COMMISSION OF THE EUROPEAN COMMUNITIES

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REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

Pursuant to Article 16 of Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 and to Article 32 of Council Regulation (EC) No 111/2005 on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors

(Text with EEA relevance)

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1. INTRODUCTION

Drug precursors are chemicals that are used for the manufacturing of illicit drugs. There is, in fact, no production of illicit drugs without precursors. However, in the majority of cases chemicals used as drug precursor have primarily multiple legitimate and important uses (e.g. in the synthesis of plastics, pharmaceuticals, cosmetics, perfumes, detergents, or aromas).

The United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances (hereafter referred as UN 1988 Convention), contains in its Article 12 specific reference to measures to prevent diversion of drug precursor chemicals for use in the illicit manufacture of narcotic drugs and psychotropic substances.

In this context, the EU has put in place since the early nineties legislation to ensure that diversion of drug precursors is prevented through control and monitoring of their legitimate trade. Historically, the EU was a significant exporter of precursors and an importer of illicit drugs, but progressively the EU has become a major exporter of illicitly manufactured synthetic drugs and an importer of the precursors required to manufacture them.

Consequently, the most recent Community legislation on monitoring and control of trade in drug precursors**,** namely Regulation (EC) No 273/2004[1] and Regulation (EC) No 111/2005[2] were, therefore, designed to strengthen the import controls as well as to extend the previously existing monitoring requirements.

Article 16 of Regulation (EC) No 273/2004 and Article 32 of Regulation (EC) No 111/2005 foresee that three years after their entry into force, an evaluation of their implementation and functioning is performed and reported to the European Parliament and to the Council. In the interest of efficiency, this report presents the conclusion of the evaluation of both Regulations.

2. COMMUNITY LEGISLATION ON THE CONTROL OF TRADE IN DRUG PRECURSORS

The Community system of control of operators and/or transactions relies on the close cooperation between competent authorities and the economic operators concerned (mainly chemical manufacturers and traders). In particular, the notification of suspicious transactions

[1] OJ L47 of 18.02.2004, p.1
[2] OJ L22 of 26.01.2005, p.1

by operators is key in preventing diversion of precursors while allowing gathering intelligence to identify traffickers.

The severity of controls applied to operators and/or transactions depends on the sensitivity of the regulated drug precursors (the so-called scheduled substances), which are classified into three categories entailing different requirements, thus allowing to strike an appropriate balance between all possible means to prevent drug precursors reaching illicit drug laboratories and avoiding the creation of unnecessary burdens for the legitimate needs of all operators.

Building on this cooperation, a voluntary monitoring system is in operation for additional substances - so called non-scheduled substances - frequently found to be diverted for illicit drug manufacture. It provides flexibility to address rapidly changing diversion patterns, while avoiding increasing administrative burdens for legitimate operators.

The current regulatory framework of the Community for drug precursors is made up of Regulation (EC) No 273/2004, which lays down harmonised rules for the intra-Community control and monitoring, and Regulation (EC) No 111/2005, which lays down the rules governing the monitoring of the trade between the Community and third countries in drug precursors.

3. IMPLEMENTATION OF THE COMMUNITY LEGISLATION

3.1. Regulation (EC) No 1277/2005[3]

Regulation (EC) No 1277/2005 sets up detailed implementing rules for Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005. Aiming at ensuring a more uniform implementation of the Community legal framework by competent authorities and economic operators, it lays down provisions on the licensing of operators, the provision of information by operators to competent authorities, the pre-export notification system, the export and import authorisations as well as the control of transit and transshipments.

3.2. Guidance

To complement the legal instruments, the Commission has developed and agreed with Member States and operators comprehensive guidance documents and activities to assist competent authorities and industry operators with their tasks.

- Questions & Answers

  A guidance document was drawn up to provide Member States competent authorities and economic operators with consensual answers to questions of interpretation raised since 2005 for a smooth and harmonised implementation of some provisions of the Community legislation. It is regularly updated and publicly available[4].

