EUROPEAN PARLIAMENT

IMPA
Impact Assessment

Initial appraisal of a European Commission Impact Assessment

European Commission proposal for a Regulation amending Regulation (EC) No 273/2004 on drug precursors

Impact Assessment (SWD (2012) 279, SWD (2012) 278 (summary))
for a Commission proposal for a Regulation amending Regulation (EC) No 273/2004 on drug precursors (COM (2012) 548)

- **Background**

This note seeks to provide an initial analysis of the strengths and weaknesses of the European Commission's Impact Assessment (IA) accompanying the proposal for a Regulation on drug precursors.

Drug precursors are chemical substances that may be produced for licit purposes, but which can be misused for illegal drug production. A specific regulatory framework has been set up both at international level[1] and within the EU[2] to prevent the diversion of drug precursors to illicit drug production.

A European Commission report of 7 January 2010 on the implementation and functioning of the Community legislation on monitoring and control of drug precursors identified weaknesses in the current control system.[3] On 25 May 2010, the Council of the European Union invited the Commission 'to set up a work programme to address the identified weaknesses in close cooperation with the Member States and to propose legislative amendments before the end of 2011 after carefully assessing their potential impact on Member States' authorities and economic operators.'[4]

The present proposal and the IA accompanying it deal with the intra-EU trade component of the problem whereas a separate proposal and IA address the extra-EU trade aspects.[5]

[1] United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988.
[2] Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:047:0001:0010:EN:PDF; Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:022:0001:0010:EN:PDF
[3] COM(2009)709.
[4] http://register.consilium.europa.eu/pdf/en/10/st08/st08427.en10.pdf
[5] PE 496.746 or via http://www.europarl.europa.eu/studies

- **Identification of the problem**

The present proposal and IA attempt to address the weaknesses identified by the above-mentioned Commission report of 7 January 2010 in the implementation and functioning of EU legislation on the monitoring and control of drug precursors, as far as they concern the intra-EU trade. The need for action became apparent in 2008 when competent authorities in the EU seized or stopped 223,000 litres (241 tonnes) of Acetic anhydride (AA) suspected for illicit drug production. In 2008, the EU alone seized 75 per cent of all global seizures of AA (IA p.4). With this quantity it would have been possible to produce approximately 200,000 kg of heroin from Afghan opium. In 2009, Afghanistan produced 6,900 tonnes of opium, of which an estimated 2,700 tonnes were transformed into about 380 tonnes of heroin. This production requires between 380 and 570 tonnes of AA smuggled into the country. It can be assumed that the AA seized and stopped in Europe in 2008 would have satisfied about 50 per cent of the yearly Afghan demand for AA to be used in heroin production (IA p.13).

AA diverted from legal trade in Europe is trafficked via three main routes ('Balkan Route', 'Southern Route' and 'Northern Route') following the 'reverse route' of heroin trafficked to Europe from Afghanistan.

The IA rightly poses the question of whether the driver for the 'diversion of AA' problem is an inadequate control mechanism for AA only, or for all substances in category 2 (of scheduled substances according to Regulation (EC) No 273/2004). It argues that it is not, pointing to the fact that in the 2010 stakeholder consultation, both Member States and enterprises have reported more than double the amount of suspicious transactions for AA alone than for the four other category 2 substances combined (IA p.14).

AA is licitly used for producing plastics, textiles, dyes, photochemical agents, perfumes, explosives and aspirin. AA is used illegally mainly for the production of heroin, but also of other drugs, like amphetamine, methaqualone, coca paste and cocaine. Heroin use has been a contributing factor to public health problems in Europe since the 1970s. It still accounts for the greatest share of morbidity and mortality-related drug use in the European Union. (IA p.11)

Almost 20 per cent of the global heroin production, mainly produced in Afghanistan, is then sold on the European market. The ultimate consequence of diversion of AA in Europe is an aggravation of the health and social problems associated with heroin use in regions throughout the world, including a substantial part of Europe (IA p.16).

