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Drug Precursors Committee

**Subject: Communication from Member States pursuant to Article 13.1 of
Regulation 273/2004**

Delegations will find attached a discussion paper on the monitoring and evaluation of the
EU legislation on drug precursors

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DISCUSSION PAPER – MONITORING AND EVALUATION OF THE IMPLEMENTATION OF THE DRUG PRECURSORS LEGISLATION

The new EU legislation on drug precursors entered into force more than one year ago. Since the entry into force, the Drug Precursors Committee has been working considerably, notably by determining common approaches on a number of questions of interpretation, revising the guidelines to operators, and being actively involved in a number of international projects and negotiations. **The Drug Precursors Committee should now fully focus on the implementation of the new legislation.** In that perspective, it is necessary to set up the necessary tools to monitor the implementation of the legislation, and at a later stage, evaluate its efficiency and benefits. The Commission has also the duty to ensure that the legislation is evenly implemented throughout the EU, in order to avoid any distortion of competition on the internal market. This monitoring can only be based on **the collection of simple and comparable information** from the competent authorities of Member States, which have the responsibility to implement the legislation. It is necessary to open this debate now since a review of the legislation is required by **August 2008**, and should be based on this collection exercise.

Furthermore, it is necessary to reflect on the **use** that should be made of the collected information. Information sharing, on the one hand between authorities, and on the other hand with operators, is undoubtedly a powerful tool to identify and reduce existing and new risks. It is worth noting that the recommendations made in the “Gilmore” study of 2003 with regard to the “general” and “specific” feedback to be provided by authorities to operators are not yet fully implemented.

In the following paper, the involved Commission services proposed a number of indicators and types of information which they consider would be necessary to collect in order to achieve these objectives, and for each of them, addressed the following issues:

- For what purpose should this information be collected?
- Which use should be made of it?
- Should this information be shared with all Member States? With operators?

These proposals are only **a first step in the reflection** and will in any case require refinement and further reflections. Competent authorities are welcome to provide with all suggestions and comments in that respect.

1. LEGISLATIVE FRAMEWORK

A) *Intra Community trade*

Article 13 of Regulation 273/2004 foresees the following:

*“1.To permit any necessary adjustments to the arrangements for monitoring trade in scheduled substances and non-scheduled substances, the competent authorities in each Member State shall each year communicate to the Commission **all information on the implementation of the monitoring measures** laid down in this Regulation, in particular as regards substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances and methods of diversion and illicit manufacture.”*

Currently, Member States report through “Form D”, a reporting form designed by the INCB, which requires the following information:

- Quantities of scheduled substances seized, by country of origin.
- Quantities of seized substances not included in table I or II of the UN Convention, by country of origin and country of destination.
- Methods of diversion and illicit manufacture.
- Stopped shipments
- Information on licit trade (quantities of scheduled substances imported or exported, by country of origin / destination);
- Information on domestic licit uses and needed quantities of scheduled substances.

Member States send the filled in “Form D” to the Commission, which forwards them to the INCB. The INCB publishes an annual report which contains country by country data on seized quantities. The information provided by Member States through “Form D” contribute to the identification of risks of diversion, in terms of substances actually diverted or misused, and countries of destination or origin. Eventually, these data can be used to identify the main trade flows in scheduled substances, and to cross-check export and import data provided by parties.

However, this information:

- is insufficient to measure and to evaluate the effectiveness and efficiency of the mechanisms and procedures contained in the EU drug precursors legislation, because the reported indicators are not focused on the implementation of the legislation, but mainly on trade flows and seizures;
- does not always cover intra country or even intra Community transactions and activities. The EU as a whole has committed itself to provide annual information

to the INCB via the "Form D". Consequently, such information should principally not cover intra Community information.

Therefore, it is necessary to complement it by indicators specifically related to the implementation of Regulation 273/2004 and its effects.

Furthermore, Regulation 273/2004 contains a review clause in Article 16:

“The Commission (...) shall evaluate the implementation of the Regulation three years after its entry into force.”

This evaluation, which should be carried out by 18 August 2008, should be based on sound data and information relating to a period of time that should be as long as possible. It seems clear that the information provided pursuant to Article 13 (1) should serve the purpose of the evaluation foreseen by Article 16.

In the light of the recent and ongoing enlargement exercises, the intra-Community trade is becoming increasingly more important. The Community market is growing and this also means that a number of transactions previously controlled through the mechanisms governing external trade (through PENs for example) have now moved into the scope of Intra-Community trade control. The review of the instruments of Regulation 273/2004 should take account of these developments.

