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Delegations will find attached Commission document SWD(2012) 278 final.

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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

Draft Proposal for a Regulation amending Regulation (EC) No 273/2004 on drug precursors

{COM(2012) 548 final}
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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

Draft Proposal for a Regulation amending Regulation (EC) No 273/2004 on drug precursors

1. PROBLEM DEFINITION

1.1. Why is ineffective prention of diversion of acetic anhydride a problem?

Drug precursors are chemicals that have a wide range of legitimate uses, but can also be misused for the illicit manufacture of narcotic drugs and psychotropic substances. In order to prevent their diversion from legal trade to illicit drug production a specific regulatory framework has been set up (both on international level[1] and in the EU[2]) in order to identify suspicious transactions.

Ineffective prevention of the diversion of Acetic Anhydride (AA), the key drug precursor for heroin production, has been identified as the main problem over the last years under the applicable internal market legislation on drug precursors[3]. AA diverted from legal trade in Europe is trafficked to Afghanistan, which is the main global source of heroin, of which Europe alone consumes almost 20%.

The underlying drivers of the problem and its consequences are visualised below:

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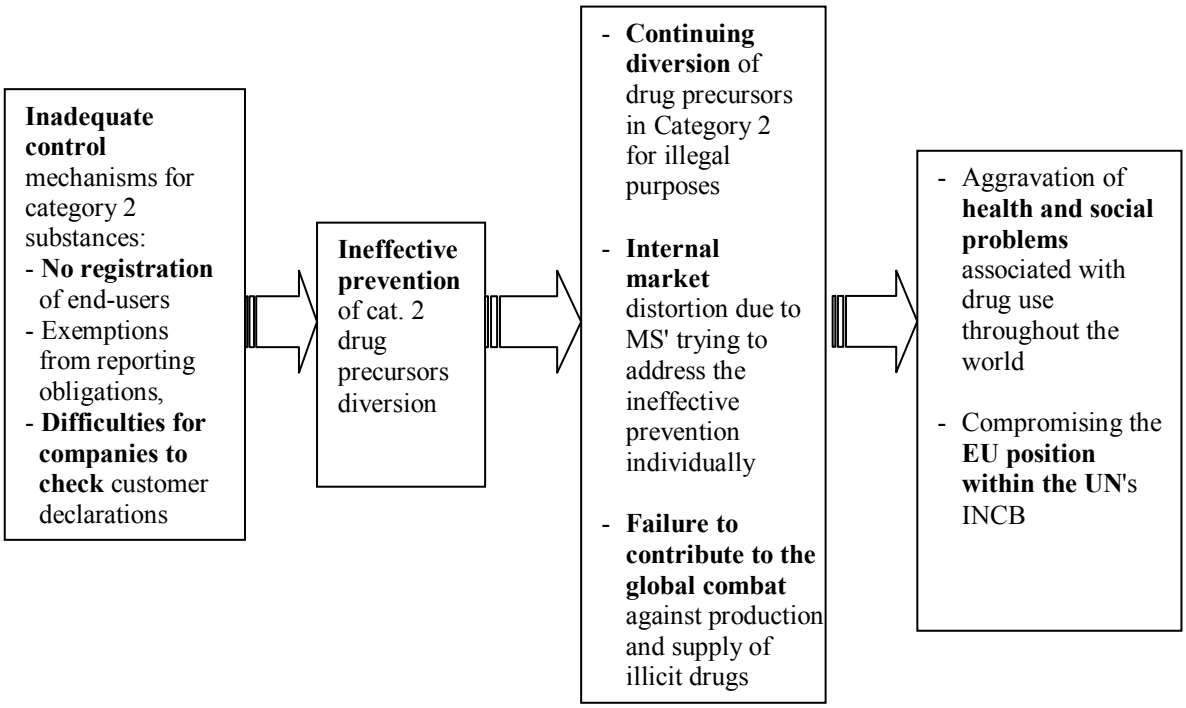
1 United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, available at: HTTP://WWW.INCB.ORG/PDF/E/CONV/1988_CONVENTION_EN.PDF

