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PROPOSAL

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2025) 397 final
Subject:	COMMISSION STAFF WORKING DOCUMENT Subsidiarity Grid Accompanying the document 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

Delegations will find attached document SWD(2025) 397 final.

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COMMISSION STAFF WORKING DOCUMENT

Subsidiarity Grid

Accompanying the document

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} - {SEC(2025) 328 final} - {SWD(2025) 398 final} - {SWD(2025) 399 final}

Subsidiarity Grid

1. Can the EU act? What is the legal basis and competence of the EU's intended action?
1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?
The legislative proposal has the same legal bases as Regulation (EC) No 273/2004 on drug precursors and Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries. Regulation (EC) No 273/2004 is based on Article 114 of the Treaty on the Functioning of the EU (TFEU), for the approximation of measures to control and monitor drug precursors in EU countries, while Regulation (EC) No 111/2005 is based on Article 207 TFEU on common commercial policy, for custom controls of drug precursors.
1.2 Is the EU competence represented by this Treaty article exclusive, shared or supporting?
In the case of measures to control and monitor drug precursors in the internal market, EU competence is shared, while for custom controls measures, competence is exclusive. Given that the subsidiarity principle does not apply to policy areas where the EU has exclusive competence as defined in Article 3 TFEU, this subsidiarity grid will further down refer only to the subsidiarity and proportionality of the measures proposed concerning the control and monitoring of drug precursors in the internal market.
2. Subsidiarity principle: Why should the EU act?
2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[1]: - Has wide-ranging consultation been carried out before proposing the act? - Is there a detailed statement with qualitative and, where possible, quantitative indicators making it possible to establish whether EU action is the best course to take?
For the preparation of this proposal, the Commission consulted national authorities, industry associations, companies (including small and medium-sized enterprises), and civil society. It also consulted the Expert Group on Drug Precursors. The proposal, based on a comparative impact assessment of a number of policy options, reflects the option that scored best in terms of economic, social, environmental and health impacts, effectiveness, efficiency and coherence. It will replace Regulation (EC) No 273/2004 on drug precursors. It will also replace Regulation (EC) No 111/2005. The evaluation of the Regulations[2] concluded that they had added value for preventing the diversion of drug precursors and for the functioning of the internal market. It also highlighted regulatory fragmentation alongside the Regulations (such as additional rules in some EU countries) and differing approaches that lead to an imbalance in the level of controls and in administrative burdens for economic operators. During the impact assessment, it became clear that EU countries and industry welcomed, in particular, a coherent approach to the challenge of designer precursors, in cases where separate national rules have been introduced.
2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification for following the principle of subsidiarity?

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN
[2] EUR-Lex - 52020DC0768 - EN - EUR-Lex

Yes, they do.
The explanatory memorandum points out: 'The Union has shared competence in setting out rules on the control and monitoring of drug precursors within the internal market. The EU has set out harmonisation rules on drug precursors since 1990. Two key arguments continue to justify EU action in this field. Firstly, illegal drug production is a Union-wide problem, not confined to a few Member States. EU action is needed to ensure that the efficiency of controls of drug precursors across the Union is not diminished by the existence of differing national rules with various degrees of strictness, which would inadvertently lead to weaknesses. Secondly, Member States have the obligation to control and monitor transactions with drug precursors, in accordance with the UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances[3]. Maintaining harmonised rules would ensure a smooth licit trade of chemicals in the single market. EU action would have clear benefits for businesses, national authorities and society as a whole, by empowering national authorities to better fight against illicit drug production, ensuring the smooth functioning of the internal market and reducing administrative burdens for economic operators and national authorities.'
The impact assessment also contains a section on the principle of subsidiarity (Section 3.2).

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by EU countries acting alone (need for EU action)?

No, the objectives of the proposal cannot be sufficiently achieved by EU countries acting alone, due to the EU-wide problems with, and significant cross-border legitimate trade in, drug precursors and incidents of diversion towards the illicit manufacture of drugs.