B) Trade between the EU and third countries

Article 32 of Regulation 111/2005 contains a similar provision as Article 13 of Regulation 273/2004:

“The competent authorities in each Member State shall at least once each year, communicate to the Commission all relevant information on the implementation of the monitoring measures laid down in this Regulation, and on scheduled substances used for the illicit manufacture of narcotic drugs and psychotropic substances and methods of diversion and illicit manufacture, and their licit trade, uses and needs.

On the basis of that information, the Commission shall, in consultation with the Member States, evaluate the effectiveness of this Regulation, and in accordance with Article 12 (12) of the United Nations Convention, draw up an annual report to be submitted to the International Narcotics Board”

Furthermore, Regulation 111/2005 contains a review clause in the same Article:

“The Commission shall report to the Council on the functioning of this Regulation by the end of August 2008.” The legislator had chosen this formula in order to common approach of evaluation on both intra-Community and external trade Regulations.

2. INFORMATION THAT NEEDS TO BE COLLECTED FOR THE INTRA COMMUNITY TRADE

A) Notified suspicious transactions and orders (Art. 8 (1) of Regulation 273/2004)

The requirement of operators to report suspicious transactions is one of the key provisions of the Regulation, which is likely to produce measurable results in terms of identification of criminal activities and prevention of diversion.

Proposed information to be reported by the competent authorities of Member States (on an annual basis):

(Only orders or transactions placed or carried out on the internal market are concerned)

- (1) For each substance (either scheduled substance, EU voluntary monitoring list substance or other), indicate the number of suspicious transactions notified by operators to the authorities
- (2) Investigations undertaken by the authorities. For each substance (either scheduled substance, EU voluntary monitoring list substance or other), indicate the number of suspicious transactions having led
 - (a) to a controlled delivery under the supervision of the authorities
 - (b) other types of investigations (backtracking...)
- (3) Information provided by the notifier: indicate the number of notifications for which the authorities consider the information provided incomplete or insufficient.
- (4) Recommendations and information provided to the notifier. For each substance (either scheduled substance, EU voluntary monitoring list substance or other), indicate the number of suspicious transactions having led:
 - (a) the notifier to refuse to satisfy the request, following recommendations by the authorities
 - (b) the notifier to deliver the requested substance, following recommendations by the authorities
- (5) Outcome. For each substance (either scheduled substance, EU voluntary monitoring list substance or other), indicate the number of suspicious transactions having led:
 - (a) to the likely identification of criminal activities, either on the territory of the Member State or in another country (cases where an illicit laboratory was discovered, where the substance was proved to have been intended for diversion, where criminal investigation was triggered...)
 - (b) to the conclusion that the request subject to the notification transaction was most probably not intended for diversion and that further investigations concerning the customer are not to be undertaken.
 - (c) the authorities to provide the notifier with information with regard to the follow up of the notification
- (6) Operators having notified at least one suspicious transaction:

- (a) Indicate the number of operators having notified a suspicious transaction involving a substance that belongs to the 5 following “categories”: category 1, category 2, category 3, EU voluntary monitoring list, other substances.
 - (b) Indicate the number of operators belonging to each of the following sectors that have notified at least one suspicious transaction: chemicals production, chemicals distribution, pharmaceuticals production, pharmaceuticals distribution, cosmetics production, cosmetics distribution, laboratories, universities, other non economic operators. (to be refined).
- (7) number of operators subject to enforcement action taken by the competent authorities for infringement of Article 8 (1)

Accompany this information with all relevant comments and suggestions.

Objective: Evaluate the extent to which operators notify suspicious transactions to the authorities, the relevance of these notifications and their benefits.

Use of these indicators: these indicators could be aggregated and presented in the review of the Drug precursor legislation.

B) Customer Declaration (Art. 4 of Regulation 273/2004)

The customer declaration is a tool provided by the legislation to operators to check the identity of the company or person placing an order and identify suspicious transactions. A customer declaration must be obtained and thoroughly gone through before satisfying a request for a scheduled substance of category 1 or 2. In case of any doubt, the request should be notified to the authorities.