2 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

3 Commission Report on the functioning of the existing EU legislation on drug precursors (COM(2009)709 final), available at: HTTP://EUR-LEX.EUROPA.EU/LEXURISERV/LEXURISERV.DO?URI=COM:2009:0709:FIN:EN:PDF



In 2008, 241 tons of AA were seized or stopped in the EU, which would have been sufficient to produce ca. 150 - 223 tons of heroin, which amounts to about 50% of the yearly Afghan heroin production. Even though statistics in 2009-2010 have shown a sharp decline of AA stopped and seized in the EU[4], many Member States and the International Narcotics Control Board (INCB) are concerned that the mechanisms of Regulation (EC) No 273/2004 for the control of AA are not sufficient.

1.2. Who is affected

Member States are affected when conducting enforcement actions as well as by the health costs resulting from the use of heroin. In addition, there are significant costs to the public from drug-related crime.

EU citizens are affected through the supply of heroin produced with the diverted AA and also through drug-related crime.

Companies producing or trading AA may experience diversion (attempts) at any stage of handling the substance. Apart from securing their premises and processes against theft, they have to register their premises with the authorities and have to be vigilant to critically assess whether their customers use the substance only for the claimed licit purpose[5]. Suspicious transactions have to be notified to the authorities. End-users (who only buy AA for production

[4] 33 tons in 2009 and 21 tons in 2010.

[5] AA is legally used as an acetylating agent in chemical, photographic and pharmaceutical industry. It is used for producing plastic, textile, dyes, photochemical agents, perfumes, explosives and aspirin.

purposes) have more limited obligations: they do not have to register but must provide a customer declaration when placing orders.

2. ANALYSIS OF SUBSIDIARITY

Regulation (EC) No 273/2004 on drug precursors is based on Article 114 TFEU (formerly Article 95 TEC). The Regulation has set common requirements for monitoring and control of the trade in drug precursors, in order to ensure the free licit trade of these chemicals within the EU. Even though Art. 10 of the Regulation requires Member States to adopt national measures to enable the competent authorities to perform their control and monitoring duties, any general revision of the control and monitoring mechanism would have to be adopted at the European level in order not to unduly hinder the licit trade of drug precursors within the EU.

3. OBJECTIVES

General policy objectives

- **To contribute to the world-wide combat against the illicit traffic in drugs.** Preventing the diversion of drug precursors is an important element by which the EU fulfils its obligations under Art. 12 of the 1988 UN Convention.

- **To ensure a proper functioning of the internal market for drug precursors**, by ensuring that operators are subject to harmonised rules within the EU whilst avoiding unnecessary administrative burden for enterprises **and** competent authorities.

Specific policy objectives

- Preventing diversion attempts in the EU internal market, thus limiting the input of diverted AA originating from the EU to the production of illicit drugs, namely heroin.

- **Avoiding market distortions resulting from non-harmonised control** of drug precursors within the EU and thereby to limit the costs for operators involved in the drug precursor value chain.

Operational policy objectives

- To achieve a downward trend of diversion attempts and seizures in the EU.

- To introduce **a uniform, effective and efficient standard of controls** for drug precursors across the EU internal market.

4. POLICY OPTIONS

Option 1: no action: EU legislation remains unchanged (baseline option)

Regulation (EC) No 273/2004 will not be modified. The Commission and Member States will continue efforts to improve the implementation of current rules. Member States could adopt

further national legislation if considered necessary in accordance with Article 10 of the Regulation, subject to notification and scrutiny in accordance with Directive 98/34/EC.

Option 2: strengthened reporting obligations

Reporting obligations for operators would be strengthened to increase Member States' knowledge in order to better target inspections and other enforcement activities. Two sub-options could be applied separately or in combination: (a) increasing the frequency and (b) extending the scope of reporting.