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

Illegal drug production is an EU-wide problem. The 500 illegal production sites dismantled in 2023 suggest that a significant amount of drug production activities take place in the EU.
Drug precursors are chemicals needed for the illicit production of drugs. Many of them have extensive legitimate uses as critical components of various industrial supply chains, such as pharma, cosmetic, textile, oil refinery, food additive, or dyes industries. The legal use of precursors in the EU exceeds 10.6 million tonnes a year, unevenly spread across EU countries, depending on the degree of development of their chemical industries. 4000 economic operators are involved in supply chains with the major drug precursors. Such supply chains are often complex, with operators from two or more Member States performing various roles. Although these supply chains represent a small proportion of the chemical industry overall, there are plenty of risks of drug precursors being diverted from licit channels towards the illicit manufacture of drugs all across the EU.

(b) Would national action or the absence of EU action conflict with the achievement of core objectives of the Treaty[4] or significantly damage the interests of other EU countries?

No longer maintaining harmonisation rules in this sector would unavoidably impede the smooth functioning of the internal market. The control and monitoring of drug precursors is an international obligation of the EU and EU countries. Setting up national control systems to replace the existing harmonised one would weaken the fight against the diversion of these substances towards illicit channels. The evaluation and the impact assessment have identified an increase in

[3] The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, adopted in Vienna on 19 December 1988.
[4] https://europa.eu/european-union/about-eu/eu-in-brief_en

the number of challenges in this sector, pointing to the need to strengthen the existing rules, instead of replacing them with various national rules, given the EU-wide nature of the situation.
(c) To what extent do EU countries have the ability or possibility to enact appropriate measures?
If the EU decides to no longer maintain harmonisation rules, EU countries would have the obligation to adopt such measures at national level, to meet their international obligations. While such measures could tackle efficiently internal issues, they would not be sufficient in dealing with cross-border incidents, which are common in the illicit manufacture of drugs. In addition, legitimate trade would face unnecessary burden when extending their activities to other EU countries.
(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary nationally, regionally and locally in the EU?
Some EU countries have a more developed chemical industry. This increases the risk of diversion of drug precursors from licit to illicit channels. Illegal drug manufacturing and drug consumption is also not evenly spread, resulting in various degrees of awareness of, and commitment to identifying, suspicious transactions among national authorities and economic operators.
(e) Is the problem widespread across the EU or limited to a few EU countries?
The problems are widespread. See question (a) for more details.
(f) Are EU countries overstretched in their efforts to achieve the objectives of the planned measure?
No. The consultation activities carried out as part of the evaluation and impact assessment show a strong commitment from EU countries to monitoring and controlling drug precursors.
(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?
National authorities share the objective of fighting the illegal manufacture of drugs. Nevertheless, there are significant discrepancies: both the chemical industry and illegal activities are not evenly spread across the EU, resulting in various degrees of prioritisation of the control of drug precursors across the EU. The evaluation points to uneven implementation across the EU. This is also because of the variations in the resources mobilised at national level to control and monitor drug precursors. Authorities and industry advocate a targeted approach to drug precursors that does not lead to undue enforcement costs and administrative burdens for legitimate businesses.
2.4 Based on the answers to the questions below, can the objectives of the proposed action be better achieved at EU level by reason of the scale or effects of that action (EU added value)?
Yes, the objectives of the proposal can be better achieved at EU level, as harmonised control and monitoring measures will reduce the administrative burden for economic operators and improve the efficiency of national authorities' controls.
(a) Does EU action have clear benefits?

The proposal is expected to lead to a reduction of the illicit trade in drug precursors and a decline in the trafficking of designer precursors and other non-scheduled precursors (no less than -60% for two years based on similar previous measures). This would reduce the availability of drug precursors for the illicit manufacture of drugs, with social benefits that cannot be estimated because of their indirect nature.
Based on Section 8 of the impact assessment, the proposal would lead to significant simplification of the existing rules on drug precursors and to net benefits for operators. The net benefits of the proposed option for economic operators would amount to approximately EUR 25.27 million a year.