Proposed information to be reported by the competent authorities of Member States (on an annual basis):

- (8) Number of suspicious transactions notified on the basis of the customer declaration received by the operator (or the refusal of the customer to provide a complete customer declaration):
 - (a) For substances of category 1
 - (b) For substances of category 2
- (9) Number of requests for written information or inspections (pursuant to Art. 10 (1) (a) and (b)) having led to the identification of the requests that were satisfied although the customer declaration was incomplete or missing:
 - (a) For substances of category 1
 - (b) For substances of category 2

Accompany this information with all relevant comments and suggestions.

Objective: Evaluate the extent to which operators apply the provisions of the Regulation pertaining to customer declarations, and use these to identify suspicious transactions.

Use of these indicators: Include in the review report referred to in section A). Inform operators about their obligations and the use which they can make of the customer declaration. Refine if necessary the requirements and conditions for the customer declaration as well as the detailed rules concerning their use.

C) Operators: state of play

In order to evaluate the volume of administrative work generated by the legislation, it seems necessary to have precise figures about the number of operators for each category of substance.

Proposed information to be reported by the competent authorities of Member States (on an annual basis):

- (10) Number of operators licensed for placing substances of category 1 on the internal market (Article 3 (2) of Regulation 273/2004).
- (11) Number of natural or legal persons licensed for being supplied with substances of category 1 (Art. 3 (3) of Reg. 273/2004).
- (12) Number of operators having registered premises for the purpose of placing on the market substances of category 2 (Art. 3 (6) and 3 (1) of Reg. 273/2004).
- (13) Number of operators engaged in the placing on the market of substances of category 3 that are known to the authorities (e.g. those that have notified the competent authorities with the name and contact details of a “contact person” (cf. “guidelines for operators”)).
- (14) Number of operators engaged in the placing on the market of non-scheduled substances that are known to the authorities (e.g. those that have notified the competent authorities with the name and contact details of a “contact person” (cf. “guidelines for operators”).

Accompany this information with all relevant comments and suggestions.

Objective: Evaluate the number of companies subject to the control measures laid down in the Regulation and the number of companies in contact with the authorities.

Use of these indicators: Include in the review report referred to in section A). Identify the need to strengthen the links between authorities and operators engaged in the placing on the market of substances of category 2 and 3 and non scheduled substances.

D) Administrative activity

In order to evaluate the volume of administrative work generated by the legislation, it is necessary to have precise figures about the number of licences and registrations.

Proposed indicators to be reported by the competent authorities of Member States (on an annual basis):

- (15) applications for licences pursuant to Article 3 (2) of Reg. 273/2004 (excluding special licences):
 - (a) number of such licences granted by the authorities (for the first time or renewed)
 - (b) number of such licences refused by the authorities (Art. 3 (4) of Reg. 273/2004)
 - (c) number of such licences that have been suspended on the basis of Art. 3 (4) of Reg. 273/2004
 - (d) number of such licences that have been revoked on the basis of Art. 3 (4) of Reg. 273/2004
- (16) applications for licences pursuant to Article 3 (3) of Reg. 273/2004 (excluding special licenses): same indications as for item (15)
- (17) number of registrations received from operators engaged in the placing on the market of substances of category 2 (excluding special registrations) pursuant to Article 3 (6) of Reg. 273/2004

Accompany this information with all relevant comments and suggestions.

Objective: Evaluate the volume of administrative activity of competent authorities. Evaluate the extent to which companies willing to place substances of category 1 on the market are found not to comply with the requirements of competence and integrity through ex-ante and ex-post controls (application for a license; revocation or suspension of licences that have already been granted).

Use of these indicators: Include in the review report referred to in section A). Refine the requirements and conditions for the granting of licences if necessary. Evaluate the efficiency of registration and licence requirements.

E) Monitoring and control

The Regulation requires Member States to enable their competent authorities to carry out monitoring and control activities, both in the business premises of the operators and by the way of requests for information. Combined with Article 5 of Regulation 273/2004, which provides for the appropriate documentation of all transactions, and the keeping of records for 3 years, this provision enables the authorities to trace substances of category 1 or 2 traded in the preceding three years through the documentation which they have access to.

Proposed information to be reported the competent authorities of Member States (on an annual basis):

(18) Regular checks. Through licensing and registration procedures, the authorities have the full list of operators engaged in the placing on the market of substances of category 1 and 2. They are therefore in a position to set up annual or multi-annual programmes of checks of operators, or carry out “random checks”

(a) Indicate the number of on-site inspections carried out in the framework of annual or multi-annual programmes, or as “random checks”. Indicate which share of these inspections concerned licensed operators (category 1), registered operators (category 2) and other operators.