Option 3: strengthened obligations on operators related to customer declarations from end-users

Operators would not be allowed to deliver scheduled substances in category 2 unless the customer declaration received with an order is completely filled in and they have verified that the end-user has genuine motives for placing the order. If required, operators would have to involve their authorities. The verification of the information would have to be documented. Furthermore, a copy of the customer declaration would have to accompany the delivered substances. The option could be reinforced by reducing or abolishing the threshold of minimum quantities foreseen in Article 6 of the Regulation. Two sub-options could be differentiated: the obligations apply to AA only (a) or to all cat. 2 substances (b).

Option 4: require operators to systematically notify new end-users to the authorities for verification

Operators placing scheduled substances in category 2 on the market would have to systematically notify all orders from end-users who are first time customers to the authorities, and would only be allowed to deliver after having received the authorities' agreement. The authorities would verify the legitimate motives of the end-users, if necessary by co-operating with the authorities of another Member State. The option could be reinforced by reducing or abolishing the threshold of minimum quantities foreseen in Article 6 of the Regulation. Two sub-options could be differentiated: the obligations apply to AA only (a) or to all cat. 2 substances (b).

Option 5: require registration for end-users and reinforce requirements regarding registration

End-users for scheduled substances in category 2 would be required to register. The registration number would have to be included in every customer declaration to allow operators to verify that orders are legitimate. Authorities will have to verify end-users' businesses before registration to give legitimacy to the registration number. European legislation would specify more detailed requirements and conditions for the granting, refusal and withdrawal of registration of end-users (and of operators in general). The option could be reinforced by reducing or abolishing the threshold of minimum quantities foreseen in Article 6 of the Regulation, and/or foresee exemptions for certain categories of end-users, such as universities or research institutions. Two sub-options could be differentiated: the obligations apply to AA only (a) or to all cat. 2 substances (b).

Option 6: move AA from category 2 to category 1

AA would be moved from category 2 to category 1, which would mean that all those involved in the trade and use of AA would need to obtain a licence before they possess or place AA on the market, and would have to comply with all other requirements of licensed operators.

5. ASSESSMENT OF IMPACTS

The costs from increased administrative burdens under the different options have been quantified and are summarised in the comparative table in section 6. Benefits are described qualitatively.

5.1. Option 1: no action

No additional administrative burden would be imposed on *European level* on either enterprises or competent authorities, but an increase of administrative burdens at *national level* could be expected should Member States introduce complementing national measures.

In terms of effectiveness in preventing diversion, recent statistics of seizures and stopped shipments have shown a clear downward trend, which suggests that the efforts to improve implementation have already tangibly improved the effectiveness of the current legislation in preventing diversion.

On the other hand, the identified weaknesses of Regulation (EC) No 273/2004 would persist – even though these may be reduced by better implementation. Member States could still see the need adopt further national measures to reinforce control of trade in drug precursors[6]. This would be counterproductive to the objective of preserving the internal market. Finally, the international criticism of the EU (also shared by some Member States) as remaining "inactive" despite continued calls for stepping up the control of its internal market legislation would persist.

5.2. Option 2: strengthened reporting obligations

In terms of effectiveness in preventing diversion, competent authorities could expect to have a better knowledge of the legal trade flows. This could allow detecting more easily unusual trade patterns indicating diversion. However, in order to be able to match trade data from all operators within the EU, a very large amount of data would need to be collected and would have to be matched across EU-internal borders. Even this EU-wide cross-checking may prove ineffective as only 0.2% of the total AA production is diverted, so that a general "check all transactions" approach is less promising than targeted, risk-based actions.

Member States might still consider that it would be necessary to adopt further national measures to reinforce control of trade in drug precursors. This would be counterproductive with regard to the objective of avoiding fragmentation of the internal market.

5.3. Option 3: strengthened obligations on operators related to customer declarations from end-users

The cost calculation for this option distinguishes 2 scenarios (detailed in the overview table in section 6). In Scenario 1, already today operators only conduct business with clients known to

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[6] For instance: Belgium, Hungary and Italy require its operators to notify each AA transaction to the authorities prior to the delivery of orders.

them and which they verified. Therefore, the main obligation under option 3, verification of the customer declaration, would be considered 100% business as usual. The only additional administrative costs would stem from sending a copy of the customer declaration. Operators are able to verify themselves their customers, so that there would be no additional costs for authorities.

