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COVER NOTE

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PART 1/2

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

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) 397 final} - {SWD(2025) 399 final}

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Glossary

Term or acronym	Meaning or definition
AEO	Authorised economic operator.
ATS	Amphetamine-type stimulants comprise two groups: • the amphetamines group: amphetamine, methamphetamine and non-specified amphetamines, and • the ecstasy group.
CAS Number	Unique identification number assigned by the Chemical Abstracts Service (CAS) in the US to every chemical substance described in the open scientific literature. The number is up to 10 digits long and has no significance to the chemistry, structure, or chemical nature of the molecule. It is a unique and unambiguous identifier for a specific substance to enable communication and links together available data and research about that substance.
Catch-all clause	Provisions of the Regulations according to which Member States may adopt measures concerning scheduled and non-scheduled substances. This is to enable authorities to obtain information on any orders or operations and to enter business premises. The internal market catch-all clause (Article 10) also includes detention and seizure of consignments. The external trade catch-all clause (Article 26) includes stopping consignments. Member States must adopt such measures for scheduled substances and can choose to adopt them for non-scheduled substances.
CND	Commission of Narcotic Drugs, one of the functional commissions of the United Nations' Economic and Social Council (ECOSOC), and the central drug policy-making body within the UN.
CUS Number	Identification number assigned to chemical products in the European Customs Inventory of Chemical Substances (ECICS) database.
Designer precursor	Drug precursor chemically related to scheduled substances, that has no known legitimate use, except in research and innovation and which has been designed with the sole purpose to avoid controls set out for other drug precursors.
Drug precursor	Chemical substances that can be used to manufacture illicit drugs.
ECICS	European Customs Inventory of Chemical Substances
EUDA	The European Union Drugs Agency, which replaced the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) as of 2 July 2024.
The evaluation	Report from the Commission to the European Parliament and the Council on the Evaluation of the EU drug precursors regulations, COM(2020) 768.

The Expert Group	The Commission Expert Group on Drug Precursors (E01317).
External Trade Regulation	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, OJ L 22, 26.1.2005, p. 1.
FTE	Full-time equivalent (unit of measurement of the workload of an employed person).
INCB	International Narcotic Control Board, the independent and quasi-judicial monitoring body for the implementation of the United Nations international drug control conventions.
Incident	Case reported by Member States in the European drug precursors database concerning the illicit use of drug precursors, which may be a seizure of drug precursors in the EU, shipments of drug precursors stopped by customs or thefts of drug precursors.
Internal Market Regulation	Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors, OJ L 47, 18.2.2004, p. 1.
Key precursors	Key precursors are substances containing the core molecule of the drug.
Non-scheduled substance	Any substance which, although not listed in the Regulations, is identified as drug precursor.
Operator	Any natural or legal person engaged in • supply of scheduled substances in the Union; or the storage, manufacture, production, processing, trade, distribution or brokering of these substances for the purpose of supply in the Union; • import, export of scheduled substances or intermediary activities relating thereto.
PEN	Pre-export notification.
PICS	Precursors Incident Communication System, a secure online tool developed by the INCB to enhance real-time communication and information sharing between national authorities on precursor incidents.
Scheduled substance	Any substance listed in the Annexes to the drug precursors regulations; mixtures and natural products containing such substances are included if they are compounded in such a way that the scheduled substance can be easily used or extracted by readily applicable or economically viable means. Medicinal and veterinary products containing ephedrine or its salts, pseudo-ephedrine or its salts are scheduled drug precursors for the purpose of external trade.
SDG	United Nations Sustainable Development Goals.

The study	Impact Assessment Study on the Revision of the EU drug precursors regulations, Economisti Associati, 2025, ISBN 978-92-68-25970-2.
Traditional drug precursor	Drug precursors which have legitimate uses in the production of various products, such as pharmaceuticals, food additives, cosmetic products, paints or fertilisers.
The UN Convention	The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, adopted in Vienna on 19 December 1988.
User	Any natural or legal person other than an operator who possesses a scheduled substance and is engaged in the processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, transformation or any other utilisation of scheduled substances.
VML	The EU Voluntary Monitoring List set out in accordance with Article 9(2) of the Internal Market Regulation and Article 10(2) of the External Trade Regulation.

1. Introduction

1.1. Political context: EU drugs policy and the single market

Illicit drugs like cocaine, heroin, opioids, and amphetamine-type stimulants (ATS), pose serious health and security problems. Several Member States are witnessing a rise in drug-related violence and criminal activity. Moreover, the drug market is increasingly marked by a widespread availability of a broader range of drugs, often with higher potency or purity, and in new forms[1].

Drug precursors are chemicals needed in the illicit production of drugs. Traditional drug precursors have significant legitimate uses. The evaluation of EU rules on drug precursors (Regulation (EC) No 273/2004 and Council Regulation 111/2005)[2] found several deficiencies, especially tackling designer precursors – drug precursors without known legitimate use[3] and saw a potential for administrative burden reduction[4].

Global proliferation and trafficking of designer precursors present significant challenges to drug precursor control. In response, both the United Nations Commission of Narcotic Drugs (CND)[5] and the International Narcotics Control Board in its 2024 report recommend controlling chemicals that are closely related to controlled precursors - such as families or derivatives of controlled precursors. In alignment with this strategy, countries like the USA, Canada, Argentina, Mexico and recently China (1st September 2024) introduced extended scheduling to families or derivatives of controlled precursors. Substance-by-substance scheduling is considered as a reactive approach to address the new substances used by criminals whereas innovative scheduling of families or derivatives of controlled precursors is a proactive approach making it harder to use new designer precursors in illicit manufacture.

At the multilateral level, the March 2024 Commission on Narcotic Drugs marked a significant milestone. For the first time, the INCB recommended scheduling as a direct application of UN Resolution 65/3, introducing proactive scheduling at the UN level. Several derivatives (esters) of controlled precursors have been added to Table I of the 1988 UN Convention. Although most of these esters had never been detected before, and thus did not meet the convention's requirement for evidence of use in illicit drug manufacture, all members of the Commission on Narcotic Drugs voted in favour of proactive scheduling. This decision underscores the urgent need to address designer precursors.

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[1] European Union Drugs Agency (2025), European Drug Report 2025: Trends and Developments, https://www.euda.europa.eu/publications/european-drug-report/2025_en.

[2] Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors, OJ L 47, 18.2.2004, p. 1. 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, OJ L 22, 26.1.2005, p. 1.

[3] except in research and innovation.

[4] Report from the Commission to the European Parliament and the Council on the Evaluation of the EU drug precursors regulations, COM(2020) 768. For security reasons, the document accompanying the report is not publicly available.

[5] CND Resolution 65/3 'Intensifying efforts to address the diversion of non-scheduled chemicals frequently used in the illicit manufacture of drugs and the proliferation of designer precursors' agreed in March 2022.

Drug precursor controls are a crucial component of drug supply reduction policy as outlined in the EU Drugs Strategy 2021-2025[6]. The EU Drugs Action Plan 2021-2025[7] further highlights the need to address the challenge posed by designer precursors. Additionally, the 2023 EU Roadmap to fight drug trafficking and organised crime[8] stresses the need to set out innovative ways to speed up and broaden the current approach to regulating drug precursors in response to new methods of illicit drug production.

The newly adopted Protect EU: a European Internal Security Strategy[9] announced a new EU Drugs Strategy and an EU Action Plan against drug trafficking to disrupt routes and business models[10].

The political guidelines of the Commission for 2024-2029 also announce the facilitation of business operations, particularly for small and medium enterprises (SMEs)[11], and aims to deepen the Single Market. The Competitiveness Compass emphasizes simplification as a key factor in boosting industry competitiveness[12].

Chemicals are omnipresent in society and economy. The EU chemical industry is a strategic sector, relevant for a multitude of products, with 56 % of chemicals going to other sectors. Europe's chemical industry has increasingly come under pressure in the recent years. It is therefore vital to ensure that legitimate industry does not bear the cost of criminal actions but is able to reap the benefits of the Single Market to the largest extent possible.

In the evolving political landscape, the fight against drugs and controlling drug precursors has emerged as pivotal element in strengthening diplomatic ties with the United States who engaged in family scheduling of fentanyl designer precursors.

The 2025 Commission Work Programme, in its security heading, announces proposing new rules governing drug precursors[13].

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[6] Council Conclusions on the EU Drugs Strategy 2021-2025, 14178/20, 18 December 2020.
[7] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, EU Agenda and Action Plan on Drugs 2021-2025 of 24.7.2020, COM/2020/606.
[8] Communication from the Commission to the European Parliament and the Council on the EU roadmap to fight drug trafficking and organised crime of 18.10.2023, COM/2023/641.
[9] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on ProtectEU: a European Internal Security Strategy, COM(2025) 148 final.
[10] The EU Ports Alliance's public private partnership on strengthened port protection will be extended to include smaller and inland ports and ensure maritime security rules are enforced. Moreover, in developing the upcoming EU Port Strategy, building on the EU Ports Alliance, the Commission will explore ways to further strengthen maritime security legislation to effectively address emerging threats, secure ports, and enhance EU supply chain security: European Ports Alliance Public Private Partnership.
[11] Ursula von der Leyen, Political Guidelines for the next European Commission 2024-2029, 18 July 2024, e6cd4328-673c-4e7a-8683-f63ffb2cf648_en (europa.eu).
[12] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A Competitiveness Compass for the EU, COM(2025)30 final.
[13] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Commission Work Programme 2025, COM(2025)45 final.

This initiative will contribute to the achievement of three of the United Nations Sustainable Development Goals (SDGs): SDG #9 'Industry, innovation'; SDG #3 'Good health and well-being and infrastructure' and SDG #16 'Peace, justice, and strong institutions'.

1.2. Legal Context

1.2.1. Current EU rules on drug precursors

The UN Convention against Illicit Traffic in Narcotic Drugs[14] obliges the Parties to take measures to prevent the diversion of substances frequently used in the illicit manufacture of drugs. The EU concluded the UN Convention in 1990[15] and subsequently adopted rules on drug precursors. Currently the UN Convention is implemented by Regulation (EC) No 273/2004 ('the Internal Market Regulation')[16] on monitoring and control of drug precursors for their possession and placing on the market and Regulation (EC) No 111/2005 ('the External Trade Regulation')[17], for their trade between the EU and third countries. Drug precursors may be either scheduled (listed and controlled in the regulations) or non-scheduled (for which there are no legally binding obligations).

Scheduled drug precursors are classified into four categories depending on their role in the illicit drug production and the existing legal trade. Category 1 substances are the most critical, comprising chemicals that form the essential core molecules of drugs, making it impossible to produce these drugs without them. Some of them have legitimate uses, while others have no known legitimate use, except research (designer precursors). Category 2 covers less sensitive substances compared to category 1[18], while category 3 contains contain bulk chemicals. They are significant in the illicit drug production but also have widespread legitimate uses. For external trade, Category 4 includes medicinal products that contain ephedrine and pseudoephedrine. Depending on the category, operators and users must either hold a license or registration, secure their premises, report suspicious transactions, ensure proper labelling and documentation, maintain transaction records for three years, designate a responsible officer, obtain import and export authorisations, including pre-export notification, and limit trade to customers which have a licence or a registration. [19]

Some *non-scheduled substances* are listed in the EU Voluntary Monitoring List (VML), which carries no legally binding obligations. In addition, a catch-all clause allows national measures to control suspicious transactions involving such substances.