(b) Indicate the number of requests for written information carried out in the framework of annual or multi-annual programmes, or as “random checks”. Indicate which share of these inspections concerned licensed operators (category 1), registered operators (category 2) and other operators.

(19) Requests for information (Art. 10 (1) (a) of Reg. 273/2004):

(a) number of such requests

(b) number of such requests having led to enforcement action (detainment of consignments, revocation/ suspension of a licence or others). Indicate the main reasons why enforcement action was undertaken (licence or registration missing, supporting documents incomplete or missing...)

(c) number of such requests having led to written comments addressed to the operators. Indicate the main comments addressed to operators (supporting documents incomplete or missing, identifications transactions or orders that should have been notified due to their suspicious character...)

(20) On-site inspections (Art. 10 (1) (b) of Reg. 273/2004):

(a) number of such inspections

(b) number of such inspections triggered by the reception of information received from the police, another company, the authorities of another Member State or third country, or any other source

(c) number of such inspections having led to enforcement action (detainment of consignments, revocation/ suspension of a licence or others). Indicate the main reasons why enforcement action was undertaken (licence or registration missing, supporting documents incomplete or missing, security of premises...)

(d) number of such inspections having led to written comments addressed to the operators. Indicate the main comments addressed to operators (supporting documents incomplete or missing, identifications

transactions or orders that should have been notified due to their suspicious character, security of premises...)

Objective: Evaluate the volume of monitoring and control activity and their outcome. Evaluate the compliance of the operators with the administrative requirements (license, registration, customer declaration, records keeping, security of the premises). Evaluate the need to take action to better inform operators about the legislative requirements under Reg. 273/2004.

Use of these indicators: Include in the review report referred to in section A. Evaluate the need to strengthen the control and monitoring activities carried out by the authorities or focus them on certain categories of substances and operators.

F) Cooperation between authorities and operators

The cooperation between authorities and operators is largely viewed as the cornerstone of drug precursors' control in the EU. In particular, the provision of information and the close contacts with the operators maintained by the authorities is of crucial importance to raise their awareness on the risks of diversion.

Proposed indicators to be reported annually by the competent authorities of Member States (on an annual basis):

- (21) number of memorandum of understanding or similar arrangements in place in your Member State (indicator of the EU Drugs Action Plan 2005-2008)
- (22) number of seminars, conferences and workshops organized in your Member State to inform / raise awareness of operators - or certain categories of operators. (indicator of the EU Drugs Action Plan 2005-2008). In particular, indicate the number of seminars aiming at making the revised EU guidelines known to the operators
- (23) number of periodic information reports, newsletters and circulars circulated to operators with regard to current techniques, methods and trends in the field of diversion and illicit manufacture, substances frequently used for the illicit manufacture of narcotic drugs and psychotropic substances...
- (24) number of alerts and bulletins warning one or several operators on a specific risk

Objective: Identify the main activities in the field of cooperation between authorities and operators.

Use of these indicators: Include in the review report referred to in section A.

F) Volume of intra Community trade

(Information on intra-Community trade could be gathered as an element to review the legislation).

3. INFORMATION THAT NEEDS TO BE COLLECTED FOR THE TRADE WITH THIRD COUNTRIES

Several of the elements specified under Section 2 will also be relevant external trade (e.g. suspicious transactions, co-operation with industry, licensing, administrative capacity, etc). Further specific elements will be suggested, in particular:

- control of import
- control of exports
- control of transshipment consignments.

Specific methodology and indicators to follow.

4. INFORMATION THAT NEEDS TO BE COLLECTED FOR THE BOTH THE INTRA COMMUNITY TRADE AND THE TRADE WITH THIRD COUNTRIES

G) Illegal drug manufacturing activities involving drug precursors diverted from licit trade

This part lists a number of indicators that attempt to measure the share of diverted drug precursors from the licit trade on the EU internal market/external trade in the overall use of drug precursors in the illicit manufacture of narcotic drugs and psychotropic substances. Relevant information could be retrieved from the Form D if reported. Proposed indicators to be reported by the competent authorities of Member States on an annual basis (

- (25) Illicit laboratories discovered in the EU, where scheduled and/or non scheduled substances were found to be used. For each illicit laboratory:
- (a) lists all the substances involved (category 1, category 2, category 3, non scheduled)
 - (b) indicate for each of the substances involved whether it has been sourced:
 - by purchase from a licit EU operator
 - by purchase from a licit non EU operator
 - by theft from the premises of a licit EU operator, carrier or user
 - by smuggling into the EU
 - by self-production, or production by criminals associated with the runner of the illicit laboratory