Under Scenario 2, 30% of operators do not yet act in an ideal way and thus would have to increase their efforts. Furthermore, it is assumed that about 10% of all customer declarations would require verification by authorities, because operators cannot conduct full verification themselves.

In terms of effectiveness in preventing diversion, Option 3 would increase the responsibility of operators for the choice of their customers. Even though diligent operators already conduct the necessary verifications, the clarification of the legal text would lead to higher vigilance of operators and also increase the number of cases where operators would contact their authorities.

The benefits for the internal market would probably be similar to Option 1: Member States might still consider that it would be necessary to adopt further national measures to reinforce control of trade in drug precursors, which would be detrimental to the internal market.

5.4. Option 4: require operators to systematically notify new end-users to the authorities for verification

In terms of effectiveness in preventing diversion, option 4 would focus efforts of operators on new customers – in particular those claiming to be end-users not having a registration number for whom it is more difficult to verify genuine motives for placing an order. Systematic notification of all new clients to the authorities will allow them to conduct all appropriate verifications. If necessary they can prevent and/or monitor delivery. However, shifting the responsibility to authorities, who would ultimately decide on potential new business relationships, could be a counter-incentive for operators' own vigilance.

As Option 4 would increase the knowledge of authorities on a part of the end-users, this would probably reduce the likelihood that Member States would adopt additional national measures. However, some could still consider option 4 insufficient and adopt further control measures, which would be detrimental for the internal market.

5.5. Option 5: require registration for end-users and reinforce requirements regarding registration

In terms of effectiveness in preventing diversion, registration would allow Member States to verify the genuine motives of end-users before a first order. This would enable operators to verify more easily their customers as the customer declaration would include an official registration number.

Option 5 would greatly increase the knowledge of authorities on all end-users and this would strongly reduce the likelihood that Member States consider it necessary to adopt further national measures. Option 5 would thus be very effective in preserving the internal market.

5.6. Option 6: move AA from category 2 to category 1

In terms of effectiveness in preventing diversion, benefits are expected to be similar or higher than those of option 5, as all end-users and operators of AA would fall under the strict licensing regime under direct control of the authorities. This would also strongly reduce the likelihood that Member States adopt further national measures, so that Option 6 would be very effective in preserving the internal market.

6. COMPARISON OF OPTIONS

Table 1[7] compiles the information regarding expected benefits (in terms of effectiveness to achieve the operational objectives) and costs for each of the (sub-)options.

Options 4a and 5a have the most favourable cost-benefit ratio. Option 4a scores most favourably based on total costs for authorities and companies combined. However, when disregarding the 'one-off' costs for registration of all existing end-users in option 5a, differences in ongoing yearly costs are less pronounced: Option 5a is les onerous for companies, whereas Option 4a is less burdensome for authorities.

In addition to lower annual costs for companies, Option 5a has been supported by a majority of the Member States during the stakeholder consultations. Option 5a would also better respond to the criticism expressed on international level that a systematic control of AA end-users is lacking in the EU.

In view of the relatively low costs of either option in relation to the overall market value of the European AA production, a tangible impact on the **competitiveness** of European industry is not expected.[8]

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[7] Total costs in this table are based on the sum of the exact individual components. Therefore they do not fully correspond with the totals of the (rounded) components in this table.

[8] The combined total costs of either option (€ 0.05 mio for Option 4a and € 0.06 mio for Option 5a are very limited in relation to **total European market value** of AA (> € 257 mio/year). Also the one-off costs of € 0.16 million for companies and of € 0.29 million for authorities are low in comparison.