The regulations establish the European database on drug precursors, a centralised database with three functions: to support the Commission in reporting data on legal trade and incidents with

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[14] The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, adopted in Vienna on 19 December 1988.

[15] Council Decision (90/611/EEC) of 22 October 1990 concerning the conclusion, on behalf of the European Economic Community, of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, OJ L 326, 24.11.1990, p. 56.; Annex 9 provides details on the implementation of the UN Convention by the Internal Market and External Trade Regulations.

[16] Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors, OJ L 47, 18.2.2004, p. 1.

[17] 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, OJ L 22, 26.1.2005, p. 1.

[18] For internal trade, category 2 is divided into categories 2A and 2B due to a higher risk of diversion of category 2A substances.

[19] More details on the legal provisions can be found in Annex 9.

drug precursors to the UN, to maintain a register of operators holding licenses or registrations so that their status can be consulted by other authorities and to enable operators to fulfil their reporting obligations online. However, when the third function was discussed in around 2011, there were doubts about the cost-benefit ratio of such a function, and this is why it has not been implemented to this date.

1.2.2. Interplay with other legislation and initiatives

The drug precursors regulations help determining the material scope of minimum national rules on criminal acts concerning precursors set out by Member States in accordance with Council Framework Decision 2004/757/JHA.[20] The Commission is conducting an evaluation of the Council Framework Decision and in that context is assessing the extent to which the Framework Decision has contributed to tackling designer precursors.[21]

The EU Drugs Agency (EUDA) plays an important role in the field of drug precursors. Its tasks as set out in the Agency's new mandate[22] are detailed in Section 5.1.

Drug precursors are also governed by EU chemicals rules. Under the REACH Regulation[23], companies producing or placing a substance on the market in quantities of one tonne or more per year must register it and provide data on its properties, hazards and uses[24]. The CLP Regulation[25] obliges companies to classify, label and package hazardous substances before placing them on the market. Some drug precursors may also be subject to sector-specific rules, such as the Cosmetic Products Regulation[26] or the Detergents Regulation[27]. These rules concern the inherent safety and health risks and characteristics of the substances concerned. Drug precursor rules, on the other hand, have different objectives related to the dual use nature of these products and the prevention of illegal trade of otherwise legal substances.

This initiative also supports the EU Customs Reform[28], which aims to establish a new EU Customs Authority maintaining and EU Customs Data Hub. The Data Hub will replace the

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[20] Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, OJ L 335, 11.11.2004, p. 8–11, https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004F0757

[21] Criminal acts and penalties for drug trafficking – evaluation

[22] Regulation (EU) 2023/1322 of the European Parliament and of the Council of 27 June 2023 on the European Union Drugs Agency (EUDA) and repealing Regulation (EC) No 1920/2006, OJ L 166, 30.6.2023, p. 6.

[23] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30/12/2006, p. 1.

[24] A targeted revision of the REACH Regulation is announced in the Commission Work Programme 2025.

[25] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353, 31/12/2008, p. 1.

[26] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22/12/2009, p. 59.

[27] Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents, OJ L 104, 8.4.2004, p. 1.

[28] See European Commission, *EU Customs Reform*, available at: https://taxation-customs.ec.europa.eu/customs-4/eu-customs-reform_en

current fragmented customs IT infrastructure in EU Member States, enhancing interoperability with related policy areas. Data on drug precursors will be integrated into the Data Hub[29].

1.3. Economic context: the licit drug precursors market

Drug precursors are critical components of various industrial supply chains[30], serving essential roles in industries such as pharmaceuticals, flavouring and fragrance, batteries, cosmetics, textiles, oil refinery, water treatment, food additives, explosives, rubber production, fertilisers, plastics or dyes[31].

The supply chain for drug precursors involves a diverse range of actors, including large-scale chemical manufacturers who produce these substances in bulk for industrial use, as well as specialised producers who create more refined or custom chemical products tailored to specific industrial needs. Distributors and logistics providers also play key roles in ensuring that these substances are transported and stored safely.

Due to the use of drug precursors across all chemical sectors[32], the market to be analysed concerns the entire chemical industry. The EU chemical industry is one of the largest and most competitive industries globally, contributing significantly to the EU economy and employment (about 1.2 million jobs in 2022[33]). It displays a 77% higher labour productivity (2020) and 48% higher paying wages (2022) than the EU's manufacturing average. The EU chemical sector is the second-largest global spender on capital, consistently contributing over 15% of the EU chemical industry's value added (19.5% in 2023). Since 2021, it has spent around EUR 10 billion annually on R&I, which represents 6% of the sector's value added. In 2023, the EU led the sector with nearly EUR 850 billion in trade, comprising EUR 525 billion in exports and EUR 325 billion in imports, yielding a trade surplus of approximately EUR 200 billion[34]. However, the sector's high energy intensity has made it vulnerable to rising energy prices, negatively affecting the EU's competitive position in the global chemical industry.

Nonetheless, while having important uses, the overall market share of scheduled drug precursors is limited. The legal use of precursors in the EU amounts to 10.6 million tonnes per year[35], with exports to third countries totalling representing approximately **0.15%** of total chemical exports (worth EUR 765.67 million) and **1.07%** of total chemical imports (worth EUR

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[29] Further detail is provided in Annex 8.

[30] Annex 10 lists all scheduled substances, their main known legitimate uses, if any, and information on legitimate trade.

[31] For more detailed information, including the latest trends in the (diversion of) legitimate trade of these substances and their regulatory challenges, see the INCB's technical reports on precursors, available at: https://www.incb.org/incb/en/precursors/technical_reports/precursors-technical-reports.html.

[32] Annex 10 lists all scheduled substances, their main known legitimate uses, if any, and information on legitimate trade. For further analysis of the industry, please see Annex 10.

[33] Statista, Number of employees in the European Union's chemical industry from 2008 to 2022, 20.11.2023, available at: https://www.statista.com/statistics/1307411/chemical-industry-number-employees-eu/#:~:text=The%20number%20of%20employees%20in%20the%20European,with%20around%20355%20thousand%20people%20in%202022

[34] Eurostat (2023 data), EU trade since 1999 by SITC – Chemicals and related products, n.e.s, 20.08.2024, available at: https://ec.europa.eu/eurostat/databrowser/view/ds-018995__custom_12626041/default/table?lang=en

[35] Source: data on legal use and trade gathered in the EU drug precursors Database, 2018-2022 average.

3.48 billion)[36]. This also indicates an inverted pattern for drug precursor trade (where imports exceed exports) compared to the overall chemical industry (where exports exceed imports).

Within the EU, there were approximately 4 000 active licenses or registrations to trade in drug precursors in 2023[37]. 92% of these companies are SMEs[38].

2. Problem definition

2.1. What are the problems?

2.1.1. Problem #1: Drug precursors continue to be available for the illicit production of drugs

Illicit drug use affects society as a whole, be it through illegal drug use, the operation of the markets and their operation. These can be indirect effects such as the strain on health budgets or corruption and criminal practices affecting institutions and businesses[39]. Processed illegal drugs require drug precursors, either as solvents or as essential elements of the drugs[40].

Drug trafficking is a major profit-generating activity of organised crime, representing about one-fifth of global crime proceeds.[41] The EU's illicit drug retail market is valued at EUR 31 billion[42]. However, from a drug precursor policy perspective, the EU plays a significant role in the production of amphetamine type stimulants (ATS), indicating a substantial availability of the necessary drug precursors within the region[43].

The exact volumes of illegal drugs and their precursors are unknown due to their illicit nature, reliable data exists only on uncovered illegal activities. Data describing the illicit use of drug precursors is therefore by definition limited.

Data on illegal production sites dismantled in 2023 suggest that significant drug production activities take place in the EU. Specifically, nearly 500 production sites were dismantled across the EU in 2023, of which 379 were involved in ATS production[44]. Secondly, the frequency of incidents involving drug precursors (seizures and thefts), as reported in the European drug precursors database, shows an upward trend in drug precursor trafficking with a notable decline

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[36] Source: DG TAXUD Surveillance database, 2023.
[37] Namely, economic operators holding at least one active licence or registration for the EU market of drug precursors. Note that, as a proxy, this underestimates the figure since – at present – economic operators trading in Category 3 internally only, are not required to register and those trading in Category 4 are not required to register.
[38] There is no public source regarding share of SMEs trading in drug precursors. The percentage of the relevant (closest) manufacturing chemicals sub-sectors according to Eurostat data is 92%, which aligns with the view of public authorities consulted.
[39] European Drug Report 2025, p. 11.
[40] Cannabis cultivation does not rely on the use of drug precursors. For an overview by drug, see Annex 10, section 3.1.
[41] Joint analysis of Europol and the EUDA, EU Drug Markets: In-depth analysis | www.euda.europa.eu
[42] EUDA and Europol (2024), EU Drug Markets Analysis: Key insights for policy and practice, Publications Office of the European Union: https://www.europol.europa.eu/cms/sites/default/files/documents/EU%20Drug%20Markets%20Analysis%202024.pdf, p. 10 .
[43] While cannabis and cocaine are the most widely consumed drugs in the EU and heroin or other opioids account for the majority drug-related deaths, these drugs are primarily produced outside the EU.
[44] European Drug Report 2025, tp. 50-51.

in volume in post-COVID 2022. In 2023, the number of reported incidents was 2 100, corresponding to approximately 541 tonnes of precursors. Most of incidents regard substances involved in the production of amphetamine group, which in 2019-2023 accounted for 88 % of total cases (around 60 % in terms of volume). In the same period, precursors involved in the production of ecstasy accounted for 8 % of cases (but 29 % in terms of volume), while the rest of cases are almost evenly shared between cocaine and heroin precursors.

In 2022, as shown in Figure 1, 28.94 tonnes of key precursors[45] to produce drugs of the amphetamine group were seized in Europe. Most of these seizures included designer precursors (25.6 tonnes) [46].

Figure 1: Total seizures of drugs and drug precursors in 2022

Total seizures in 2022	Cocaine (in tonnes)	Heroin (in tonnes)	ATS (in tonnes)	
			Amphetamine group	Ecstasy
Of the drug	322.5	8	8.5	1.2
Of the corresponding drug precursors - key precursor - equivalent drug production - other chemicals	0.17 0.85	0.15 0.04 – 0.13	28.94 7.24 – 20.26	18.82 4.70 - 13.17 152.92

Source: the European Drug Report 2024, the European drug precursors database

In addition, as shown in Figure 2, it is estimated that 3.1 million EU citizens consumed 101.2 tonnes ATS in 2022[47]. Depending on the production methods, 197.5 to 378.5 tonnes of key precursors would have been needed to produce that quantity of drugs.

