EUROPEAN COMMISSION
IMPACT ASSESSMENT BOARD

Brussels,
D(2012)

Opinion

Title **DG ENTR - Impact Assessment on: Proposal for a Regulation amending Regulation (EC) No 273/2004 on drug precursors**

(draft version of 19 January 2012)

(A) Context

Drug precursors are chemicals produced for a lawful purpose which can be misused in illegal drug production. A specific regulatory framework has been set up to prevent the diversion of drug precursors to illicit drug production: the intra-EU trade of drug precursors is governed by Regulation (EC) No 273/2004, and the control of extra-EU trade by Regulation (EC) No 111/2005. In January 2010, the Commission adopted a report on the implementation and functioning of the EU legislation on monitoring and control of trade in drug precursors. While the report concluded that the legislation is overall functioning well, it also identified some weaknesses of the current system. This IA report assesses possible amendments of Regulation (EC) No 273/2004 related to the intra-EU trade. It focuses on a specific weakness which has been detected in the EU, when large quantities of acetic anhydride (AA), the main drug precursor for heroin, were diverted from the EU-internal trade.

(B) Overall assessment

The report provides a comprehensive and adequate analysis overall, although certain issues should be explained in a more detailed and transparent fashion. Firstly, the report should expand the problem definition by providing 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, improve the presentation of the baseline scenario. Secondly, it should strengthen the subsidiarity analysis to better justify the need for EU action. Thirdly, the report should provide a more substantiated assessment of the costs and of the effectiveness of the envisaged measures to better demonstrate the difference the preferred policy option will make. Finally, the views of stakeholders should be reported more transparently throughout the text.

(C) Main recommendations for improvements

(1) Develop further the problem definition and the baseline scenario. The report should provide a more detailed overview of the market players involved in the legitimate production and distribution of drug precursors (number of companies, their size etc), and should explain how they are affected by the identified problems. It should also indicate which Member States are most affected, and should be more specific about the individual measures taken by them to prevent the diversion of drug precursors. It should then explain in greater detail how these measures impact on the functioning of the internal market, including on the companies operating in the Member States with stringent national rules. The report should clarify whether the insufficient enforcement and compliance with the current EU legislative framework contributes to the identified problems. On that basis the report should improve the presentation of the baseline scenario. Finally, the report should be clearer about the current situation and its probable evolution with respect to diversion of substances of category 2, other than AA, and should better justify the specific focus on the AA substance.

(2) Strengthen the subsidiarity analysis. The report should further enhance the justification of the need for action at EU level, given the significant decline of AA stopped and seized in the EU over recent years and given that a significant number of stakeholders seem not to support further EU action in the area of prevention of diversion of drug precursors.

(3) Strengthen the analysis of impacts. The report should provide a more substantiated assessment of the effectiveness of the envisaged measures. In particular, it should better differentiate between the expected impacts of options which foresee stricter measures for new end-users only (option 4) versus for all end-users (option 5). In this context, the report should clarify whether option 4 does not risk creating an unlevel playing field between the existing end-users and the new entrants. The report should also make clearer the fact that the suggested measures are likely to improve the situation as regards the diversion attempts in the internal EU trade, but will have no or little impact on the total global heroin production. It should discuss whether the introduction of more stringent measures at EU level aiming to further reduce the diversion attempts could trigger third countries to introduce similar measures. The social impacts – even if indirect – should be discussed for all the assessed policy options. Finally, the assumptions used in the Standard Cost Model for the estimation of the administrative costs for enterprises and Member States should be clarified. In particular, the report should better differentiate between Member States likely to incur lower costs as a result of more stringent national measures already in place.

(4) Improve the presentation of stakeholders' views. The report should present the different stakeholders views (including from non-business interest groups) more transparently, making clear when no explicit positions on the suggested policy options were communicated by the affected businesses and the competent Member States authorities. It should explain why the consultation was focused on Member States administrations and industry only, and indicate the reasons why a wider public consultation was not considered necessary.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report.

(D) Procedure and presentation
The report should present more clearly up-front how this initiative is situated in the overall policy framework and the on-going work on the EU strategy on drugs. It should clarify whether/how this initiative is likely to interact with a possible revision of the Regulation (EC) No 111/2005 on control of extra-EU trade of drug precursors.

(E) IAB scrutiny process	
Reference number	2011/ENTR/021
External expertise used	No
Date of Board Meeting	15 February 2012