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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	4 December 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SEC(2025) 328 final
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on monitoring and controlling drug precursors and repealing Regulations (EC) No 273/2004 and (EC) No 111/2005 - Regulatory Scrutiny Board opinion

Delegations will find attached document SEC(2025) 328 final.

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EUROPEAN COMMISSION

Brussels, 6.6.2025
SEC(2025) 328 final

REGULATORY SCRUTINY BOARD OPINION

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on monitoring and controlling drug precursors and repealing Regulations (EC) No 273/2004 and (EC) No 111/2005

{COM(2025) 747 final}
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EUROPEAN COMMISSION
REGULATORY SCRUTINY BOARD

Brussels,
RSB

Opinion

Title: Impact assessment / Revision of the Drug Precursors Regulations

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

Drug precursors are chemical substances that can be used to make drugs. Many drug precursors also have legitimate uses in areas such as cosmetics, detergents and plastics. In the EU, two regulations from 2004 set rules for commerce in drug precursors to prevent their misuse while not unduly blocking legitimate use.

This initiative aims to reduce the availability of drug precursors for illicit drug manufacturing while at the same time upholding legal trade and use of drug precursors.

(B) Key issues

The Board notes the additional information provided and commitments to make changes to the report.

However, the report still contains shortcomings. The Board gives a positive opinion with reservations because it expects DG TAXUD and DG GROW to rectify the following aspects:

(1) The report does not fully address whether and how the uneven implementation and enforcement among Member States is a driving factor behind the problem. It also does not sufficiently substantiate the extent to which the existing burdens pose a problem for economic operators and public authorities and why removing some measures would not increase the risks.
(2) The report does not provide a clear justification why the two comprehensive review options are considered to be equally effective in reducing illicit trade and manufacturing.
(3) The report does not adequately present the evidence and methodology used to support the estimates of social impacts.
(4) The report does not sufficiently outline the key indicators to measure success.

This opinion concerns a draft impact assessment which may differ from the final version.

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(C) What to improve

(1) The report should provide evidence to substantiate whether uneven implementation and enforcement contribute to the problem, including the extent to which traffickers exploit vulnerabilities for precursor trafficking. It should better account for the variations in illicit market challenges, both in terms of magnitude and types of challenges, across Member States, assessing the rationale, costs and benefits of the different approaches, including the more stringent ones. In addition, the report should make use of the full evaluation and expand on its findings to support and substantiate the identified problems and drivers.
(2) The report should provide more robust evidence substantiating to what extent administrative requirements can be streamlined or removed while at the same time ensuring an adequate level of risk protection. It should also provide a more nuanced picture of the mixed stakeholder views on the existence of the problem.
(3) The options chapter has an overly complex structure. The report should clearly describe the key novel measures such as innovative scheduling. It should better explain the reasoning and necessity behind the new set of categories. This should be done keeping in mind both general objectives. The differences between policy options should be more clearly outlined.
(4) The report should elaborate on the expected evolution of the social impact under the baseline scenario, including the anticipated change in illicit trade or manufacturing and clarify whether the baseline is static or dynamic for the purpose of comparing the impacts of the options.
(5) The report should clarify the measures for the envisaged IT system for drug precursors and related costs.
(6) The report should clearly state the appraisal period used to determine and compare the benefits and costs. Where applicable, one-off costs should be annualised to allow for final comparison of options.
(7) The report should transparently outline the methodology used to calculate the expected percentage reduction in illicit trade for each option, with a clear explanation of the underlying assumptions and calculations. Similarly, it should provide a detailed explanation and substantiation behind the estimated 60% reduction in the availability of precursors for illicit drug manufacturing.
(8) The report should provide a clearer comparison of the options to strengthen the assessment of effectiveness and proportionality. It should assess to what extent the two comprehensive options can be considered equal in terms of social impacts, considering the difference in ambition and scope. It should also clarify the costs for authorities and economic operators for each option taking into account the scope and other factors in implementation and enforcement.
(9) The report should discuss how reliably it can assess the proportionality of the proposed interventions given that it is unclear to what extent the proposed measures will result in desired social impacts (reduced health detriments and crime etc.); and also unclear to what extent they will have impacts in terms of reduced rates of innovation in the industries concerned.
(10)The report should clearly qualify what it will take to measure success. The monitoring framework should include indicator(s) on social and economic benefits building on the methodology behind the estimates related to the reduced availability of precursors.

Some more technical comments have been sent directly to DG TAXUD and DG GROW

(D) Conclusion **DG TAXUD and DG GROW should revise the report in accordance with the Board's findings before launching the interservice consultation.**	
Full title	Revision of the EU drug precursors legislation Proposal for a revision of the EU drug precursors regulations (EC) No 111/2005 and (EC) No 273/2004
Reference number	PLAN/2022/1454
Submitted to RSB on	6 May 2025
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