Figure 2: Estimated consumption of drugs and drug precursors needed to produce them

Total 2022 EU market	Cocaine	Heroin	ATS	
			Amphetamine group	Ecstasy
Estimated EU drug market:				
- number of users (millions)	3	1	1.3	1.8
- drug consumption (tonnes)	158	124	90.2	11
Estimated drug precursors market in tonnes *(how much is needed to produce the drug market)*				
- key or essential precursors[48]	31.6	340	181 t – 362	16.5
- other chemicals	2.4 to 3.2	214	-	-

Source: the European Drug Report 2024 and EUDA estimations

[45] Key precursors are Category 1 precursors and their related designer precursors.
[46] European Monitoring Centre for Drugs and Drug Addiction (2024), European Drug Report 2024: Trends and Developments, https://www.emcdda.europa.eu/publications/european-drug-report/2024_enp. 11-12.
[47] The European Drug Report 2024.
[48] Key precursors are substances containing the core molecule of the synthetic drug. Essential chemicals are the chemicals without which cocaine or heroin cannot be extracted.

A Dutch study[49] revealed that 614 tonnes of the amphetamine group drugs and 147.7 tonnes of ecstasy were produced in 2017[50] only the Netherlands. In that same year, 1.7 million EU citizens consumed 118 tonnes of amphetamine and 2,6 million citizens consumed 16 tonnes of ecstasy[51]. These significant differences in production and consumption estimates suggest that the EU is an important production hub for the worldwide drug market of ATS.

2.1.2. *Problem #2: Economic operators and public authorities face unnecessary burdens and inefficiencies in the free movement of licit drug precursors*

The evaluation[52] highlighted opportunities to simplify the complex legal framework and improve procedures for drug precursors without compromising the levels of controls of legitimate drug precursor trade.

According to the study, feedback of both the economic operators and national authorities about the administrative burden of the regulations was mixed It is true that in the targeted survey, only a minority of public authorities consider implementation burden as problematic. Specifically, only 3 out of 28 consider the burden imposed on authorities to be excessive, and only 5 out of 28 consider the burden imposed on legitimate operators to be excessive. According to the evaluation, for some 36% of operators surveyed (29 out of 81 in total), the drug precursors imposed unnecessary burdens on legal businesses, against an equal number of respondents (29 out of 81) of respondents who considered burdens to be acceptable. SMEs had a more favourable view compared to large firms.

Likewise, the public consultation for the evaluation confirmed that the benefits achieved in terms of controlling the supply of the drug precursors required to manufacture illegal drugs justify the burden borne by businesses: 56%. Only 16% of the respondents disagreed with this assessment, with the rest being neutral or having no opinion. Yet, during the public consultation for the impact assessment more mixed views have been gathered on the regulatory burden for operators. Certain requirements are considered as particularly burdensome – e.g. the need to obtain declarations of intended use from customers (very/moderately burdensome for 27 out of 53 respondents), and the need to obtain import/export authorisations (very/moderately burdensome for 23 out of 53 respondents) - while others are not – e.g. the obligation to notify suspicious transactions, labelling obligations, etc.[53]. Most respondents of the public consultation consider the administrative burden as 'highly' or 'moderately' heavier for SMEs[54].

These burdens and inefficiencies cause administrative cost for both companies engaged in the legal trade of drug precursors and the public authorities overseeing them, as shown in Figure 3. For internal trade, about 3 500 operators incur significant costs to verify paper-based customer declarations without adequate safeguards that these are correct. Approximately 4 000 economic operators must annually report a summary of their transactions[55].

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[49] Tops, Pieter, van Valkenhoef, Judith, van der Torre, Edward, van Spijk, Luuk, *Where a Small Country Can Be Big: The Netherlands and Synthetic Drugs in the Past 50 Years* , Koninklijke Boom Uitgevers, Den Haag, 2018.
[50] The most recent study that estimates the drug production instead of the consumption relates to the year 2017.
[51] The European Drug Report 2018, https://www.euda.europa.eu/publications/edr/trends-developments/2018_en, p 15.
[52] Report from the Commission to the European Parliament and the Council on the Evaluation of the EU drug precursors regulations, COM(2020) 768 and confidential document accompanying the report p. 59ff
[53] Please see Annex 2 for further details on the consultation results on this aspect.
[54] 28 out of 46 respondents
[55] Annex 4 provides detailed information on the calculations and assumptions.

Public authorities face burdens, manually compiling and transmitting data to the Commission and ultimately the UN.

Figure 3: Estimated baseline administrative costs for complying with the main legal obligations

In millions of EUR	Licences & registrations	Import & export authorisations	Customer declaration	Annual reporting
Public authorities				
One-off costs	1.28 (new)	N/A	N/A	N/A
Annual costs	0.71 (renewals)	6.87	N/A	3.21
Economic operators				
One-off costs	0.74 (new)	N/A		N/A
Annual costs	0.22 (renewals)	6.41	15.6 (SMEs) 6.9 (large companies)22.50	2.57 (SMEs) 0.64 (large companies)3.21

Source: the study (see Annex 4 for more details on assumptions and calculations based on standard costs model)

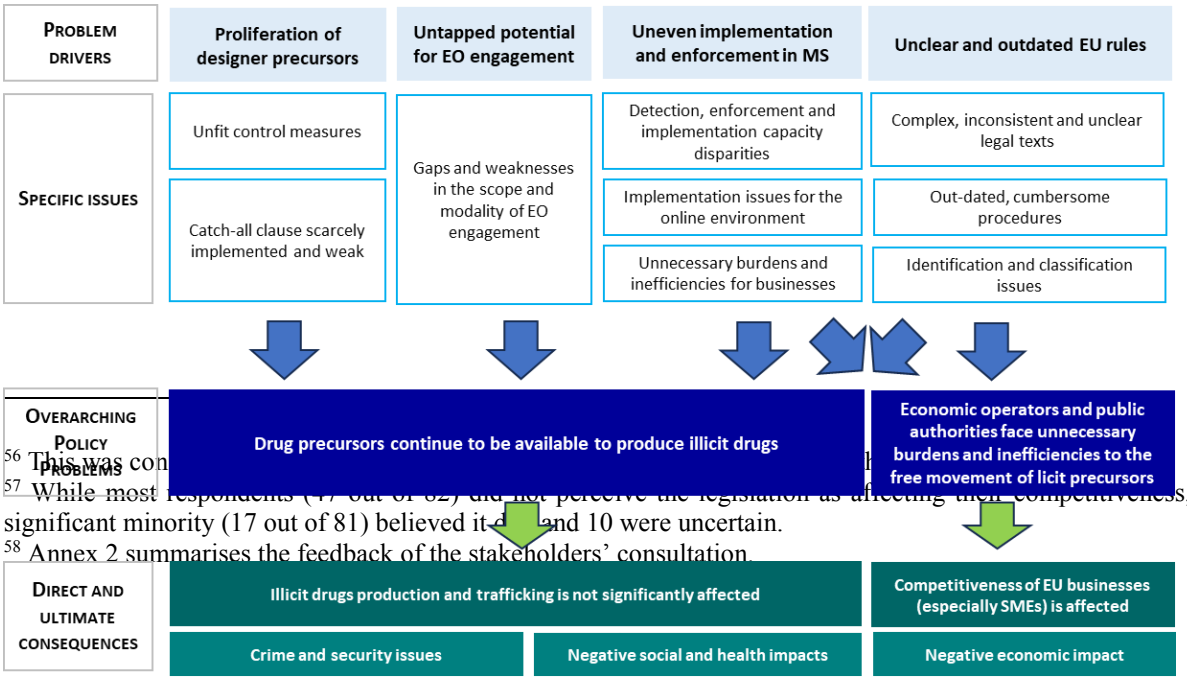
Furthermore, outdated and unclear EU rules create inefficiencies and long wait times for businesses, hindering swift adaptation to market changes or price fluctuations demands. Especially given that there is an increasing recourse to designer precursors, the existing control mechanisms are becoming increasingly ill-targeted and therefore unnecessary as well as burdensome[56].

This might negatively impact EU companies' competitiveness. Survey responses on the regulations' impact on competitiveness are mixed, with most respondents noting no effect and some noting it did.[57] While the regulations may not broadly undermine the EU competitiveness, particularly SMEs expressed concerns in the context of intra-EU competition[58].

2.2. What are the problem drivers?

The problems are caused by 4 drivers, as shown in Figure 4.

Figure 4: Problem tree

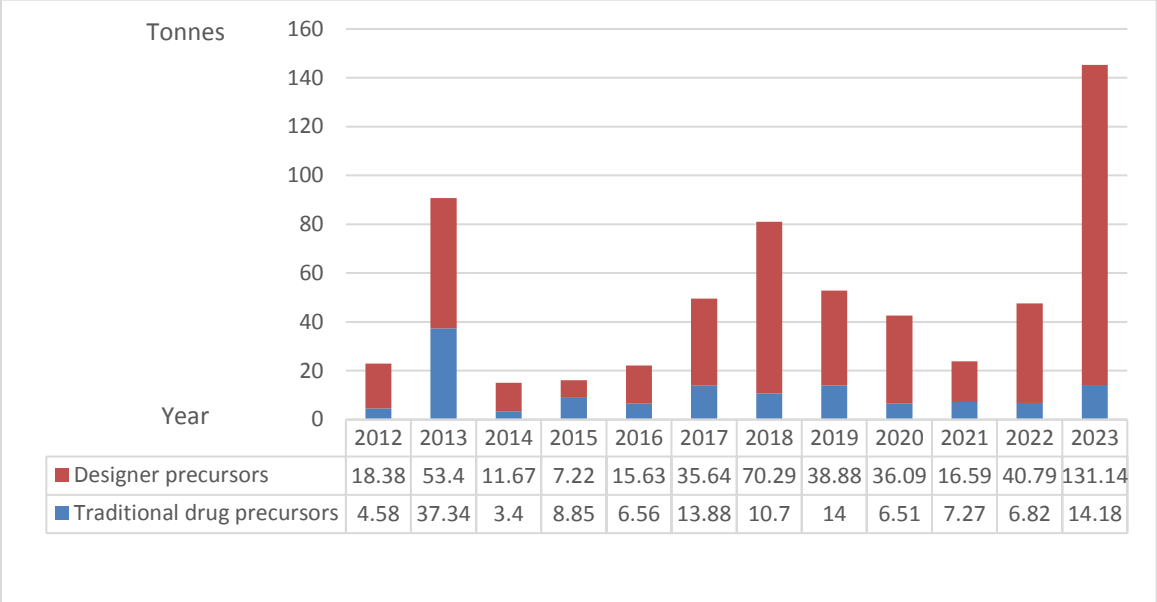


[56] This was con
[57] While most respondents (47 out of 82) did not perceive the legislation as affecting their competitiveness, a significant minority (17 out of 81) believed it d and 10 were uncertain.
[58] Annex 2 summarises the feedback of the stakeholders' consultation.

2.2.1. Driver 1: Proliferation of designer precursors

As described in section 2.1., the main challenge to the current EU control system consists of the proliferation of designer precursors, as shown in Figure 5.

