings. The attorney may then help direct the organization of evidence and the course of any further investigation.

B. Bases for Sanctions

The following acts could be the basis for various types of sanctions.

- Unlawful import, export, or transit;
- Unlawful manufacture, distribution, or possession for the purpose of distribution;
- Unlawful transportation;
- For a licensed person, firm, or institution to engage in activities that exceed those permitted by the applicable license;

- To refuse to make or maintain any information or documents required by law or regulations;
- To furnish false or fraudulent information or omit any information required by law or regulations;
- To refuse lawful entry for inspection of premises as permitted by law or regulation; or
- To distribute, seek to acquire, or to acquire a listed chemical by misrepresentation, fraud, forgery, deception, or theft.

Particularly when considering criminal actions, the Investigator and prosecutor should determine whether licensees or non-licensees have engaged in the following activities, which support substantive criminal acts:

-- organization, management, direction, and financing;
-- indictment, inducement, or advice;
-- conspiracy, collusion, participation, or aiding and abetting;
-- harboring, association, and accessory after the fact;
-- attempt; and
-- facilitation of illegal activities in which listed chemicals are involved.

C. Choice of Sanctions

Competent authorities (and the attorneys representing them) should consider the range of available administrative, civil, and corrective actions and sanctions. Generally, lesser corrective actions and sanctions should be applied in the following circumstances:

- Relatively minor and technical violations;
- First-time violations; and
- Violations that have not resulted, or are less likely to result, in diversion of chemical products.

Stricter sanctions should be applied in the following circumstances:

- Relatively significant violations;
- Repeated violations, especially if the licensee has been previously notified or warned;
- Violations that have resulted in, or significantly increase the possibility of, diversion;
- Violations that result in death or serious injury; and
- Violations engaged in knowingly, intentionally, or willfully.

The choice of sanctions requires the exercise of judgment on a case-by-case basis. A firm, as opposed to an individual, may be a more appropriate defendant for civil penalties than administrative sanctions because (a) it is able to hire different people or change its systems to correct past violations, (b) its continued licensure serves the community, and (c) a business typically has a greater ability to pay a substantial penalty. An individual may be a more appropriate criminal target. However, where

high-level company officials or numerous mid-level officials have been involved in wrongdoing, the firm may well be "rotten to the core." In these cases, the full panoply of sanctions should be utilized: criminal prosecution of wrongdoers and even the company itself, revocation of the firm's license, civil money penalties if available and feasible, and seizure and forfeiture of ill-gotten assets.

D. Tailoring the Investigation to the Intended Sanction

For a criminal prosecution, the Investigator needs to develop sufficient evidence to show that the subject facilitated illegal activities with regulated chemical activities. The investigation should show that these activities were undertaken with the knowledge of the illicit destination or use of the chemicals and/or intent that the chemicals would be diverted to clandestine drug manufacture. In some cases, it will be necessary to prove knowledge or intent by indirect or circumstantial evidence. Thus, the art of investigating these cases is in assembling their evidence of knowledge or intent. Indicators may include:

-- Efforts at concealment of sales (e.g., by cash, outside of regular business hours, or in separate locations on or off business premises);

-- Sale of extraordinary quantities of chemicals;

-- Unusual methods of payments or delivery;

-- Sales to customers who seem to have no legitimate business need for their sales to persons or firms known to have engaged in diversion in the past; or

-- Any other circumstance that would lead a reasonable, legitimate person in the business to know that the sale is suspicious.

Civil fines or monetary penalties are an effective tool in sanctioning licensees who show an egregious pattern and/or history of failure to comply with controlled substances laws and regulations. Civil penalties should be used where it appears that the violator lacked criminal intent to violate the law, was simply negligent or sloppy, or was unfamiliar with the country's laws and regulations.

Administrative sanctions are penalties against the license or registration. They can range from a private (non-public) reprimand to revocation of the license; intermediate sanctions could range from a public reprimand to supervision of practice by a monitoring body to temporary suspension of the license, subject to conditions on reinstatement. Administrative sanctions should be used when and to the extent necessary to protect the public. When it is clear that continued licensure of a firm threatens the public health and welfare, administrative sanctions are appropriate. When continued licensure poses an immediate threat to public health and welfare, an immediate, emergency revocation – if provided for by law – is the best course. Emergency suspension should be used sparingly, as it could deprive a licensee of a business or livelihood even before affording the opportunity for due process.

F. Examples of Administrative Actions

The following paragraphs supply examples of administrative sanctions and processes (subject to legal / regulatory authority).

1. Letter of Admonition

A letter of admonition advises the licensee of any violations which are alleged to have occurred and documents these violations in written form, with specific citations to the laws and regulations. The letter should require a response by the licensee within a specified time period (for example, 30 days), which should describe the corrective actions taken.