TABLE 1: COMPARATIVE TABLE ON COSTS AND BENEFITS

Option		Benefits/Effectiveness		Costs for companies	Costs for authorities	Total Costs
		Prevent diversion	*Preserve int. market*			
1		0	0	€ 0 Risk of fragmented market	€ 0	€ 0
2	**2a**	0	0	€ 5.6 mio/year	€ 1 mio/year	€ 6.6 mio/year
	2b	0	0	€ 1.5 mio/year	€ 0.3 mio/year	€ 1.8 mio/year
	2a+2b	0	0	€ 11.4 mio/year	€ 2.1 mio/year	€ 12.5 mio/year
3	**3a (AA only)**	+	0	Scen. 1 (100% business as usual): € 0.2 mio/year Scen. 2: (70% business as usual): € 4.7 mio/year	Scen. 1: (no authority involvement) € 0 Scen. 2: (authorities involved in 10% of cases) € 0.2 mio/year	Scen. 1: € 0.2 mio/year Scen. 2: € 4.9 mio/year
	3b	+	0	Scen. 1: € 1 mio/year Scen. 2: € 26.3 mio/year	Scen. 1: € 0 Scen. 2: € 1.2 mio/year	Scen. 1: € 1 mio/year Scen. 2: € 27.5 mio/year
4	**4a (AA only)**	+[+]	++	€ 0.04 mio/year	€ 0.005 mio/year	€ 0.05 mio/year
	4b	+[+]	++	€ 0.5 mio/year	€ 0.03 mio /year	€ 0.53 mio/year
5	**5a (AA only)**	++	+++	€ 0.16 mio + € 0.01 mio/year *Alt. Scen: (company registration fees)* € 0.55 mio + € 0.06 mio/year	€ 0.39 mio +€ 0.05 mio/year *Alt. Scen:* *€ 0*	€ 0.55 mio + € 0.06 mio/year *Alt. Scen:* € 0.55 mio + € 0.06 mio/year
	5b	++	+++	€ 0.5 mio + €0.07 mio/year *Alt. Scen: (company registration fees)* € 2.3 mio + € 0.3 mio/year	€ 1.8 mio + € 0.2 mio/year *Alt. Scen:* *€ 0*	€ 2.3 mio + € 0.3 mio/year *Alt. Scen:* € 2.3 mio + € 0.3 mio/year
6	**(AA only)**	+++	+++	€ 0.3 mio + € 0.2 mio/year *[or: incl. ext. trade* + 0.5 mio/year] *Alt. Scen:(company licensing fees)* € 2.0 mio + € 0.3 *[or* + 0.9*]* *mio/year*	€ 1.7 mio + € 0.1 mio/year *[or: incl. ext. trade* + 0.4 mio/year] *Alt. Scen:* *€ 0*	€ 2.0 mio + € 0.3 mio/year *[or incl. ext.tr.* + 0.9 mio/year] *Alt. Scen:* € 2.0 mio + € 0.3 *[or* + 0.9*]* *mio/year*

The preferred options would have effects on **SMEs**, which are dealing with AA primarily as end-users. During the consultation, option 5 was the second preferred option (after keeping the status quo). This result corresponds to the present analysis that option 5 would be less burdensome for enterprises.

None of the preferred options envisages a general exclusion of **micro-companies**, as this would create an easy possibility of circumventing the controls of the legislation. However, micro-companies benefit from the existing thresholds in the legislation[9]. Finally, a specific protection of micro-SMEs would be foreseen in option 5a to prevent Member States to impose registration costs on micro-SMEs[10] in order to recover their own costs.

7. MONITORING AND EVALUATION

Commission:

- Collection, analysis, and reporting of Member States' annual statistics of seizures and stopped shipment.
- Monitoring of Member States' additional national legislation.
- Support the implementation of the amended Regulation (update of existing guidelines, e-learning tool, FAQ document, etc)
- Implementation of a database currently being developed to facilitate the collection and analysis of statistics.
- Five years following the implementation of the legislative amendments: an evaluation of the amended legislation will be carried out in consultation with Member States and stakeholders.

Member States:

- Ongoing monitoring activities on correct implementation of the legislation.

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9 Art. 6 of Regulation (EC) No 273/2004 foresee that companies with sales/purchases of AA below yearly quantities of 100 l are excluded from most of the obligations under the legislation.

10 The effects of a potential passing-on of the authorities' costs to companies have been calculated as an "alternative scenario" under Option 5.