Figure 5: Seizures of traditional and designer key precursors in the period 2012-2023



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Designer precursors	18.38	53.4	11.67	7.22	15.63	35.64	70.29	38.88	36.09	16.59	40.79	131.14
Traditional drug precursors	4.58	37.34	3.4	8.85	6.56	13.88	10.7	14	6.51	7.27	6.82	14.18

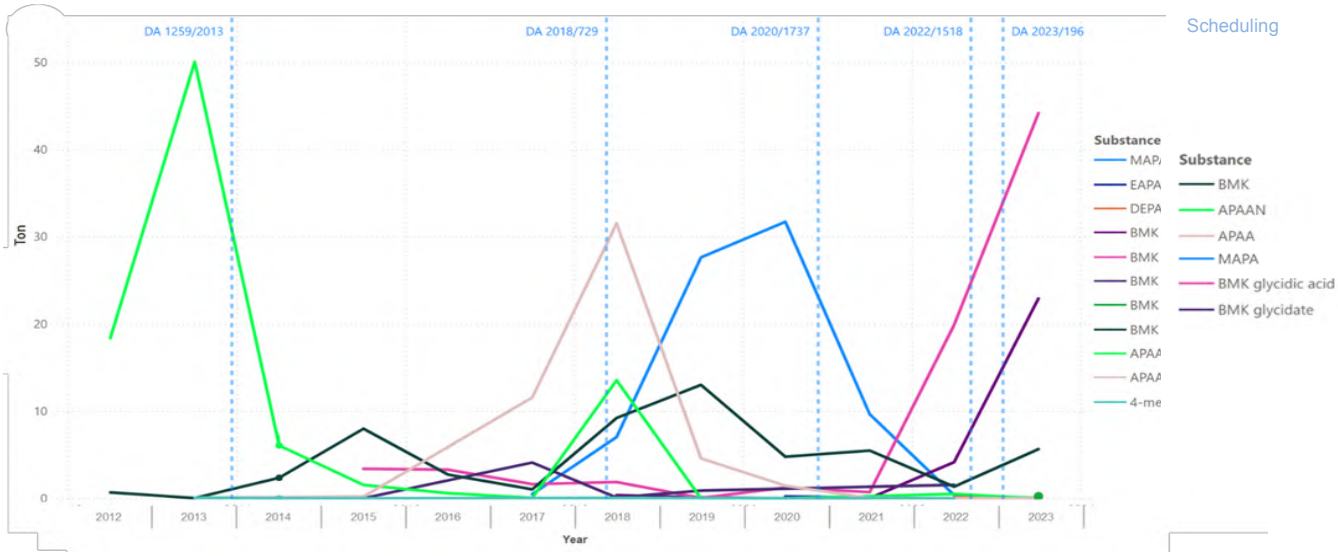
Source: The European drug precursors database

Designer precursors are intentionally designed key precursors created by criminals to circumvent regulatory controls, and as such they are exclusively known for their illicit uses. Designer precursors are especially used in the production of synthetic drugs, i.e. MDMA, amphetamine, methamphetamine, and synthetic opioids. They have emerged because of the controls applied to traditional drug precursors, which prompted criminals to find ways to bypass such controls. Since their first appearance around 2010, designer precursors have rapidly replaced traditional drug precursors in the illicit drug supply chain. In 2023, about 90 % of the 142.5 tonnes of key precursors seized were designer precursors. The issues with designer precursors can be considered as part of drug criminality as the modus operandi is identical i.e. designer precursors are misclassified as another product, packages are mislabelled, fake addresses and names of companies are used etc. The current regulations are not adapted to respond to this development.

The proliferation of designer precursors implies an increase of trafficking of non-scheduled substances. As already explained, there are no legal obligations attached to non-scheduled substances in the regulations. The evaluation revealed that the catch-all clause for non-scheduled substances did not prove successful for various reasons. Firstly, the catch-all clause allows but does not oblige Member States to adopt rules empowering their authorities to act swiftly in the event of suspicious transactions with non-scheduled substances. Consequently, only a few Member States have adopted such measures. Secondly, national authorities face difficulties in identifying sufficient evidence to justify their intervention, as these substances are not formally scheduled. Thirdly, the External Trade Regulation' only prohibits import or export, with no provision for seizure, thereby limiting the deterrent effect on criminals.

To reinforce the response of national authorities, the Commission scheduled designer precursors in Category 1. However, the ordinary substance-by-substance scheduling is unfit for designer precursors regarding both timeliness and scope. Firstly, while it could easily take one year until a delegated act is published[59], criminals need less time to design new substances. Secondly, scheduling of individual substances at a time also implies that criminals can switch to the next generation of designer precursors in response to the placement of a given substance under control. Figure 6 illustrates the progression of designer precursors of BMK[60], a key precursor of amphetamine. To evade control measures, criminals began using various designer precursors. APAAN[61] was the first designer precursors to be scheduled late 2013. After its scheduling, seizures of APAAN dropped significantly. In 2018, APAA[62] emerged as the new designer precursors. Criminals, anticipating the scheduling of APAA, quickly turned to MAPA[63] as the next alternative. Following the EU's scheduling of APAA and MAPA in 2020, seizures of these designer precursors also declined, with criminals already preparing the next set of designer precursors.

Figure 6: Seizure of BMK and its designer precursors – impact of scheduling



Legend: Commission Delegated Regulation (EU)1259/2013, scheduling APAAN; Commission Delegated Regulation (EU) 2020/1737, scheduling APAA, MAPA; BMK glycidic acid, BMK methyl glycidate64; Commission Delegated Regulation (EU) 2022/1518, scheduling EAPA65; Commission Delegated Regulation (EU) 2023/196, scheduling DEPAPD66.

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[59] Several consultations need to take place (publication for public feedback, Technical Barrier to Trade notification), in addition to the 2-month for the Council and the EP to object to the delegated regulation.
[60] 1-phenyl-2-propanone, BMK, is a chemical substance used as a fragrance or flavouring agent. It is a Category 1 substance since the 1990's.
[61] Alpha-phenylacetoacetonitrile.
[62] Alpha-phenylacetoacetamide.
[63] Methyl alpha-phenylacetoacetate.
[64] BMK glycidic acid and BMK methyl glycidate remained highly available, because it was not yet scheduled as international level. See the study.
[65] Ethyl alpha-phenylacetoacetate.
[66] Diethyl (phenylacetyl) propanedioate.

Source: The European drug precursors database

2.2.2. Driver 2: Untapped potential for economic operators' engagement

The identification of illicit use of drug precursors heavily depends on the cooperation of the legitimate operators, especially on the notification of suspicious transactions[67]. While a relative majority of operators expressed a positive opinion on the current cooperation between authorities and the industry, national authorities are comparatively less satisfied[68]. In accordance with the study, there is a large discrepancy in the number of notifications across the EU: in 2023, 16 Member States received 324 notifications, three out of them received roughly 2/3 of the total, while seven reported no notification at all.[69] These 324 notifications[70] can be compared to the 1 900 seizure cases[71] of 'traditional' precursors in 2023 that have been diverted from the legal trade circuit[72]. Various reasons can lead to a reduced number of notifications, including a lack of awareness of the rules or of the common ways to produce drugs. Besides the known complexity of the legal framework, the access to information is difficult. The guidelines for the identification of suspicious transactions and the VML are communicated by national authorities only to trusted operators. This unavoidably leads to situations where operators dealing with non-scheduled substances do not have access thereto.

2.2.3. Driver 3: Uneven implementation and enforcement in Member States

The 2020 evaluation concluded that the implementation varied significantly among Member States due to differences in resources, verification practices and national circumstances influencing their priorities[73]. The in the targeted survey, authorities reconfirmed this uneven implementation and enforcement across EU countries[74]. This creates paths of least resistance that may be exploited for trafficking precursors with open internal borders, the EU's security is only as strong as its weakest point of entry [75][76].

The efficient enforcement of the regulations is challenged by the difficulties in identifying designer precursors. 11 of the 37 national authorities[77] in the targeted survey indicated

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[67] The evaluation pointed out to deficiencies in the application of the regulations to acetic anhydride, a drug precursor with significant legitimate trade. Nevertheless, the study could not find any evidence that any such difficulties would be of a general nature or in any way caused by an inappropriate regulation at EU level. The remaining explanation seems to be the insufficient cooperation with the industry, which is the first line of defence to avoid the diversion from legitimate uses to illicit manufacture of drugs, by notifying suspicious transactions.

[68] Targeted survey :33 out of 80 operators replied positive, against 22 negative and 12 out of 28 authorities replied negative against 8 positives.

[69] Targeted survey.

[70] Targeted survey.

[71] Source: EU drug precursors database

[72] The 2025 EU Drug Market analysis on MDMA of EUDA and Europol confirms that the supply is typically assured by dedicated criminal networks with connections to legitimate business.

[73] Confidential document accompanying the evaluation report, p. 84, See also Annex 10, Section 3.3.

[74] Targeted survey:15 out of 27 national authorities are of opinion that the EU drug precursors policy is unevenly implemented or enforced across EU countries.

[75] Study, Annex 6, p. 69. Also, EUDA, OLAF and Europol investigators confirmed the exploitation of weak entry points by criminals as one of the modus operandi.

[76] Given the decentralisation of the current drug precursors systems, the seizures of precursors at an EU border that differs from their destination country indicates the use of paths of least resistance. In 2023, 40% of the key precursors seized were seized at EU borders other than their intended destination.

[77] 37 national authorities, based in 21 Member States participated in the survey.

insufficient enforcement capacity, and interviews pointed, *inter alia*, to the lack of reference standards for forensic purposes and of detection equipment at EU entry points.

The European drug report 2025 listed online trafficking of precursors among the trends and development for illicit drug markets[78]. Surface websites are used to sell drug precursors and other substances used in drug production. According to the report, buyers and sellers favour especially social media platforms while the attractivity of the darknet has diminished. In accordance with Europol, the illegal trade of precursors takes place on both the surface web and the darknet, but the available evidence is largely anecdotal, as no systematic monitoring of this issue is carried out in the EU.

In addition, the uneven enforcement and implementation capacity generates unnecessary burdens and inefficiencies for businesses. For example, the limited resources available in combination with the current rules lead to up to three-months waiting periods for receiving a (renewed or modified) license or registration[79].

The evidence collected both during the evaluation and the study confirm that there are various national rules implementing the regulations. For example, licenses and registrations have various periods of validity, some are renewed after three years - others automatically. In several Member States, licenses cost the same as registrations (EUR 1 700 in Sweden, EUR 350 in Belgium, EUR 110 in Germany), while in others a distinction is made (EUR 170 license fee in Poland compared to just EUR 2.30 for registration). Finally, some Member States have additional requirements at national level (such as a ban on certain designer precursors based on a national list in the Netherlands; Czechia controls the quantity of Category 4 products that individuals can buy in pharmacies; Denmark has special rules for issuing licences for substances with no known legal use or Italy requires to notify antidrug authorities of shipment of precursors within 24 hours since the movement has physically occurred). The lack of harmonisation in Member States is problematic especially for companies that operate in multiple markets, as they must customise procedures depending on the specific country.[80]

2.2.4. Driver 4: Unclear and outdated EU rules

EU rules on drug precursors are not sufficiently clear and targeted.