2. Administrative Hearing

An administrative hearing provides the opportunity for both the competent regulatory authority and the licensee to explain their respective views on the apparent violations and to discuss the necessary remedial or corrective actions. At the conclusion of the hearing, an agreement will usually be prepared either confirming that the violations did, in fact, occur or finding that they did not. Proposed corrective action should be discussed. Some record should be made of the hearing, whether by recording, transcription or careful note-taking.

Hearings of this type may serve two distinct purposes. An administrative hearing may be part of the due process afforded under the administrative sanction process. In other situations, the hearing is itself the administrative action. In either case, the notice asking the licensee to attend a hearing should clearly state its purpose.

3. Administrative Charges

The administrative charge should include a summary of the violations alleged together with the supporting evidence. This initial charging document should trigger whatever due process and hearing rights are available under the national law. The person or firm charged should have the opportunity to show why it should retain its license to handle chemical substances. The competent authority should make and retain a formal or informal record of proceedings.

If the charges seek an immediate suspension because the activity or violative conduct is continuing, making the suspension necessary to prevent imminent danger to the public health and safety, the charges should so state. In addition, reflective of the urgency of the matter, the charges should be filed as soon as possible after the competent authority learns of the violative conduct. Whatever procedural process is otherwise available to licensees should be provided – or at least offered -- on an expedited basis in such cases, and the competent authority and its attorneys should be prepared to go forward to prove the case. A license to handle chemical substances is a privilege rather than a right, but an immediate suspension reverses the normal expectation that a license, once issued, will remain in full force and effect.

4. Voluntary Surrender

A license may be voluntarily surrendered by the licensee at any time. A voluntary surrender should be accompanied by the original license, unused government forms, and chemical substances in the licensee's control. The licensee should also complete a form indicating whether the surrender is due to failure to comply with the state's laws and regulations or due to a voluntary desire to discontinue business. The form should be signed by the licensee and witnessed by an Investigator.

Where the license surrender is due to failure to comply with the state's laws and regulations, the competent authority should make a record of this fact. The licensee's file should reflect the circumstances of the surrender, and the state's database should include that information for reference in case the surrendering licensee later seeks registration.

# ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

**FINAL DISPOSAL OF CHEMICAL SUBSTANCES**

## FINAL DISPOSAL OF CHEMICAL SUBSTANCES

When the group of national representatives met to discuss final disposal, it became clear that there was a need for training in preliminary identification, proper handling, and final disposal of controlled chemical substances.

### Description

Background and Justification:

The challenge of integral prevention is to identify and reduce risk factors in the areas of both supply and demand. In order for the project for continuing training in the handling of chemical substances to meet its objectives, the weaknesses of each country must be identified and control agencies must promote better practices in the handling, treatment, and final disposal of controlled chemical substances, minimizing the risks involved. A global view of the problem is needed—one that includes cultural, social, economic, environmental, and political factors—in order to determine actual needs and undertake actions to meet them.

This requires the technical training and upgrading of all professionals who deal with controlled substance management, to bring about continuing education in this area, with the ethical and legal issues defined, and with technical supervision and evaluation mechanisms that can be applied in the various areas at the national level.

### General objective:

To design a process of continuing training for control officials on different topics related to preliminary identification, proper handling, and final disposal of controlled chemical substances.

### Strategy

Training, with emphasis on the practical, for personnel specializing in chemical substance control. This personnel will be responsible for the continuing training process in each country.

Specialized personnel to be trained should meet the following basic requirements:

- Practical experience in chemical substance control
- Expectation of remaining at least three years in his/her position, so as to ensure the continuity of training in each country

- Teaching skills

The second phase of training will be conducted within each country by the personnel trained in the first phase. This training should be imparted to operational staff with chemical substance control functions, such as customs officers, police, inspectors, etc.

Training will focus on the following topics:

- Preliminary identification of chemical substances
- Dismantling of production infrastructure (clandestine laboratories)
- Transport
- Storage
- Final disposal

**Expected results:**

- Establishment of a continuing training process in each country.

- Implementation of a uniform methodology leading to improved practices in the preliminary identification of chemical substances.

- Specialized teams that will ensure the correct dismantling of clandestine laboratories.

- Establishment of proper procedures for the transport of confiscated chemical substances.

- Establishment of proper procedures for the storage of confiscated chemical substances.

- Implementation of proper means of final disposal.

**Activity timeline:**

From the first half of 2006 until 2011.

# ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

**PRE-EXPORT NOTIFICATION BULLETIN**

# PRE-EXPORT NOTIFICATION BULLETIN

**The use of pre-export notifications for transactions involving trade in chemical substances is an effective way to minimize the diversion of these substances. The effective implementation of this process requires the cooperation of both exporting and importing countries.**

**CICAD member states are encouraged to:**

1. **improve their pre-export notification (PEN) procedures.**

2. **adhere to the format established by the INCB and provide as much information as possible to help identify the transaction.**

3. **keep up-to-date the CICAD and INCB information on competent authorities authorized to receive and/or reply to pre-export notifications and to transmit this information to their technical operations areas (focal points)**

4. **respond as quickly as possible to pre-export notifications.**

**The basic elements of the pre-export notification mechanism should include:**

**- application to competent authority for an export authorization by the exporting company**
**- evaluation of application by the competent authority.**
**- transmittal of pre-export notification to competent authority in importing country (with sufficient time for review and reply prior to shipping)**
**- acknowledgement or notice of receipt of pre-export notification.**
**- evaluation of pre-export notification by competent authority of country of destination.**
**- reply to pre-export notification.**
  **a. If response is affirmative, export process continues.**
  **b. If response is negative, product's country of origin is advised and given the appropriate explanation.**
**- countries of origin may consider the lack of a response within a predetermined length of time defined by the destination country as a positive response to the PEN.**

# ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

**Matrix for Evaluation of Chemical Control Legislation, Systems and Procedures**

| Matrix for Evaluation of Chemical Control Legislation, Systems and Procedures | | | |
|---|---|---|---|
| **Elements** | **Current Situation** | **Problems** | **Proposed Approach** |
| | | | |
| **General** | | | |
| Designation of Competent Authority | | | |
| Responsibilities of Competent Authority | | | |
| Other agencies involved | | | |
| *Law Enforcement (Which? Must be identified.)* | | | |
| *Chemist.* | | | |
| *Prosecutor.* | | | |
| *Regulatory (Which? Must be identified.)* | | | |
| *Fire Department (Hazardous Materials - handling and disposal)* | | | |
| *Legislature* | | | |
| | | | |
| **Licensing** | | | |
| Responsibility for licencing process | | | |
| Elements of the licensing process | | | |
| Application process | | | |
| Minimum requirements, qualifications or conditions for licensing | | | |
| Criteria for assessment of applications | | | |
| Duration of license (one year, multiple years, indefinite etc) | | | |
| Conditions for license withdrawl, revocation, suspension or limitations | | | |
| Regulatory/administrative violations | | | |
| *Regulatory Inspections (Scope, frequency, etc.)* | | | |
| Nature of sanctions (administrative, criminal or other) | | | |
| Responsibility for assessing sanctions | | | |
| Process for investigating violations and assessing sanctions | | | |
| Appeal process *(Administrative and/or judicial?)* | | | |

| Matrix for Evaluation of Chemical Control Legislation, Systems and Procedures | | | |
|---|---|---|---|
| **Elements** | **Current Situation** | **Problems** | **Proposed Approach** |
| | | | |
| National registry of licensed companies | | | |
| Responsibility for registry | | | |
| Nature of information maintained in registry | | | |
| Requirements, responsibilities and process to update the information | | | |
| Access to registry and for what purpose | | | |
| | | | |
| **Permits** | | | |
| *How to obtain?* | | | |
| *How Long are they good for?* | | | |
| *Necessary requirements for permits.* | | | |
| *Who issues them?* | | | |
| | | | |
| **Licenced companies** | | | |
| *How to become a licensed company.* | | | |
| *Requirements.* | | | |
| *How can licenses be lost/revoked?* | | | |
| | | | |
| **Records and reports** | | | |
| *Who keeps them?* | | | |
| *How long are they kept?* | | | |
| *What information must appear?* | | | |
| | | | |
| **Inspections and Investigations** | | | |
| *When and how are investigations conducted?* | | | |
| *Who conducts the investigations?* | | | |
| | | | |
| **Security** | | | |
| *Physical Security Requirements?* | | | |
| *Alarm Systems Requirements?* | | | |
| *Personnel Security Requirements?* | | | |

| Matrix for Evaluation of Chemical Control Legislation, Systems and Procedures | | | |
|---|---|---|---|
| **Elements** | **Current Situation** | **Problems** | **Proposed Approach** |
| | | | |
| **Transportation** | | | |
| *Do shipments meet requirements of dangerous goods regulations?* | | | |
| *Who authorizes shipment?* | | | |
| | | | |
| **Infractions** | | | |
| *What constitutes an infraction?* | | | |
| *How are infractions categorized and/or penalized?* | | | |
| | | | |
| **Sanctions** | | | |
| *What are the sanctions?* | | | |
| | | | |
| **Mechanisms for information exchange and cooperation** | | | |
| How often? | | | |
| *Formal?* | | | |
| *Informal?* | | | |
| | | | |
| ***Training*** | | | |
| *How and by whom are investigators trained?* | | | |
| *Are there provisions to inform/train the Chemical Industry and by whom?* | | | |
| *What are the provisions for Conferences & Seminars?* | | | |
| | | | |