The IA could have set out more clearly the problem that illicit trafficking of drug precursors can help fuel and sustain criminal networks more generally, promoting corruption, fraud and other illegal activities, in several other areas.[6]

[6] See e.g. the Frontex 2012 report on Anti-Corruption Measures in EU Border Control http://www.frontex.europa.eu/assets/Publications/Research/AntiCorruption_Measures_in_EU_Border_Control.pdf or the EU Drug Markets Report: A Strategic Analysis, EMCDDA/Europol, January 2013 http://www.emcdda.europa.eu/publications/joint-publications/drug-markets.

• Objectives of the legislative proposal

The IA summarises the general and the specific objectives as follows:[7]

General policy objectives:

- to contribute to the worldwide fight against the illicit traffic in drugs. Preventing the diversion of drug precursors is an important element by which the EU fulfils its obligations under Article 12 of the 1988 UN Convention;
- to ensure a proper functioning of the internal market for drug precursors, by ensuring that operators[8] are subject to harmonised rules within the EU, whilst avoiding an unnecessary administrative burden on enterprises and the 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 limiting the costs for operators involved in the drug precursor value chain.

The IA rightly does not limit the objectives to the prevention of the diversion of AA, but pursues effective control of drug precursors in the EU. Given the fact that no less than 65 new synthetic drugs emerged in the last two years[9], this more general approach seems justified.

• Range of the options considered

The range of options set out in the IA are:

Option 1: No action: EU legislation remains unchanged (baseline option)
Regulation (EC) No 273/2004 would not be modified. The Commission and Member States would 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. The IA explains this option also in terms of the status of category 1 vs. category 2 substances, the registration needs for operators of category 2 substances, customer declarations and reporting requirements of the operators.

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** are identified, to 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

[7] Executive summary of the IA, p.4
[8] 'Operator' as defined in Regulation 273/2004 is any natural or legal person engaged in the placing on the market of the scheduled substances.
[9] Thematic Paper on Organised Crime: Drug Cartels and their Links with European Organised Crime, by MEP Diaz De Mera, September 2012, European Parliament Special Committee on Organised Crime, Corruption and Money Laundering (CRIM), p.8.

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** are differentiated: the obligations apply to AA only (a) or to all category 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 make deliveries 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** are differentiated: the obligations apply to AA only (a) or to all category 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** are differentiated: the obligations apply to AA only (a) or to all category 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.

The options identified appear complete at first sight, and possibly in line with the Commission report of 7 January 2010 concerning the control of drug precursors.[10] However, the latter suggested in its recommendations *inter alia* amending the definition of 'operator' or of 'placing on the market' in Regulation 273/2004. 'Placing on the market' encompasses any 'supply of scheduled substances in the Community, the storage, manufacture, production, processing, trade, distribution or brokering of these substances for the purpose of supply in the Community'. The IA could usefully explain directly whether, in this definition, the restriction 'for the purpose of supply in the Community' is not too restrictive, as in particular AA is diverted mainly for purposes outside the EU.

[10] COM(2009)709, p.10.

- ## Scope of the Impact Assessment

According to the IA, the most relevant **economic impacts** include the administrative costs/burdens on businesses and public authorities. The IA quantifies them meticulously, based on calculations by an external contractor using the 'Standard Cost Model'.

The IA confirms that there are **social impacts**, including those on **health and safety** as well as **crime and security**; these impacts correlate with the *effectiveness of each option to prevent diversion* of the precursors, but the IA weakens this recognition by noting that heroin would be supplied to the EU even if all diversion of European AA was stopped.

The IA sees no **environmental impacts** associated with the issue. This is surprising as the more drugs and their precursors are subject to illicit trafficking and fabrication, in whatever jurisdiction, the more likely these substances are to be released into the environment. The IA mentions briefly only environmental aspects arising from the destruction of seized drug precursors, regulated by the applicable waste legislation.

The IA does not mention impacts on the **fundamental rights** of the citizen. Possibly, these could be affected by data protection issues related to registration obligations for operators and end-users. In any case, the proposal addresses this issue by including an article on data protection (new Article 13b).