Firstly, the legal framework is too complex. Two regulations govern the trade of the same substances: e.g. some of the provisions are not aligned leading to difficulties in implementation. Most of the public authorities that responded to the targeted survey (16 out of 28) found the co-existence of two regulations inconvenient[81].

Secondly, the interviews conducted during the study showed that the regulations are interpreted variously across Member States. For example, one company had to request a registration for

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[78] EUDA, The European Drug Report 2025, p. 14; While online trade was identified as an issue by the evaluation, this assessment predates the adoption of the DSA. Illegal online trade is therefore no longer treated as a separate problem driver but as an aspect of enforcement. The DSA regulates online intermediaries and platforms such as marketplaces, social networks, content-sharing platforms, app stores, and online travel and accommodation platforms. Its main goal is to prevent illegal and harmful activities online and the spread of disinformation. Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market for Digital Services and amending Directive 2000/31/EC (Digital Services Act), OJ L 277, 27.10.2022, p. 1–102.
[79] Study, p. 38.
[80] Study, p. 33.
[81] Annex 9 points out the numerous situations where there are differences in drafting the same obligations.

activities in one Member State but not for identical activities in another due to various interpretation of 'placing on the market'. Similarly, discussions in the 2023 and 2024 meetings of the Commission Expert Group on drug precursors ('the Expert Group') pointed out that national authorities have various understandings as regards which mixtures containing scheduled substances remain subject to control rules. A different treatment of the same mixture (as precursors or not) can lead to substantial differences in administrative burdens between Member States but ultimately also to an uneven enforcement of the rules.

In addition, there are disparities between the legal obligations of various actors in the supply chain, which leads to possible weaknesses in the overall anti-diversion controls. Thus, users of Category 1 substances do not have the same obligations to secure premises and report thefts as operators dealing with the same substances. This represents a potential loophole for the control of drug precursors. Similar discrepancies exist as regards intermediary activities.

Thirdly, the risk-based approach underpinning the regulations is insufficiently tailored. There are disproportionate obligations as regards low-risk transactions, concerning small quantities of Category 1 substances needed for research or as reference samples. These quantities are insufficient to produce illegal drugs at a commercial scale. More generally, several interviewed operators trading in Category 3 substances considered it excessive to require registration if these substances are exported above the annual export amount in Annex 1 of Delegated Regulation (EU) 2015/1011.

Fourthly, the regulations set out only paper-based monitoring rules. At national level, very few Member States (such as Portugal) have digital offerings that span the requirements. Many Member States have digitalised aspects of their systems but still rely on paper as well (for example, Italy, the Netherlands, Belgium, Poland, Greece or Denmark). In addition, significant differences exist in terms of the level of digitisation depending on the type of formality considered[82]. In Belgium, the introduction of a digital tool reduced the period for granting licences and registrations from three months to two weeks. This example gives an indication of the delays encountered by a lack of digitisation. In interviews, especially the customer declaration was regarded as inefficient, prone to errors and falsifiable[83].

The main burden in terms of annual reporting is felt by national authorities who are obliged to submit data on licit trade and incidents involving drug precursors. Authorities are required to manually validate and input the data from operators, which arrive in various formats. Public authorities' responses on the effort spent on annual reporting vary from 14 days, to weeks, to months, to 2 or even 4 full-time equivalent (FTE), per year. Operators spend hours or days to fulfil their reporting obligations[84]. One of the reasons estimates vary is that reporting requirements are highly detailed in some Member States (Romania, Spain, Czechia) but less so in others (Germany and Finland). When individual transactions must be reported separately, the burden becomes more substantial. Again, these differences can also have an adverse effect on the level of controls in different Member States.

[82] Annex 8 provides more details on the digitisation in the Member States.
[83] The study, p. 40.
[84] 22 out of 81 operators claimed to spend hours, while 35 out of 81 operators claimed to spend days in fulfilling their reporting obligations.

Finally, a large majority of respondents to the public consultation (38 out of 53) qualified identification of substances as a 'major' or 'moderate' problem[85]. Authorities and economic operators are not familiar with new substances that can be used as designer precursors. There is limited information available to national authorities to characterise the threats posed by the numerous new substances (illicit uses, processing methods, etc.)[86]. Such substances have frequently not been assigned a Chemical Abstracts Service (CAS) number and do not have a univocal Combined Nomenclature (CN) code. They are also typically not registered under REACH[87], their chemical name is not standardised and their spectrum[88] is unknown. As a result, authorities struggle to identify substances that are then used in illicit drug production.

2.3. How likely is the problem to persist?

Drug precursors rules no longer correspond to new trends in the illicit production of drugs or digitised business practices. There is no indication that illegal drug production will shift away from designer precursors. This means that controls will become less targeted on the evolving practices of illicit precursor trade and, as a result, less effective. On the other hand, administrative burdens on businesses would remain.

In addition, disparities in national legal systems and Member States' capacity will continue to be exploited by criminals for trafficking precursors through 'paths of least resistance'. Therefore, drug precursors will continue to be available for the illegal production of drugs. While it is difficult to quantify the effect of drug precursor rules on public health, unchanged rules will increase the illicit use of drug precursors and indirectly have an adverse effect on security and public health.

Legal trade in drug precursors is following an upward trend. Between 2020 and 2023, the total trade volume of drug precursor exports amounted to approximately 15.68 million tonnes, so approximately 2.61 million tonnes per year.[89] At the same period, the import volumes of drug precursors gradually declined from 0.72 million tonnes in 2020 to 0.67 million tonnes in 2023, peaking at 0.73 million tonnes in 2021. In the absence of specific actions, the industry's awareness and capacity to support national authorities is set to decline as the control mechanisms are likely to become ever less targeted to the problems related to the illicit use of drug precursors, especially designer precursors, and the realities of legal trade in a digitised environment. The negative consequences of outdated and increasingly ineffective control processes are likely to increase over time as the digitisation of supply chains advances. Additionally, concerns about legal clarity and the fragmentation of requirements within the

[85] Especially public authorities (for 12 out of 15 this as a major problem, vis-à-vis 9 out of 29 among economic operators).
[86] Law enforcement authorities and specialists in chemistry explained during the evaluation that there are hardly any limitations to the innovations of the producers of designer-precursors.
[87] The Regulation on the registration, evaluation, authorisation and restriction of chemicals (REACH) is the main EU law to protect human health and the environment from the risks that can be posed by chemicals. Information on the properties of chemicals manufactured or imported in the EU are registered in a central database in the European Chemicals Agency (ECHA). Substances that are manufactured or imported at above 1t per year require a REACH registration.
[88] Law enforcement authorities are equipped with Raman devices. It allows them to identify chemical substances on the spot by inserting a sample of the substance in the device. The device contains a library of spectra and checks the spectrum of the sample with the spectra of its library.
[89] The export and import data include the UK for 2020, but not for 2021-2023. The import data include Northern Ireland for 2021-2023.

internal market and between internal and external trade are likely to worsen as the rules no longer reflect the business environment for drug precursors in a straightforward manner.

Therefore, the unnecessary burdens and inefficiencies may affect the industry's overall competitiveness and SMEs disproportionately so. This is likely to have a small (given the comparative size of drug precursor trade) but negative economic impact for the EU.

For several businesses, the proliferation of designer precursors has made research on new chemicals more difficult and expensive due to restrained access to certain substances[90]. Considering that nearly one-third of operators in the targeted survey engaged in Category 1 precursors-related activities perform R&D activities[91], this issue does not regard only universities or research entities.

3. Why should the EU act?

3.1. Legal basis

The Internal Market Regulation is adopted based on Article 114 of the Treaty on the functioning of the EU[92], TFEU, on the adoption of measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

The External Trade Regulation is based on Article 207 TFEU[93] on common commercial policy.

3.2. Subsidiarity: Necessity of EU action

The Union has exclusive competence as regards customs union and common commercial policy. Therefore, the subsidiarity principle is relevant only as regards the intra-EU trade.

The EU set out harmonisation rules on drug precursors since 1990. Two key arguments justify the EU action to improve and adapt the existing rules to the recent developments in the illegal drug production and to take due account of digitisation.

Firstly, the illegal drug production is a Union-wide problem, not confined to a few Member States. EU action is needed to ensure the efficiency of controls across the Union and avoid the risk that some Member States implement more permissive rules on the control of drug precursors and thus undermine inadvertently the efforts of the other Member States.

Secondly, Member States have the obligation to control and monitor internal and intra-EU legitimate transactions with drug precursors, in accordance with the UN Convention. The adoption of distinct national systems in Member States would increase the burden for companies trading in several Member States, as they would have to follow different country specific rules for similar activities. Maintaining harmonised rules would ensure a smooth licit trade of chemicals in the single market. While the chemical industry is more developed in some Member States, drug precursors are used across all Member States.

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[90] This issue was reported by 6 out of the 15 economic operators in the targeted consultation who reported adverse side-effects for the industry linked to the growth in illicit trade of designer precursors.
[91] 10 out of 36 economic operators in the targeted consultation
[92] ex-Article 95 of the Treaty on the European Community, TEC.
[93] ex-Article 133 TEC.

3.3. Subsidiarity: Added value of EU action

EU action would have clear benefits for businesses, national authorities and society as a whole, by empowering national authorities to better fight against the illicit drug production and addressing uneven enforcement and framework shortcomings. This may also reduce unnecessary administrative burdens for economic operators and national authorities.

The EU added value lies in facilitating Member States cooperation in drug enforcement and managing significant trade across Member States and with third countries. By ensuring uniform rules, EU action strengthens competitiveness.

While Member States could adopt national measures, these would create regulatory barriers across the EU and negatively impact legitimate trade, falling short of the benefits offered by uniform EU measures. Additionally, digitisation at EU level would provide for interoperability, benefiting both industry and national authorities.

4. Objectives: What is to be achieved?

4.1. General objectives

There are two general policy objectives to be pursued when revising the regulations to address the problems outlined above. These general objectives are in line with the current objectives of the regulations and can be described as follows:

1) reduce the availability of drug precursors for illicit drug manufacturing.
2) facilitate legitimate trade and use of drug precursors.

Globally, and with strong advocacy from the United States, drug precursor control is recognised as a major tool in the fight against illicit drugs. In fact, about 87 % of participants to the public consultation consider their control as highly important for anti-drug purposes, with 49 % considering it important to 'a very high extent'. On the other hand, the objective to reduce administrative burdens also received high rates of support in the public consultation.[94]

There are trade-offs between these two overarching objectives[95]. Overly strict controls of drug precursors could hinder the functioning of legal trade and the internal market, while inappropriate controls may facilitate diversion and weaken the effectiveness of the drug precursor regulations. Therefore, the initiative should focus on creating a comprehensive framework that enables effective, proportionate control of drug precursors while creating an economic equilibrium that does not unduly affect legal trade. This is even more important bearing in mind that interventions on illegal trade are of limited effect in time, while interventions for legal trade are permanent[96].