- EU Guidelines on drug precursors' control for operators

[3] OJ L202 of 3.08.2005, p.7

[4] http://ec.europa.eu/enterprise/chemicals/legislation/precursors/index_en.htm

In order to facilitate the partnership and co-operation between the competent authorities and operators, the "EU Guidelines on Drug Precursors Control for Operators" have been agreed in 2006. These guidelines provide a set of practical recommendations (e.g. risk indicators for identification of suspicious transactions) and lists of scheduled substances and non-scheduled substances (i.e. the "EU voluntary monitoring list"-) aimed at helping the economic operators to fulfil their obligations in close cooperation with authorities. Given that these Guidelines contain sensitive information, they are disseminated directly by Member States' competent authorities only to trustworthy operators.

- Seminars

The Commission services and the Member States have organised a series of seminars in close cooperation with economic operators aimed at increasing knowledge about the new Community legislation on drug precursors and further promoting the importance of partnership.

- Expert roundtables

The Commission services and Member States have conducted ad-hoc expert roundtable meetings to address specific issues regarding the diversion and trafficking of heroin precursors (acetic anhydride) and of synthetic drug precursors for making amphetamine or ecstasy (BMK, PMK).

3.3. Mutual Administrative Assistance

Council Regulation (EC) No 515/97 provides a legal basis for exchange of information, including rules of confidentiality, between Member States, and between Member States and the Commission.

Through the exchange of information on suspect consignments, prevented diversion and seizures of drug precursors between all Member States and the Commission, a coordinated approach within the EU is ensured, Member States' investigations are supported and traffickers are prevented from "shopping around" for potential weaknesses in the Intra-Community market. In addition, assistance with enquiries into established or suspected irregularities involving drug precursors may be requested/provided to third countries with which the EU has concluded bilateral drug precursor agreements.

3.4. EU Action Plan on Drugs[5]

Measures countering diversion and trafficking of drug precursors continue to be an essential part of the new EU Action Plan on Drugs 2009-2012[6], established under the overall EU Drugs strategy set up for the period 2005-2012. Action 42 of the EU Drugs Action Plan for 2009 - 2012 calls for the evaluation of EU drug precursor legislation and its implementation.

3.5. Actions under the Customs 2013 Programme

Customs 2013 is an EU cooperation programme providing national administrations with the possibility to create and exchange information and expertise. It allows developing and

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5 COM (2008) 567/4

6 OJ C 326, 20.12.2008, p. 7–25

operating major trans-European IT systems in partnership and establishing human networks by bringing together national officials from across Europe.[7] Several activities have been conducted to enhance the implementation of the Community legislation on drug precursors.

An **eLearning Course on Drug Precursor Control for Economic Operators,** developed on the basis of the "EU Guidelines on Drug Precursors control for operators", has been released in June 2009.

An **eLearning Course for Customs** is being prepared in close cooperation between the Commission services and Member States experts from Customs, Police and other competent authorities for the Drug Precursor legislation.

A **Project Group of operational customs controls experts** was set up to enhance operational performance in detecting suspicious drug precursor consignments entering and/or leaving the Community Customs territory. Several operational workshops were organised to exchange best practices.

A **mind-mining exercise** was organised with operational customs officers to establish risk analysis criteria for drug precursors entering and/or leaving the Community.

3.6. Bilateral agreements

The Community has concluded ten bilateral agreements with third countries in order to strengthen control with major players by addressing specific issues of mutual interest in the area of drug precursor control. Such agreements have been concluded with Bolivia, Colombia, Ecuador, Peru and Venezuela[8], Chile[9], Mexico[10], United States[11], Turkey[12] and China[13]. Moreover, in March 2009, the Council has authorised the Commission to negotiate a bilateral agreement with the Russian Federation.

These agreements aim at strengthening regulatory co-operation with third countries on the basis of the instruments set out in Regulation (EC) No 111/2005, activating the mechanisms of mutual assistance and creating 'Joint Follow-Up Groups' of contracting parties.