- ## Subsidiarity and proportionality

The legal basis of the proposal is Article 114 TFEU, which has the objective of establishing an internal market while ensuring a high level of protection of human health and the environment.

The issue of subsidiarity has been discussed in the IA and in the Explanatory Memorandum to the proposal (pp 5-6). The latter refers to the Union's obligations under Article 12 of the 1988 UN Convention and points out that some Member States feel legally prevented from adopting national control measures going beyond EU legislation, whereas other Member States have gone ahead with stricter rules. This, it says, 'might be detrimental to the functioning of the Union Market and, secondly, isolated actions in individual Member States risk shifting the problem from one Member State to the next, as traffickers will exploit the 'weakest link' in the Union market. A combination of different national measures will not be as effective as a harmonised approach at EU level. This is also confirmed by the fact that both, Member States and concerned industry sectors have called on the Commission to act to preserve the internal market with a level playing field, and not to rely too much on supplementary national measures.'

No EU national parliament has raised objections based on subsidiarity.

On proportionality, the proposal states that it does not go beyond what is necessary in order to achieve the intended objectives. The IA discards options 3b, 4b, 5b and 6 as it sees the associated costs for companies and Member States disproportionate in view of the expected benefits.

- ## Budgetary or public finance implications

According to chapter 4 of the Explanatory Memorandum, the proposal does not have any impact on the EU budget or on the human resources needed in the institutions.

- **SME test / Competitiveness test**

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 of the competitiveness of European industry is not expected.

The preferred options 4 and 5 would both have effects on SMEs. SMEs dealing with AA are primarily end-users. SMEs have been involved in the consultation process through a targeted consultation via the Enterprise Europe network. While about 50 per cent of them expressed a preference for not changing the legislation at all, option 5 was the second most preferred option (15 per cent or respondents). This result is in line with the analysis that option 5 would be less burdensome than option 4 in terms of annual costs for enterprises (provided authorities do not pass on all costs to registrants), an argument which is particular relevant for SMEs.

The present initiative would, under none of the options, envisage a general exclusion of micro-companies, as this would create an easy possibility of circumventing the controls of the legislation. Traffickers could establish themselves as micro-entities in order to evade controls by the authorities. It should, however, be borne in mind that micro-companies are most likely to benefit from the existing thresholds under the current legislation: Article 6 of Regulation (EC) No 273/2004 foresees that companies with sales/purchases of drug precursors below the maximum yearly quantities are excluded from most of the obligations under the legislation. Finally, a specific protection of micro-SMEs would be foreseen in option 5 to prevent Member States to impose registration costs on micro-SMEs (IA p.51; proposal Article 2 (2) (e)).

In view of the relatively low costs of option 5a in relation to the overall market value of the European AA production, a tangible impact of the competitiveness of European industry is not expected by the IA (p.51).

- **Relations with third countries**

The IA describes the international context of the issue and refers to the United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, to the UN International Narcotics Control Board (INCB) and the UN Commission on Narcotic Drugs (CND).[11]

- **Stakeholder consultation**

In 2009-10, the Commission Services (DG ENTR) consulted industry stakeholders through their EU trade associations on the weaknesses in the control of drug precursors, notably the difficulties in preventing diversion of AA, and how to best address them. The Commission subsequently developed six possible options. In June 2010, these options were discussed with the Member States and industry representatives at a special meeting of the Drug Precursor Working Group. Subsequently, Member States and industry stakeholders were consulted on the six options via a written consultation, carried out from 23 July to 18 October 2010. The Commission received responses from 54 operators, 106 end-users, 60 SME end-users and 17 Member States. The preferred option of Member States was option 5 and of SME end-users option 1, whereas most of the end-users and of the operators had no opinion on a preferred option (IA p.7).

[11] See also the Commission report of 7.1.2010 COM(2009)709 on the functioning of the Community legislation on monitoring and control of trade in drug precursors, chapter 3.6. on bilateral agreements.