4.2. Specific objectives

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[94] 46 out of 53 respondents of the public consultation consider drug precursors control as highly important. 22 out of 25 respondents saw a need to revise the current rules.

[95] For the classic economic framework for drug policy as the minimization of the total social costs of both drug consumption and policy enforcement, see Becker, G., Murphy, K., & Grossman, 'The market for illegal goods: The case of drugs', *Journal of Political Economy*, Vol. 114 No. 1, (2006), pp. 38–60.

[96] Benjamin Blemings, Scott Cunningham, 'Temporary gains and permanent costs in methamphetaime precursor controls', *International Journal of Drug Policy, vol. 138, (2025), p. 3*

Specific Objective (SO) 1.1 – To establish more effective and rapid control measures to address designer precursors

The aim of SO 1.1 is to ensure that rules do not only address traditional drug precursors but also newly emerging designer precursors, for which a global approach is crucial, notably in alliance with the United States. The idea is to future proof EU drug precursor rules to the extent possible, based on the risk presented by new criminal activities and especially designer precursors, while enabling businesses to innovate and place new substances with a legitimate use on the market.

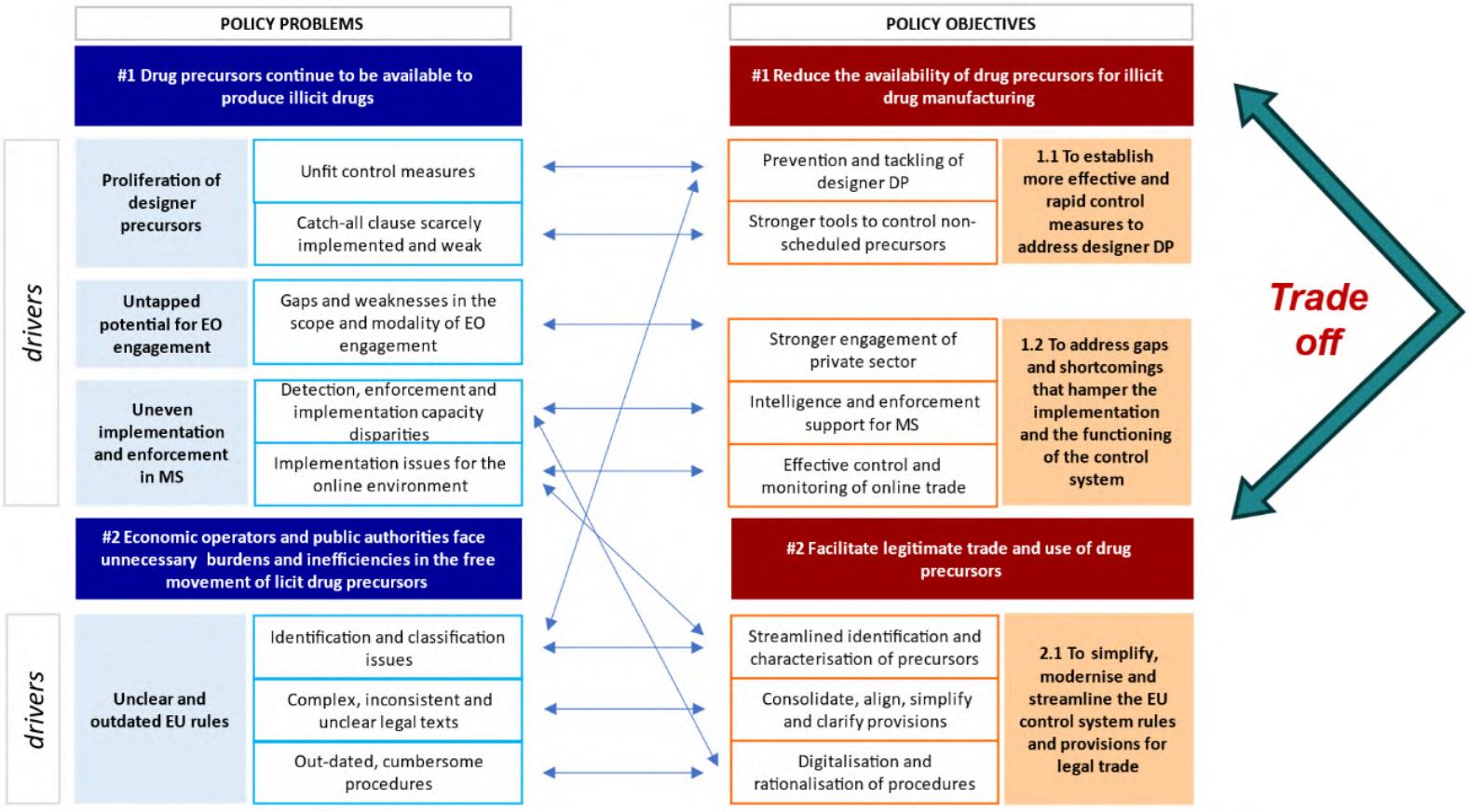
Specific Objective 1.2 – To address gaps and shortcomings that hamper the implementation and the functioning of the control system

SO 1.2 is to improve the regulations by filling in identified gaps and clarifying existing provisions to provide for a uniform application across the EU and enhance cooperation between authorities as well as with businesses.

Specific objective 2.1 – To simplify, modernise and streamline the EU provisions for legal trade

SO 2.1 is about removing unnecessary obstacles and administrative burdens for legal trade in drug precursors. The aim is to improve, simplify and digitise control mechanisms while bearing in mind the importance and therefore risk for illegal drug production of various substances.

***Figure 7:** Policy problems and objectives*



5. What are the available policy options?

5.1. What is the baseline from which options are assessed?

The monitoring and control of drug precursors are done based on the existing Regulations. Under the dynamic baseline scenario, the Commission will continue adding about 30 designer precursors to Category 1, which involves the strictest controls.[97] A proactive approach has been taken for recent scheduling[98] and welcomed by national authorities[99] as adding designer precursors ahead of the evidence of their illicit use, increases the scheduling effectiveness[100].

It needs to be added that, there are also national approaches. One Member State was reluctant to extend the EU scheduling with regards to designer precursors that it had already banned nationally. They feared that due to the nature of EU rules, this would decrease levels of control, A proliferation of national approaches going beyond EU rules could potentially lead to a fragmentation of the internal market and criminal forum shopping. The cost for checking if such substances are in their portfolio (due diligence) for economic operators is estimated at a one-off of EUR 1.9 million administrative cost[101]. Scheduling designer precursors under Category 1 may impact research and innovation, as licences are also required for small quantities.

For non-scheduled precursors, the VML remains accessible to a limited number of operators, with national authorities deciding on trade monitoring and suspicious activities follow-up.

As part of the implementation of its new mandate, the EUDA will support the Commission by monitoring precursors trafficking, including by developing a notification system via email, assessing the need to change the list of scheduled substances and threat assessments[102]. EUDA only has one FTE in order to carry out those tasks, in addition to other ad hoc requests received to support the work of the Commission in this area[103]. To adequately support these tasks and fully build on the EUDA's capacity and expertise in the field of drug precursors, the Agency

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[97] This projection is based on the number of substances scheduled in recent years.

[98] Commission Delegated Regulation (EU) 2024/1331 which also scheduled ethyl, methyl, propyl, isopropyl, butyl, isobutyl, sec-butyl and tert-butyl esters of the substances in question.

[99] 22 out of 28 national authorities surveyed welcomed this development and encouraged to explore this approach further, although different views on the ideal scope of 'proactive' scheduling were expressed.

[100] In analogy with new psychoactive substances, there is evidence that class-wide scheduling may help reduce the emergence of new NPS. In February 2018, the U.S. implemented a class-wide scheduling of fentanyl-related substances, followed by China in April 2019. A Department of Justice testimony reported that this action significantly slowed the introduction of new fentanyl-related substances into the illicit market. Weedn, Victor W., Mary Elizabeth Zaney, Bruce McCord, Ira Lurie, and Andrew Baker. 2021. "Fentanyl- related Substance Scheduling as an Effective Drug Control Strategy." *Journal of Forensic Sciences* 66 (4): 1186–1200. https://doi.org/10.1111/1556-4029.14712.

[101] For a detailed description of the due diligence costs, please see section 6.2 below. Essentially, it is assumed that the time input required to conduct due diligence on listed designer precursors will be in line with what is currently required for new scheduled substances with a CAS number, i.e. *1.5 hour* (on average). From a single company perspective this is a *one-off cost*, however, from the regulation perspective it is a recurrent cost, as new substances are continuously added to the regulation, and businesses need to conduct due diligence checks whenever they start producing or selling new families of chemicals. The number of *affected companies* cannot be precisely estimated; however, it can safely be assumed that all companies that are licensed to deal with precursors falling under Category 1 - i.e. *approx. 1 200 companies* - regularly conduct due diligence checks. Assuming an average cost of labour of EUR 35.65 / hour, the aggregate 'one-off' impact on administrative costs for businesses (EU-wide) would result in EUR 1.9 million.

[102] See: Article 14 of Regulation (EU) 2023/1322.

[103] Proposal for a Regulation on the European Union Drugs Agency, COM/2022/18 final.

has estimated additional staff needs of 5 FTEs and a budget of EUR 1.8 million for 2025-2027.[104]

The Digital Services Act[105] is set to improve the enforcement of drug precursor rules in online market-places and to prevent illegal content. In addition, the EU Internet Forum creates a collaborative environment for EU governments, the internet industry, and other partners to tackle illegal content online, including drug precursors[106].

The Commission will continue collecting data on legal and illegal trade and use of precursors from national authorities, in the European drug precursors database, and transmit them to the INCB. Expansion of this database to enable operators to communicate their transactions could reduce the administrative burden of national authorities, yet cost the Commission approximately EUR 430 000[107].

The Commission will update various resources like Frequently Asked Questions, FAQ[108], the catalogue of mixtures, the EU Guidelines for operators, and the e-learning courses, although, except for the FAQ document, these will not be made public, limiting awareness.

The Expert Group, including industry representatives, will remain an important forum for raising awareness on emerging threats, and discussing implementation aspects.

More and more Member States would likely digitise their national procedures. While this could aid trade at national level, disparities among Member States would still disturb the internal market, challenging SMEs when extending their activities. Paper formalities, such as the customer declarations[109], would persist regardless of digital advancements in Member States.

Costs for economic operators will remain the same as shown in Figure 3.

5.2. Description of the policy options

Three policy options are put forward and summarised in Figure 8, while three others were discarded at an early stage (see section 5.3).

While presenting important differences, the options build on one another, with a gradual approach from a relatively light technical approach to more wide-ranging regulatory interventions. A risk-based approach has been followed in setting the proposed options, i.e. each option has been designed to address both objectives at the same time. However, bearing in mind potential trade-offs, the policy options put a various level of emphasis on either objective.

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[104] EUDA cost estimates.
[105] Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market for Digital Services and amending Directive 2000/31/EC (Digital Services Act).
[106] https://home-affairs.ec.europa.eu/networks/european-union-internet-forum_en. The roadmap also includes further measures on the online aspects of drug trafficking: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023DC0641
[107] Based on an estimation done by the Commission services.
[108] Drug precursors control - European Commission (europa.eu)
[109] Article 4 of Reg 273/2004 requires a stamped and signed customer declaration on headed notepaper.