3.7. Actions at United Nations level

The Commission and the Member States have been closely involved in the review of the achievements of the targets set by the Special Session of the United Nations General Assembly of 1998 (UNGASS) and regularly and actively participate in the yearly session of the Commission on Narcotic Drugs (CND), the central United Nations' drugs policy making body.

At the 50th session of the United Nations Commission on Narcotic Drugs (CND), a Community proposal was adopted as Resolution 50/10 on *"Prevention of diversion of drug precursors and other substances used for the illicit manufacture of narcotic drugs and*

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7 OJ L 154/25-31
8 OJ L 324, 30.12.95, p. l
9 OJ L 336, 11.12.1998, p. 46
10 OJ L 77, 19.03.1997, p.22
11 OJ L 164, 21.06.1997, p. 22
12 OJ L 64, 07.03.2003, p. 28
13 OJ L 56 of 28.2.2009, p. 6.

psychotropic substances"[14]. This Resolution promotes the main principles of drug precursor control in the Community.

In addition, the Commission services and Member States actively participate and support specific UN led operational initiatives to address particular challenges regarding the diversion and trafficking of drug precursors. In particular, the EU participates in project "PRISM" to address diversion of synthetic drug precursors and project "COHESION" to tackle diversion and trafficking of heroin and cocaine precursors, and their related specific operations.

4. EVALUATION

4.1. Commission actions taken to evaluate the implementation and functioning of the Community legislation

In 2007, the Commission requested Member States to inform it about the national measures they had adopted as foreseen in the Community legislation (i.e. measures to enable them to perform their control and monitoring duties as well as rules on penalties applicable for infringements to the provisions of the Community Regulations). Most had adopted adequate measures, except eight Member States against which the Commission started infringement procedures. In the course of 2008 most of the Member States concerned adopted or put in place steps towards the adoption of the required measures and consequently all required national measures should be adopted before the end of 2009.

In order to evaluate the functioning of the Community legislation, a working group of experts from national competent authorities was established to assist the Commission services. In addition, the Commission mandated an external contractor to gather information from all stakeholders (competent authorities and industry operators) through questionnaires, including quantitative data where available, as well as to analyse the impact of delays caused by legislative requirements placed on the trade in drug precursor and to collect proposals for improving the system in place.

All Member States replied in full or partially for the years 2006 and 2007. Detailed interviews were conducted with competent authorities in a sample of Member States. A total of 72 companies and 8 industry associations (from 10 different Member States) provided responses to the industry survey. Five of them accounted for over 90 % of all responses. The report on this study, was finalised at the end of January 2009, contains a detailed presentation of the results of the surveys. It summarises main findings and proposes recommendations on identified weaknesses. Due to the sensitive information contained in the report, the information is not publicly available. Despite considerable efforts by the contractor, the data gathered has been limited and cannot be considered as fully representative. It proved particularly difficult to gather quantified data on the costs incurred by competent authorities or by operators to implement the legal requirements.

As Regulation (EC) No 111/2005 puts strong emphasis on customs controls, a further study was conducted in 2007 to examine whether drug precursors control is a priority for customs, whether there is capacity for making controls and whether controls are actually carried out.

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[14] Resolution 50/10 , p.42 of the report of the 50th Commission on Narcotic drugs (E/CN.7/2007/16/Corr.1) http://www.unodc.org/unodc/en/commissions/CND/session/50.html

4.2. Findings of the evaluation

4.2.1. Main trends in diversion and diversion attempts

Overall, the Community legal framework for controlling trade in drug precursors seems to provide proportionate measures to prevent diversion of drug precursors for illicit drug manufacture. Since 2005, the reported seizures and stopped shipments of scheduled and non-scheduled substances show an overall increase in number of seizures and stopped shipments Furthermore backtracking investigations allow estimating *a posteriori* the quantities of substances most probably diverted. These data show on the one hand that the system is functioning well but on the other hand that traffickers are continuously trying to divert drug precursors from the legitimate trade. It seems still most valuable for traffickers to use diversion from legitimate circuits for accessing drug precursors. Even though there is a lack of available quantitative evidence that control of legal trade is indeed reducing globally diversion and trafficking of drug precursors, it is clear that the control system in place raises important barriers to access to drug precursors by traffickers and reduce overall availability of drug precursors for illicit drug manufacture. Current attempts for diversion seem to focus on a limited number of substances – both scheduled and non-scheduled:

Acetic anhydride, which is a key precursor for heroin production, continues to be targeted by traffickers in some Member States as evidenced by data of seizures and stopped shipments. Bilateral and regional assistance and cooperation between the competent authorities concerned were instrumental to prevent diversion and/or seize in 2008, approximately 220 tonnes of acetic anhydride, which represents more than 15 % of the quantities of acetic anhydride estimated to be necessary for the illicit heroin manufacture in Afghanistan.

The Customs authorities in the EU have increased vigilance on control of trade in ***ephedrine*** and ***pseudo-ephedrine*** in bulk or when contained in pharmaceutical preparations/medicinal products, mostly transiting through the EU, but on occasions also being exported, to third countries where methamphetamine illicit production take place. This has led to important increase in seizures, more importantly for pharmaceutical preparations containing pseudo-ephedrine. Since 2005, suspicious consignments of approximately 86 tons of ephedrine or pseudo-ephedrine in bulk or tablet form have been detected, seized or stopped, preventing up to 65 tons of methamphetamines of being produced (depending on the methods of synthesis employed) with an estimated street value of US $ 9,7 billion.

Gamma butyro lactone (GBL) is a non-scheduled substance included in the voluntary monitoring scheme in the Community. The data available shows that the cooperation with the industry through voluntary monitoring and notification is functioning well but also that traffickers continue to be interested in diverting GBL – and also other chemical substances submitted to less stringent control. In 2008, diversion attempts or seizures of 2170 litres of GBL have been achieved.

Since 2005, there is no evidence that the Community is targeted for diversion of other important precursors. For example, there was no major seizures or stopped shipments for potassium permanganate, a key precursor for cocaine.

4.2.2. Strengths and weaknesses of the legislation

It has to be noted that the time period foreseen in the Regulations to carry out an evaluation of their functioning was rather short in order to detect clear effects. This has been further

exacerbated by the fact that many Member States were late in adopting all necessary measures to fully comply with their obligations under the Regulations.

Nevertheless, all actions developed since 2005 have with no doubt contributed to the good and harmonised implementation and functioning of the Community legislation. Furthermore, the progressive adoption by Member States of the national measures and powers foreseen in the Community legislation have considerably strengthened their capacity to act upon infringements of the Community legislation.

Overall, the provisions of Regulation (EC) No 273/2004, Regulation (EC) No 111/2005 and the implementing rules contained in Regulation (EC) No 1277/2005 function well and reach the objective pursued, i.e. prevention of diversion without creating unnecessary barriers to the legitimate trade activities for the scheduled drug precursors. Control and monitoring focus on operators rather than on each transaction. The division of the scheduled substances into three categories has proven to be an efficient way to apply a modulated approach, depending on the sensitivity of the substances and of the quantities traded legitimately.

The key principle embedded in the legislation for intra-Community trade and for the trade between the Community and third countries – the cooperation between economic operators and competent authorities - works well. This cooperation, although differently implemented and used by Member States, facilitates the mandatory or voluntary notifications of suspicious transactions or orders, and prevents early diversion of scheduled and non-scheduled substances while allowing legal trade to function smoothly. It is a flexible, rapid and efficient tool in response to the ever changing patterns of trafficking and growing interest of traffickers in less controlled substances. The "EU Guidelines on drug precursors' control for operators" and the new eLearning course on drug precursor control for economic operators successfully complement the legislation.

The implementation and functioning of the common licensing system introduced for intra-Community trade and for the trade between the Community and third countries for operators handling precursors in Category 1 (the most sensitive substances) proves to work efficiently from both the competent authorities' and industry's perspectives.

