



EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
D(2012)

Opinion

Title

DG JUST - Impact Assessment Report for the new psychoactive substances

(draft version of 4 April 2012)

(A) Context

The rapid emergence and spread of new psychoactive substances in the internal market is one of the most challenging developments in EU drugs policy in recent years. The Council adopted in 1997 the EU Joint Action on new synthetic drugs. In 2005, this was replaced with the Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances. The Commission's assessment report (COM(2011) 430 final) on the functioning of the Council Decision concluded that it was a useful instrument for addressing new psychoactive substances at the EU level, but was inadequate for tackling this growing problem, and should therefore be revised. The Commission Communication "Towards a stronger European response to drugs" identified the spread of new psychoactive substances as one of the problems requiring a more sustainable response and set the ground for revising the existing instrument. In its Conclusions of December 2011, the Council requested the Commission to take further action to address new psychoactive substances and invited it to revise the Council Decision.

(B) Overall assessment

The report needs a significant amount of further work in a number of important respects, particularly as regards the proportionality of the temporary banning option. First, the problem definition should be improved by providing a clearer description of the scale of the problem with regard to psycho-active substances that raise cross-border concerns. It should also clarify the scope and limitations of both the existing EU action and measures implemented in Member States and should better explain why there is a need for an alternative approach to the current practice. Second, the presentation of the options should be strengthened by describing them in more detail and by explaining why a broader range of options has not been considered or is not feasible. Third, the report should strengthen the assessment of costs and benefits of the different options, including administrative and compliance costs. On that basis the report should then better demonstrate their proportionality, particularly with respect to temporary banning.

Given the nature of these concerns, the IAB requests DG JUST to submit a revised version of the IA report on which it will issue a new opinion.

(C) Main recommendations for improvements

(1) Improve the presentation of the problem. The problem definition should be strengthened by including a clearer description of the nature of psycho-active substances, how harmful these substances are and how they are identified. The report should also discuss the extent to which the substances are used for other legitimate (rather than recreational) purposes, and explain the scale of the issue with regard to psycho-active substances raising cross-border concerns. The report should clearly define the EU and Member States' competence in regulating these substances. In doing so, and in order to better highlight the shortcomings of the present system and the need for an alternative approach, the current assessment process should be explained in more detail, fully reflecting stakeholders' views. The report should give a better overview of the regulatory framework for these substances at Member State level and should explain Member States' approaches to risk assessment, highlighting where there are divergences and explaining why this poses a problem. The report should also clarify from the start the scope and limitations of the proposed EU action and whether this will focus on the production, trade, sales or consumption of these substances. Finally the legal basis of this proposal should be clarified, in particular by better explaining the reliance on internal market competences.

(2) Improve the design of policy options. The report should explain in more detail the content of the policy options proposed. How policy options target the speed and quality of the risk assessment report process should be better explained, by indicating the difference that the new process would make to the speed of decision-making, for example by including a timeline. The report should also better explain the reasoning for discarding certain options and should explain why a wider range of alternative policies, such as an age limit on the sale of these substances, licensing of producers or coordinated international action have not been considered or are not feasible. The content of the option related to individual or group assessment of substances should be better explained.

(3) Improve assessment of cost/benefits and better demonstrate the proportionality of options. The report should deepen its assessment of impacts for the different options, in particular for the effects of introducing a temporary and/or definitive ban. In that context the social and economic effects of such a measure as well as the impacts on consumers and all concerned stakeholders, should be better explained, particularly given the repercussion of the potential reversal of a temporary ban. The report should better compare the positive and negative impacts of a ban, and acknowledge any trade-offs. In doing so, the report should consider previous experiences with bans. The report should better quantify the costs of the proposed measures against the background of existing provisions, focussing not just on the costs of research and enforcement but also quantifying the additional compliance cost for all concerned stakeholders and the administrative costs these changes might entail for Member States' authorities and economic operators. On that basis the proportionality of a temporary or definitive ban on psychoactive substances should be much better demonstrated.

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 different views of the stakeholders should be better reflected throughout the report. All evidence should be clearly referenced and figures should be adequately supported by an explanation.

(E) IAB scrutiny process

Reference number	2009/JUST/016
External expertise used	No
Date of IAB meeting	2 May 2012