



# ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

cicad

## **Concept Paper Regarding the Regulation of Equipment Used in the Illicit Manufacture of Synthetic Drugs**

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## **1.0 Introduction**

Article 13 of the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*, 1988 states "The Parties shall take such measures as they deem appropriate to prevent trade in and the diversion of materials and equipment for illicit manufacture of narcotic drugs and psychotropic substances and shall co-operate to this end".

Several different types of equipment are commonly used in the manufacture of illicit synthetic drugs, as indicated by the materials that are seized by law enforcement agencies (LEA) in the process of dismantling clandestine drug laboratories. Examples of such equipment include mixers, pill/tablet presses and encapsulators among others.

While a limited number of countries, e.g. the United States, Australia, etc. have implemented a regulatory scheme for equipment, the vast majority of signatories of the 1988 Convention have not implemented any such form of controls.

It is in this regard that discussions on preliminary concepts relevant to a regulatory scheme for equipment used in the manufacture of illicit synthetic drugs took place at the August 2009 meeting of the Expert Group on Chemical Substances of the Inter-American Commission for Drug Abuse Control (CICAD). This paper is the product of those discussions as well as further discussions at the August 2010 meeting of the Expert Group on Pharmaceutical Products and Chemical Substances.

## **2.0 Purpose**

The purpose of this document is to outline the overarching principles and key elements for the regulation of the aforementioned equipment, with a view to guiding Member States interested in establishing such controls.

## **3.0 Overarching Principles**

A regulatory scheme governing activities with equipment used in the illicit manufacture of synthetic drugs should:

- serve to reduce any unnecessary domestic and/or international movement of regulated equipment;
- be supported by appropriate national resources, e.g., for administration, compliance monitoring and enforcement;

- be supported by appropriate civil, administrative and/or other punishable offences and means with which contraventions of the regulations are dealt;
- enable sharing of appropriate information amongst the different domestic agencies involved in control;
- enable and encourage cooperation and collaboration between the private sector and between Member States; and
- not hinder domestic manufacture and/or distribution for legitimate purposes by imposing a burden on the legitimate industry requiring the use of regulated equipment.

The process of developing a regulatory scheme for equipment used in the illicit manufacture of synthetic drugs should be transparent and involve sufficient consultation with national authorities and the private sector. National authorities should clearly delineate the means by which they will work horizontally within their jurisdictions.

#### **4.0 Key Elements of Equipment Regulation**

A regulatory scheme should establish baseline controls in order to curb the illicit movement of implicated equipment. As such, the scheme should include the key elements outlined below:

- the scope of regulated equipment;
- which activities will be restricted under the scheme;
- which parties will be regulated;
- definitions for terms used within the regulatory scheme;
- an effective compliance monitoring and enforcement scheme; and
- appropriate record-keeping and reporting requirements.

##### *4.1 Scope of Regulated Equipment*

Initially, the scheme should cover a limited range of equipment, e.g., tableting machines, encapsulating machines, pharmaceutical mixers, etc., as defined in a Schedule to the regulations.

##### *4.2 Restricted Activities*

Controlled activities should include possession, sale, import, export, transport, manufacture, distribution and/or other types of transactions involving regulated equipment.

##### *4.3 Parties Subject to the Regulation*

Regulated parties should include individuals, non-profit entities, and both domestic and international businesses/corporations that conduct restricted activities.

#### *4.4 Definitions*

The scheme should clearly define all terms utilized within them that are important for its consistent and correct administration. This may include the types of regulated equipment and activities, parties referenced in the regulations such as international bodies, controls applied such as requirements for licenses and permits, etc.

#### *4.5 Licensing and Permit Scheme*

The scheme should involve a licensing scheme in which regulated parties must obtain pre-authorization from the appropriate competent authority in order to carry out restricted activities involving regulated equipment.

A license should be valid for a specific period of time. In addition, pre-authorization in the form of a permit should be required for individual transactions related to import, export, transit and/or transshipment. The requirement to surrender permits to border authorities at the time of import/export should also be explored.

Finally, the scheme should also require permit holders to notify competent authorities of plans for export, transit, or transshipment, and if possible, the use of a common system, e.g., the INCB PEN-Online system, should be explored.

#### *4.6 Security*

Authorized parties should be required to ensure that reasonable security measures aimed at preventing the diversion of regulated equipment are used at each site where restricted activities take place, and during transport/delivery.

#### *4.7 Destruction of and/or Removal of Regulated Equipment from a Licensed Site*

The scheme should require the appropriate disposition of all unusable/seized/abandoned equipment (which may include the return of goods to the country of origin where appropriate) and identification of this to competent authorities within a specific time period.

#### *4.8 Compliance Monitoring and Enforcement*

The scheme should clearly set out who is responsible for administrative enforcement, where this includes compliance promotion and monitoring, and the authority to amend, refuse, suspend and/or revoke licenses and/or permits as required.

The scheme should also include provisions for the investigation and/or inspection of regulated parties by appropriate competent authorities, and the authority to securely share information (preferably electronically) among law enforcement agencies and between law enforcement and the appropriate competent authority in order to facilitate the investigation/inspection of multinational regulated parties and track trends in the movement of equipment.

Finally, the scheme should set out the penalties (administrative or criminal) applicable in the instance of non-compliance.

#### *4.9 Record-Keeping and Reporting*

Regulated parties should be required to keep accurate and reliable records, e.g., in relation to licensed sites and activities, security measures taken by the licensee, suspicious transactions, theft, etc., for an agreed-upon period of time. The scheme should enable the request and provision of such records to competent authorities.