The registration requirement for operators handling somewhat less sensitive precursors in Category 2 both as regards intra-Community trade and trade between the Community and third countries appears to be insufficient to allow adequate control by competent authorities and prevention of diversion from the important volume of intra-Community trade within these substances. In fact, end-users of Category 2 substances, who do not place on the market the substances, are neither required to register nor to report the quantities they buy for their own end-use. Thus they are hardly known to competent authorities. It is also very difficult for manufacturers or brokers of Category 2 substances to exercise their obligation to check the legitimacy of their customers and of the reported end-use of the substance and consequently to notify as appropriate any suspicious transaction to the competent authorities. The control by competent authorities of the legitimacy of operators is difficult and even more when the manufacturers/brokers and the end-users of the Category 2 substances are based in different Member States, and when the trade chain involves more than two entities based in more than one Member State. These problems have been highlighted particularly for acetic anhydride, a key precursor for illicit heroin manufacture.

The evaluation found differing interpretation of some legislative provisions that would need to be addressed in order to facilitate their correct harmonised implementation within the

Community. This includes in particular, the mandatory fields to be filled in the customer declaration, and the criteria for considering products containing scheduled substances as mixtures, the application of existing thresholds for exemption of registration for mixtures containing Category 2 substances in accordance with Article 6 of Regulation (EC) No 273/2004, when compared to the wording of Article 14 of Regulation (EC) No 1277/2005.

The provisions regarding the frequency of reporting by the operator to the competent authorities does not provide sufficient basis for carrying out the control and monitoring duties. An overview of the legal trade movements constitutes an important instrument to detect suspicious consignments.

The instruments governing the control of exports and imports allow competent authorities to make prior verifications of the licit purposes of a transaction and, in consequence, provide the means to prevent diversion at an early stage. The use of the pre-export notification system allows third countries who have requested so to verify the intended transaction and thereby to inform the Member States competent authorities whether the transaction is licit or not.

The stronger emphasis on customs procedures and controls has proven to be very useful. The Community is increasingly confronted with consignments diverted from legal distribution channels prior to entering the Community customs territory. This requires heightened attention by customs and border control. The provisions regarding the control of transit or transhipments seem to have, to a certain extent, increased the possibility to verify the licit purposes of such shipments however do not seem allowing competent authorities to verify the licit purposes in every case.

The study on customs controls of drug precursors in 2007 identified weaknesses relating to the detection of suspicious consignments for which false customs declarations are made. The evaluation revealed pockets of excellence, but also showed that in general important improvements still need to be made. In particular, the report revealed a lack of priority for the drug precursor legislation by customs administrations, lack of awareness and expertise as well as insufficient resources (e.g. testing equipment).

Pharmaceutical preparations / medicinal products for human use containing drug precursors are currently excluded from the scope of the drug precursor legislation. The manufacture, import and wholesale distribution of medicinal products, including products for export is subject to an authorisation, specific obligations and regular inspections in line with Community pharmaceutical legislation (Directive 2001/83/EC). Therefore it is considered that these activities should be under sufficient systematic control by Member States' competent authorities. However, such manufacturers, importers and wholesale distributors are not subject to specific pre-notification requirements from drug precursors' legislation when exporting those medicinal products which contain drug precursors. This has led to a situation where in some Member States exports and transit/transhipments of pharmaceutical preparations/medicinal products containing drug precursors - in particular ephedrine or pseudoephedrine - have not been stopped or seized even though it was very likely that they would be misused for illicit drug manufacture.

There appear to be further minor weaknesses related to the precursor legislation regarding the external trade. These include in particular the lack of flexibility for competent authorities as regards the period required to wait for the response to pre-export notifications, the lack of simplified authorisation procedures for repetitive consignments between well-known

operators in the Community and in the EFTA countries, and the need to further streamline the authorising procedures with the electronic customs environment.