(b) Are there economies of scale? Can the objectives be achieved more efficiently at EU level (greater benefits per unit cost)? Will the functioning of the internal market be improved?

The functioning of the internal market will be improved by maintaining harmonised rules and by adapting them to new developments. Both more efficient monitoring measures and the reduction of burden for industry and authorities will be ensured by the implementation of a centralised IT system.

(c) What are the benefits of replacing different national policies and rules with a more homogenous policy approach?

Such benefits have not been estimated as there are currently no national policies to be replaced. Harmonisation rules for drug precursors have been in place for more than three decades. This proposal is aimed at adapting the existing 20-year old EU rules.

(d) Do the benefits of EU action outweigh the loss of competence of EU countries and local and regional authorities (besides the costs and benefits of acting nationally, regionally and locally)?

EU countries agreed to common rules on drug precursors in the 1990s, when the European Economic Community was notified to the United Nations as being responsible for the implementation of Article 12 of the Convention. Ever since, the harmonisation rules for drug precursors have proven their usefulness in both ensuring the smooth functioning of the internal market and the fight against the illicit manufacture of drugs. The evaluation, while drawing attention to the need to adapt the harmonisation rules to new developments, showed no evidence that EU action would no longer have added value. On the contrary, evidence gathered both during the evaluation and the impact assessment showed the advantages of a common stance against the diversion of drug precursors towards the illicit manufacture of drugs.

(e) Will there be greater legal clarity for those who have to implement the legislation?

Yes, the proposal would lead to significant simplification of the existing legal framework. The two Regulations would be replaced with a single Regulation, streamlining the procedures applicable to both internal and extra-EU trade. More details are available in Section 8.1 of the impact assessment.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement that makes it possible to establish the proposal's compliance with the principle of proportionality?

Yes. The explanatory memorandum says: 'The proposal does not exceed what is necessary for reaching the objectives pursued. The measures target a limited number of precursors, thus better targeting the controls without unduly hampering legal trade and innovation. The proposal better reflects the risks associated with each category of precursors and takes full advantage of digitisation. It strikes a fair balance between the need to reduce the availability of drug precursors for the illicit manufacture of drugs and the need to facilitate legitimate trade. Thus, despite a reduction in controls notably on bulk materials with significant legitimate uses, the diversion risk is properly addressed by strengthening the enforcement.'

3.2 Based on the answers to the questions below and on information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposal is an appropriate way of achieving the objectives pursued and does not exceed what is strictly necessary to do so.

(a) Is the initiative limited to objectives that EU countries cannot achieve satisfactorily on their own, and where the EU can therefore do better?

Yes. The proposed measures would harmonise the various formalities operators are to follow and enable national authorities to efficiently monitor transactions with drug precursors, while ensuring the smooth functioning of the internal market. EU countries would remain responsible for adopting the national measures needed to enforce the Regulation (rules on penalties) and to react promptly in case of suspicious transactions.
The rules would identify the substances concerned, to limit the application of the control and monitoring measures to what is necessary for achieving the objectives of the proposal.

(b) Is the form of EU action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with, the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

The control and monitoring rules on drug precursors should continue to be set out in a Regulation, as this instrument is directly applicable and will ensure uniform implementation for all economic operators across the EU.

(c) Does EU action leave as much scope for national decision-making as possible while achieving the objectives that have been set? (For example, is it possible to limit EU action to minimum standards or use a less stringent policy instrument or approach?)

The adoption of control and monitoring rules on drug precursors in the internal market is an international obligation of EU countries. Such rules cannot be replaced by minimum standards.

(d) Does the initiative create financial or administrative costs for the EU, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?

Yes, the adoption of the proposal will lead to costs for the EU, national authorities and economic operators. These costs are justified by the objectives to be achieved (to reduce the availability of drug precursors for the illicit manufacture of drugs and to facilitate the legitimate trade in drug precursors).

(e) While respecting EU law, have individual EU countries' special circumstances been taken into account?
N/A.