A set of non-regulatory flanking measures strengthens rule enforcement, applicable to all three options. They should contribute to closing off or removing paths of least resistance for criminals. Although these are supplementary to primary measures, they do not serve as standalone policy alternatives.

The **flanking measures** include:

Firstly, **awareness raising** by training, guidance and other soft law tools to enhance the implementation of the rules by national authorities and operators alike, including online trade. This measure was broadly supported in the various consultations[110]. This is expected to improve cooperation with economic operators for drug precursors with legitimate uses. However, such measures would have a limited impact on designer precursors, typically not used by operators.

Secondly, **capacity for testing new substances** by supporting customs and competent authorities with analytical methods, supported by the JRC and customs laboratories, and state-of-the-art equipment, funded by over EUR 200 million through Customs Control Equipment Instrument (CCEI). The Commission will support and develop the two networks of laboratories (the Customs Laboratories European Network and the European Network of Forensic Science Institutes). These laboratories help police and customs in their investigations and controls and will encourage increasing labs' cooperation with law enforcement. Moreover, technologies stemming from the EU Horizon 2020 projects equip law enforcement with new capabilities, allowing for more effective detection of illicit drugs and precursors at the borders and thus reducing the availability of designer precursors.

Thirdly, **monitoring and control of equipment** used in the illicit drug manufacturing is supported through awareness-raising materials and Expert Group coordination[111]. These complement international efforts like INCB's *Operation Acronym*. They might be implemented in the framework of the EMPACT instrument, under the 'drug trafficking' priority.[112] The impact of this measure in comparison to binding measures is likely to be reduced, but given the scope of equipment potentially concerned, voluntary measures focussing on suspicious transactions were considered more proportionate.

Finally, **compliance checks of economic operators** are to be enhanced and are especially crucial with the reduced ex-ante controls in Options 2 and 3. The Commission would support Member States by providing a platform to exchange on compliance checks and jointly elaborating a risk assessment approach to checking economic operators.

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[110] 23 out of 24 national authorities participating in the public consultation rated the importance of this measure as 'very high' or 'high'. Similarly, in the targeted survey, 22 out of 26 national authorities and 38 out of 41 economic operators endorsed promoting awareness and cooperation with the private sector. Training of relevant staff is largely approved by authorities (20 out of 28) and operators (45 out of 54).

[111] Regulatory approaches in this area received very limited support during the consultation activities (see Section 5.3.2).

[112] See: https://home-affairs.ec.europa.eu/policies/law-enforcement-cooperation/empact-fighting-crime-together_en

***Figure 8**: Presentation of the policy options*

Baseline	Option 1	Option 2	Option 3
Designer precursors: Are currently scheduled as regular precursors	**Designer precursors:** Specific rules will be introduced for internal trade.	**Designer Precursors**: A new category is introduced for internal and external trade. A **prior notification** is required for legal activities using such designer precursors	**Designer Precursors**: A new category is introduced for internal and external trade. A **special license** is required for legal activities using such designer precursors
Scope of controlling designer precursors: Pro-active scheduling of individual designer precursors and some derivatives that have not yet been seized	**Scope of controlling designer precursors:** Baseline	**Scope of controlling designer precursors:** Schedule substances based on a chemical base molecule and a limited number of precise modifications to these base molecules (approx.100-200 substances)	**Scope of controlling designer precursors:** Schedule base molecules (represented by their structural formula) and allow for an extended number of modifications to these, resulting in approx. 300-400 substances
Traditional precursors: Categories remain unchanged	**Traditional precursors:** Baseline	**Traditional precursors:** Categories are streamlined into key precursors (cat. 1) and solvents/reactants (cat.2)	**Traditional precursors:** Categories are streamlined and controls attached are reinforced.
Administrative procedures/IT: The existing database will be extended to electronic reporting by economic operators and an electronic customer declaration will be envisaged.	**Administrative procedures/IT:** For internal trade, economic operators will provide ex ante summary reporting instead of ex post reporting.	**Administrative procedures/IT:** Processes are fully digitised, with e-licenses and registrations, e-verification (for cat. 1 and 3) as well as automated reporting. Pre-export notification wait period is lifted.	**Administrative procedures/IT:** Processes are fully digitised, with e-licenses and registrations, e-verification as well as automated reporting. E-verification is requested for all transactions and pre-export notification is only lifted for trusted economic operators.

5.2.1. Option 1: Technical adaptations

The key measures of option 1 are the following:

- **Specific rules for designer precursors in internal trade** Designer precursors rarely enter legitimate supply chains. Yet, their legitimate use in research and innovation, often in very small quantities, needs to remain possible. This is why for internal trade the obligations attached to designer precursors in internal trade are rendered more targeted. Legitimate use is notified to the competent authority who may then investigate. Failure to notify raises suspicions.
- **Simplify reporting obligations by switching from an ex-post to an ex-ante for internal trade:** In line with the idea of maintaining high levels of control while streamlining the administrative requirements linked to the controls, this option also seeks to facilitate reporting for economic operators and authorities.

Further technical adaptations in the form of guidance and transparency underpin these key aspects of option 1.

For objective 1, the Commission develops a guidance document to improve the scheduling process. This document covers all the steps, starting from the identification of substances to be scheduled and the automatic assessment of substances closely related to the candidate ones, to avoid their easy substitution. Notably, the Council and the Parliament establish a common practice to reduce the objection period to one month or even less, for faster scheduling of designer precursors.

The Commission modifies the relevant implementing and delegated acts closing the existing loophole for users.

The Commission revises the existent guidance document for the identification of suspicious transactions with a focus on designer precursors and encourages national authorities to make the information publicly available.

A drug precursors information repository covering traditional and designer precursors is set up and maintained by the EUDA. The repository provides information on the relevance of a given substance in drug production. It supports both national authorities in recognising suspicious transactions and the Commission in identifying substances to be scheduled.

For objective 2, the Commission revises the Annexes to provide for that substances are presented in a consistent way, with relevant identifiers. Scheduled designer precursors are moved to Category 2A for the internal market only and thresholds are set out below which no registration obligation applies. The registration procedure for designer precursors is simplified with a focus on the need to prove the legitimate use. For external trade purposes, designer precursors are kept in Category 1, so that imports are controlled.

The Commission changes the implementing rules on licence and registration for the internal market only, by requesting operators to make an estimation of the quantity of precursors to be used or sold during the validity of the registration or licence. If that quantity is consumed, a renewal is to be requested, with a simplified procedure. Operators will no longer have the obligation to send an annual report on Category 1 or 2 transactions in all cases for the internal market, but only upon request, in specific conditions (suspicious activity, or very complex activities).

The Commission adopts rules on the electronic form of customer declarations.

Finally, the Commission develops a guidance document on mixtures setting out objective criteria to determine if a mixture including drug precursors remains under control. The Commission also sets out guidelines for developing digital solutions at national level.[113]

5.2.2. Option 2: Comprehensive review

[113] Bearing in mind the overall legal framework such as Regulation (EU) 2024/903 of the European Parliament and of the Council of 13 March 2024 laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act). While the Interoperability Act concerns systems linking into the Single Window, it is without prejudice to the competence of Member States about their activities concerning public security.

Policy option 2 makes use of the wider opportunities provided by a full legislative revision. This notably enables a better alignment of external and internal trade controls. The idea of policy option 2 is to gauge to what extent legal controls can be streamlined without compromising effective controls of drug precursor trade. The key measures of option 2 are the following:

- **Streamlining and reorganisation of the currently existing four categories of substances:** The new set of categories therefore aim to clarify and streamline obligations and controls based on an updated perception of the risk-profile of a group of substances. Licences are still needed for new Category 1 substances (key precursors with known legal use), and self-registration is required for the new Category 2 (mainly solvents and reactants) only for external trade.

- **Introducing a new category for designer precursors** with prior notifications of legal use: Designer precursors are different from traditional designer precursors in that their legal use is often limited to research activities, but other future legitimate uses cannot be excluded *a priori.* Designer precursors intended for illegal drug production rarely enter legal supply chains. The obligations attached to this new category therefore aim to consider this dilemma. Scheduling designer precursors serves the double purpose of alerting economic operators to the potential risks of these substances and monitoring their (limited) legal use in a proportionate manner. Including them in the scope of the regulations also creates a link for criminal sanctions under the Framework Decision.

- **Innovative and more forward-looking ways of scheduling**: Option 2 would schedule substances based on a chemical base molecule and a limited number of precise modifications to these base molecules (see Figure 9 and Annex 7)[114]. The new category would include 110 to 200 designer precursors of ATS.

Option 2 includes the EUDA information repository envisaged in Option 1.

The two existing regulations are merged, applying the same rules for internal as well as external trade whenever possible. The obligations of economic operators are adapted to correctly reflect the risk of various transactions, to avoid loopholes in the monitoring system and to avoid unnecessary burden. Licences are still needed for new Category 1 substances (current category 1 substances with known legal use), and self-registration is required for the new Category 2 (current categories 2 and 3) only for external trade. Operators maintain their obligation on labelling, documentation of transactions and notification of suspicious transactions.

In addition, the Commission is empowered to make use of innovative scheduling methods for designer precursors, in addition to individual scheduling (see Figure 9 and Annex 7). Based on its current mandate, the EUDA will advise which scheduling method is the most appropriate. Key to determining the scope of scheduling designer precursors is to provide for legal certainty, minimise the administrative burden and exclude substances having legitimate uses, other than research and innovation.

[114] This would also cover designer precursors that have been scheduled under the current rules.

Figure 9: Methods of scheduling designer precursors[115]

Method	Description
Scheduling of substances individually	Indicating the chemical name, a unique identification number (CAS/CUS numbers)
Scheduling of families of derivatives	Identifying a family of derivative, such as esters, amides, carbamates, sulfonamides, acetals of a designer precursors, with a wider but clearly defined scope (e.g. by limiting the number of carbon atoms)
Scheduling with a chemical formula	Indicating the chemical formula of a designer precursors and the modifications to the chemical formula which are also included. It can be used for certain designer precursors that have the same core structure and certain specific variables
These methods are not exclusive but complementary. The last two scheduling methods are considered innovative ways of scheduling, as the long-established practice in the UN Convention and EU regulations was to schedule substance by substance.	

At international level key players have already preceded the EU in using innovative ways of scheduling. For instance, the US scheduled the core molecules for ATS and fentanyl with families of derivatives without limitations (the esters and, respectively, acetals, carbamates and amides). Canada responded to the surge of designer precursors by scheduling derivatives in general, without limiting the family of derivatives. More recently China, that is seen by the international community as a source of designer precursors scheduled on 1st September 2024 BMK and PMK glycidic acid related esters without limitations.[116] There are no examples yet of scheduling drug precursors based on chemical formulae[117].

The scheduled designer precursors are subject to a general ban[118] with a possibility for economic operators to notify a legitimate use to authorities or request a licence for a legitimate use, depending on the quantities needed.