5. RECOMMENDATIONS FOR IMPROVEMENTS

5.1. Improving harmonised implementation of the current legislation

As a first measure for improvements, the sharing of best practices between Member States' authorities, including customs and practical implementation of a real partnership between authorities and economic operators should be further promoted and facilitated. Exchange of best practices through workshops, seminars, roundtables, and tracking exercises on specific topics and/or specific drug precursors can be facilitated at Community level, in order to gain immediately from best practices in place in some Member States and *in fine* to strengthen the control systems overall.

Harmonised interpretation of some current legislative provisions, e.g. application of thresholds for registration when scheduled substances are contained in mixtures – in particular interpretation of Article 6 of Regulation (EC) No 273/2004, when compared to the wording of Article 14 of Regulation (EC) No 1277/2005, or uniform criteria for mixtures containing drug precursors, can be achieved by updating and complementing the 'Questions & Answers' guidance.

This will strengthen implementation of the Community rules while avoiding that traffickers focus their diversion attempts on Member States, where Community rules appear to be less strictly implemented and/or penalties are perceived as weak.

5.2. Enhancing reporting

The reporting obligations as defined in Article 19 of Regulation (EC) No 1277/2005 should be reviewed in order to obtain a more accurate and timely collection of information on notifications by operators. This can be achieved by increasing the reporting frequency from annually to bi-annually or quarterly while facilitating this reporting by using modern secured electronic means of exchanging information, including if appropriate creating a secured European database.

5.3. Modifying some requirements for Category 2 substances

In the light of the identified weaknesses, it seems necessary to reinforce the controls for all Category 2 substances or specifically for acetic anhydride (key precursor in heroin production) in order to ensure that operators possessing or trading Category 2 substances – or specifically acetic anhydride - are subject to adequate control in order to discourage diversion attempts. This can be achieved in different ways:

- Amending Regulation (EC) No 273/2004 in order to require registration for end-users who possess Category 2 substances for their own use, by for example amending the definition of "operator" or the definition of "placing on the market" or amending Article 3.6 establishing the registration system;

- Amending Regulation (EC) No 1277/2005 in order to introduce common registration conditions and procedures;

- Amending Annex I of Regulation (EC) No 273/2004 and accordingly Annex of Regulation No 111/2005 in order to reschedule acetic anhydride from Category 2 to Category 1.

5.4. Ensuring appropriate control of pharmaceutical preparations/medicinal products containing ephedrine or pseudo-ephedrine

Without duplicating administrative provisions on manufacturers, importers and wholesale distributors of medicinal products consideration should be given to a reinforcement of control provisions of pharmaceutical preparations/medicinal products containing ephedrine or pseudo-ephedrine transhipped or transiting through the EU. As regards exports of medicinal products the pharmaceutical legislation already includes provisions. Reflections should take place on whether specific harmonised practical provisions for the export of medicinal products containing ephedrine or pseudo-ephedrine and their supervision by competent authorities for medicinal products would be beneficial or whether the drug precursors legislation should provide a possibility to stop exports of pharmaceutical preparations / medicinal products when there are reasonable grounds for suspecting that the substances are intended for the illicit drugs manufacture.

5.5. Improving and adjusting procedural requirements with regard to the risk of diversion

In order to reach level of controls proportionate to the risk of diversion, the procedure with regard to pre-export notifications should be adapted to allow competent authorities to act on a case by case basis, simplified authorisation procedures for repetitive consignments between well-known operators in the Community and in the EFTA countries should be introduced, and authorising procedures in the electronic customs environment should be further streamlined.

6. NEXT STEPS

The identified weaknesses can be addressed through different means, some of which require amendments to the Community legislation. Any option pursued would need to be carefully examined in particular towards its impact on economic operators legally trading those substances for legitimate purposes and its effectiveness in preventing their diversion for the illicit drug manufacture.

Given that the current legislation has been fully operational for only a short time period, the Commission will primarily support, organise and facilitate measures aiming at a better implementation in order to gain immediately from established best practices.

However, the Commission will also continue to gather the necessary information with a view to identify the best options to address possible identified weaknesses in legislation and to evaluate the impacts of selected options for both competent authorities and economic operators.