- **Quality of data, research and analysis**

Concerning the illicit trafficking of drug precursors, the data available seem to depend largely on occasional seizures. Assessing the negative effects of the diversion of drug precursors and of the traffic and final use of drugs is very difficult. Possibly, the IA could have made more use of data provided from international bodies.[12]

Each (sub-)option identified is analysed for the associated costs and benefits (IA p.26-46). The costs for companies and for authorities, in millions of euros per year, are calculated based on indications from the responses to the stakeholder consultation, the Standard Cost Model, and extrapolation thereof. In contrast, the benefits in terms of 'diversion prevention' and 'preservation of internal market' could be indicated only qualitatively, in a range of 0, +, ++, +++. The results are compiled in a 'Comparative table on costs and benefits' (IA p.49).

The comparative assessment of the benefits results in options 4 and 5 being identified as equally effective in preventing diversion (++), and clearly more effective than options 1, 2 and 3. But option 5 is considered to preserve the internal market better than option 4. Option 5 was the preferred option of most Member States. However, under option 6, the strongest tools available under the current legislation would be applied to AA and therefore it received the highest effectiveness score for preventing diversion (+++) and, together with option 5, the highest score for preserving the internal market (+++).

The IA discards the sub-options 3b, 4b and 5b (generalising the obligations related to AA to all category 2 substances), as they imply considerably greater costs for companies and authorities, that could not be justified by a greater prevention of diversion of category 2 substances.

The IA discards option 6, the most effective one for preventing diversion, for creating 'very high additional cost': one-off costs of € 2.0 million (against € 0.55 million for option 5a and none for option 4a) and yearly costs of at least 0.3 million (against € 0.06 million for option 5a and € 0.05 million for option 4a).

Of the remaining options, 5a is more effective but creates more cost than 4a. Therefore the IA considers options 4a and 5a both to be good choices to address the objectives identified and leaves the final selection to political choice. The proposal puts forward option 5a.

The 'Comparative table on costs and benefits' and the analysis could be criticized for not attributing to the criterion 'effective prevention of diversion of AA' the weight it deserves. In the end, this is the main objective of the whole exercise. Possibly, option 6, the most effective one, has been discarded unjustly, as the gain in terms of health[13], safety, social benefits and prevention of organised crime would possibly outweigh by far the cost indicated above.

- **Commission Impact Assessment Board**

Commission's Impact Assessment Board assessed a draft version of the IA and issued its opinion on 17 February 2012. It made several recommendations and, in the light of these, the final version of the IA is said to:

[12] Starting from the UN ODC annual World Drug Reports with their annexes.
The 2012 World Drug Report: http://www.unodc.org/unodc/en/data-and-analysis/WDR-2012.html
[13] Quoted from the UN ODC report: 'Heroin, cocaine and other drugs kill around 0.2 million people each year, shattering families and bringing misery to thousands of other people. Illicit drugs undermine economic and social development and contribute to crime, instability, insecurity and the spread of HIV.'

- provide a more detailed overview of the market players and of the individual measures taken by Member States to prevent the diversion of drug precursors and on that basis provides a more detailed presentation of the baseline scenario;
- strengthen the subsidiarity analysis to better justify the need for EU action;
- provide more information with regard to the assessment of the costs and effectiveness of the policy options examined;
- report the views of stakeholders in more detail.[14]

- **Coherence between the Commission's legislative proposal and IA**

The proposal introduces a couple of new rules of a more technical nature that have not undergone an impact assessment, notably empowering the Commission to adopt specific implementing and delegated acts.

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This note, prepared by the Impact Assessment Unit for the European Parliament's Committee on Civil Liberties, Justice and Home Affairs, analyses whether the principal criteria laid down in the Commission's own Impact Assessment Guidelines, as well as additional factors identified by the Parliament in its Impact Assessment Handbook, appear to be met by the IA. It does not attempt to deal with the substance of the proposal. It is drafted for informational and background purposes to assist the relevant parliamentary committee(s) and Members more widely in their work. This document is also available on the internet at:
http://www.europarl.europa.eu/activities/committees/studies.html

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[14] IA p.8 '2.4. Scrutiny by the Commission Impact Assessment Board'.