- (c) indicate whether the information referred to in the subparagraph (b) is not available
 - (d) describe briefly the methods of illicit manufacture
- (26) illicit laboratories discovered in third countries where scheduled and/or non scheduled substances originating from your Member State where found to have been used (information reported by the competent authorities of third countries)
- (a) lists all the substances involved (category 1, category 2, category 3, non scheduled)
 - (b) indicate whether the substances:
 - was produced in your Member State
 - transited in your Member State but was produced in another Member State
 - transited in your Member State but was produced outside the EU
 - (c) indicate for each of the substances involved whether it has been sourced:
 - by purchase from a licit EU operator of your Member State
 - by theft from the premises of a licit EU operator, carrier or user
 - by smuggling into the third country
 - by illicit production in the EU
 - (d) indicate whether the information referred to in subparagraphs (b) and (c) is not available
 - (e) describe briefly the methods of illicit manufacture

Objective: Evaluate the share of the diversion from licit trade to supply illicit manufacturing activities with scheduled and non-scheduled substances. Reflect on the necessity to strengthen or lower certain controls (customs controls, controls on the internal market...), and on the overall strategy to prevent the supply of illicit manufacturing activities with drug precursors.

Use of these indicators: Aggregate the results and provide overall indicators in the review report referred to in section A.

H) Substances used for the illicit manufacture of narcotic drugs and psychotropic substances, methods of diversion and methods of illicit manufacture

The reporting of this information by the competent authorities of Member States is explicitly required by Article 13 (1) of Reg. 273/2004 and Article 32 of Reg. 111/2005¹.

The information on substances used for illicit manufacturing purposes is partly covered by “Form D” (“substances not included in tables I or II identified as having been used in illicit manufacture” and “methods of diversion and illicit manufacture”). Provided that this information also covers the identification of scheduled substances sourced on the internal market (and not only from non EU countries) found to have been used in illicit laboratories, it can be considered sufficient.

Aggregated information could be extracted from Form D and presented in the annual report referred to in section A) (e.g. for each substance (scheduled, non scheduled, other), number of illicit laboratories where this substance was found to have been used or was intended to be used, and methods used to manufacture the narcotic drugs and psychotropic substance).

The information provided through Form D with regard to methods of diversion and illicit manufacture could be collated and presented as a series of so called “sanitised examples”² (e.g. with no reference to the companies, Member States and third countries involved), in a specific report made available to the authorities. An agreement could also be reached with regard to a more frequent reporting on cases of actual diversion (e.g. on a quarterly basis).

Objective: Share information about new and existing trends with regard to substances frequently used for the illicit manufacture of narcotic drugs and psychotropic substances (scheduled and non-scheduled actually used, as well as new substances), methods of manufacture and diversion, between all competent authorities of Member States, in order to focus their controls on the most important risks.

Use of these indicators: The abovementioned information could be used by competent authorities for presentations, seminars, conferences, or restricted dissemination to operators.

5. WAY FORWARD

The Commission will prepare a **review report of the legislation** which will have to be carried out **by August 2008**. The Commission could be assisted by one or several expert working groups established under the auspices of the Drug Precursors Committee and/or an external consultant. The selection of one of these options will depend on the volume of information to be processed.

In order to organise the work, delegations are invited to consider the following:

¹ Reg. 273/2004 specifically requires a reporting on substances that are frequently used for illicit purpose, whereas Reg. 111/2005 does not refer to any notion of frequency).

² Wording used in the « Gilmore » study.

- To decide about the exact content of the information that will be collected and that can be made available. As the full evaluation period can only be 2006 and 2007, a final decision should be taken by the end of **December 2006**.
- In order to facilitate this decision an expert working group meeting could be established to propose elements and indicators (on the basis of the elements proposed in this document). The group could meet **in November or beginning December 2006**
- It should also be decided whether to involve one or several expert working group (s) in the evaluation of the data that will be collected. (e.g. regulatory data, Form D).
- To collect the relevant data for 2006 and 2007 **by February 2008**. (It further needs to be decided whether this information should be gathered for each year or for both years.)
- If the working group(s) are to be involved, at least 4 expert working group meetings will be necessary (between February and August 2008).
- "Review" report by **August 2008**.