The **urgency procedure** to schedule substances is set to speed up these processes (thus a delegated act could be published and start applying without awaiting the lapse of a 2-months objection period).

Furthermore, Member States will be obliged to adopt national measures to implement the **catch-all clause for external trade with non-scheduled substances**. This contains objective criteria assisting customs with the identification of suspicious transactions. Such criteria would inter alia include the listing of a substance in the EUDA repository. Based on these criteria, it is up

[115] At international level key players have already preceded the EU in using innovative ways of scheduling. For instance, the US scheduled the core molecules for ATS and fentanyl with families of derivatives without limitations (the esters and, respectively, acetals, carbamates and amides). Canada responded to the surge of designer precursors by scheduling derivatives in general, without limiting the family of derivatives. More recently China, that is seen by the international community as a source of designer precursors scheduled on 1st September 2024 BMK and PMK glycidic acid related esters without limitations. For more details on the US legislation and other third country legislations, such as Canada or China, see Annex 7. There are no examples yet of scheduling drug precursors based on chemical formulae. However, two Member States used this method for new psychoactive substances (NPS) in combination with substance-by-substance scheduling and a list of exempted substances.

to Member States to decide to launch an investigation. Suspicious shipments could be detained by customs for investigation purposes.

In line with the recommendations of the F4F Platform[119], Member States are requested to report significant incidents once only and in real-time through the EU. This would require an IT solution that allows for an exchange with the current UN alert system (PICS) to provide for that there is no duplication of reporting requirements.[120]

For objective 2, the merger of the two regulations leads to streamlining their provisions. Definitions are aligned to general chemical and customs legislation (e.g. definitions of substances, references to suspension procedure, use of CUS references). The Commission would be empowered to establish de minimis rules for individual substances as well as for mixtures. In addition, several obligations for economic operators are removed, in particular the obligation to obtain a licence for low-risk transactions, to register for internal trade, to get a paper-based customer declaration, to obtain an import/export authorisation or to wait for a PEN or to transmit an annual report with the summary of transactions. This is based on the approach that these substances are widely traded and less essential for drug production than key or designer precursors. Therefore, while remaining scheduled drug precursors, less emphasis is placed on summary reporting and administrative procedures.

A centralised IT system will provide for the automatic generation of authorisations and reporting through quantity management. This EU portal for licenses and registrations would be connected to the EU Customs Single Window Certificates Exchange System[121] and would contain information on the substances, validity, quantity and whether exemptions apply, meaning that the authorisation process, including the PEN, could be automated. The information collected will become an input for automatically generated reporting to the UN. Customer verification will be built on a key digital building block, such as e-Delivery,[122] e-ID[123], or e-Wallets[124] to promote cross-border interoperability.[125]

5.2.3. Option 3: Comprehensive review with stronger controls

Option 3 is also based on a full legislative revision. Its basic structure is shared with option 2 but it is rather based on the premise of maximising controls. Its key measures are the following:

- **Streamlining existing categories of substances and increasing control measures applicable to them:** While option 3 also entails a streamlining of categories, the focus is on increasing controls. More substances would be placed under the strictest controls[126]. No exemptions are possible for low-quantity transactions and registrations are extended to internal trade. Only trusted economic operators are exempt from pre-export notifications. Nevertheless, some obligations of operators imposing

[119] Fit for Future Platform 2021-2024: https://commission.europa.eu/document/download/f7d8be85-3d01-4d26-8124-c68f06e5ada8_en?filename=fo_2024_2_actions_methodology_to_avoid_the_build-up_en.pdf
[120] Precursors Incident Communication System, https://www.incb.org/incb/en/precursors/pics.html
[121] https://eur-lex.europa.eu/eli/reg/2022/2399/oj
[122] https://ec.europa.eu/digital-building-blocks/sites/display/DIGITAL/eDelivery
[123] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202401183
[124] https://ec.europa.eu/digital-building-blocks/sites/display/EUDIGITALIDENTITYWALLET/EU+Digital+Identity+Wallet+Home
[125] This is in line with the recommendation of the F4F Platform which advocates these building blocks to improve compliance with various reporting requirements across the EU.
[126] Currently, a registration is needed for acetic anhydride and red phosphorus in internal trade. Both substances had been identified as particularly problematic in the past.

administrative burden are removed, more precisely, the obligation to get a paper-based customer declaration, to obtain an import/export authorisation, as well as the obligation to report the annual summary of transactions.

- **Introducing a new category for designer precursors with a greater focus on ex-ante controls by requiring special licences in all cases, irrespective of the quantities used.**
- **Scope of scheduled designer precursors:** Option 3 would equally start with base molecules (represented by their structural formula) and allow for an extended number of modifications to these, resulting in a larger number of substances to be scheduled (approximately 300-400 substances). This approach has e.g. also been used in the innovative scheduling of narcotics and psychotropics in some Member and other States. Option 3 would thereby be more proactive than option 2, making it harder for criminals to find non-scheduled precursors and probably last longer than option 2 before adaptations need to be made.

Further adaptations include the urgency procedure for scheduling substances. Also, the catch-all clause for non-scheduled substances is further strengthened, by requesting authorities to assess and decide whether to investigate transactions with substances identified as designer precursors in the EUDA information repository.

Option 3 incrementally builds on the previous two options. It contains also the EUDA information repository. In comparison to Option 2, more emphasis is placed on enhancing controls of drug precursors and reducing the risk of diversion.

As in Option 2, the two existing regulations are merged, and a new category is created for designer precursors. However, when streamlining the current categories more substances would be placed under the strictest control of the new Category 1 (current categories 1with known legal use and 2A). The obligations of economic operators are changed to reinforce the monitoring of legal trade. While a licence is needed for new Category 1, no exemptions are possible for low quantities transactions. The self-registration for the new Category 2 (current Categories 2B and 3) is required both for internal market and external trade. For objective 1, the scope of the new Category 3 on designer precursors is wider (approximately 300-400 substances). It extends not only to substances where there is an imminent risk of being used for ATS but covers additional derivatives that may potentially be used for drug production. Option 3 would already make use of innovative ways of scheduling, as presented in Figure 9.

Like for Option 2, the Commission is empowered to use innovative ways of scheduling (family of derivatives or chemical formula), in addition to individual scheduling, subject to the advice of the EUDA concerning the best method for each case. There is a general ban for these substances, however, operators would need to request a special license rather than just to notify authorities as in Option 2 for small quantities. The urgency procedure for scheduling new substances is also included.

The catch-all clause for non-scheduled substances is further strengthened, by requesting authorities to assess and decide whether to investigate transactions with substances identified as designer precursors in the EUDA repository.

For objective 2, streamlining measures are implemented to a more limited extent due to Option 3's stronger focus on objective 1. Only trusted economic operators are exempt from pre-export notifications. Self-registration and e-validation requirements would also apply to internal trade

in the new Category 2, therefore effectively extending these obligations to substances that were not previously subject to registration requirements in internal trade. Nevertheless, some obligations of operators imposing administrative burden are removed, more precisely, the obligation to get a paper-based customer declaration, to obtain an import/export authorisation, as well as the obligation to report the annual summary of transactions.

Like for Option 2, these measures are underpinned by a centralised digital system for precursors' formalities and enables automated annual as well as real-time incident reporting.

5.3. Options discarded at an early stage

5.3.1. Deregulation – align the EU rules to the minimum requirements under the UN Convention

The deregulation option, presented in the Call for Evidence, consisted in cutting back the regulations by bringing them into line with the UN Convention[127]. Only drug precursors listed in the UN Convention would remain scheduled at EU level. As a result, 11 substances would no longer be scheduled, and Category 4 would be removed. In combination with the digital transition, these measures would reduce the administrative burden. To counterbalance, more precursors are listed in the VML to prevent diversion.

This option was not retained because the existence of substances scheduled only at UN level was regarded as problematic by stakeholders[128], as there are substances that are relevant in the EU but not at the global level, such as red phosphorus, that was largely used in the illicit production of methamphetamine in Czechia. In this sense, deregulation was considered counterproductive[129].

5.3.2. Setting out binding rules for equipment used in the illicit production of drugs

One option to fight against the illicit production of drugs is to set out rules at EU level to control and monitor transactions with equipment used in such activities. Such equipment varies from typical laboratory equipment to tabletting and encapsulating machines. Currently, such measures are taken at national level, based on the UN Convention.

The results of the stakeholder consultation showed that the lack of control on equipment is often perceived as a weakness of the current rules. In the targeted consultation, a substantial number of national authorities consider this as a major gap (13 out of 28). Similarly, 26 out of 47 respondents to the public consultation consider this as highly or moderately problematic. However, the share of incidents involving equipment that are reported to the UN does not exceed 1 %. A regulatory approach involving, for instance, a licensing or registration at national level, would require substantial resources to effectively combat illicit drug production. Based on national authorities' estimates, the adoption of control measures for equipment is associated with a cost increase for authorities of 35 % to 70 %. This approach was also discarded by the

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[127] Annex 9 points out the most essential aspects on which the EU went beyond the minimum requirements of the UN Convention, also in terms of reporting obligations.

[128] Only 4 out of 27 national authorities believe that the control of such substances causes an unnecessary burden, and likewise only 3 to 4 respondents out of 24) expect benefits from the deregulation of these substances. Similarly, only 4 out of 67 economic operators surveyed consider as a 'major problem' the EU scheduling of substances not under control at international level.

[129] Conversely, the literature review has shown that the effect of scheduling is greater if a substance is scheduled at both EU and international level. The study, Annex 6, p. 32.

totality of economic operators interviewed, due the substantial administrative burden involved. Therefore, this option has been discarded as disproportionate.

5.3.3. Decentralised and hybrid IT systems

Interconnected decentralised or hybrid IT systems are detailed arrangements for providing digital solutions for drug precursors formalities, alternatives to the proposed IT centralised system.[130]

While the interconnected decentralised option offers flexibility, it would introduce disproportionate complexities in cross-border validation and does not align with the long-term customs policy related to the establishment of the EU Customs Data Hub. Due to a potential for 27 duplications, the costs would be disproportionate in comparison to other solutions. A hybrid option may grant flexibility but introduces an additional layer of complexity by having to create a system-to-system interface for the replication of data from national systems to the central database. From a cost-efficiency perspective, such systems bear higher costs on Member States by design.

6. What are the impacts of the policy options?

The analysis of economic, social and environmental impacts of the policy options is based on the impact assessment study which analysed qualitative and quantitative sources, namely extensive stakeholder consultations, analysis of relevant databases on drug precursors (the European drug precursors database and the DG TAXUD Surveillance database), and the review of literature, i.e. relevant EU and INCB reports, academic literature etc[131].

On economic impacts, the assessment covers the impacts on public authorities, at national and EU level, on economic operators and on research and innovation. The number of companies is dealing with drug precursors is quite limited when comparing to the overall chemical sector. Findings on costs are based on a relatively small sample of responses and may therefore not be entirely representative. On innovation, drug precursor rules do not directly address research and innovation, their impacts are most likely an indirect result of the ease or lack of access to a wide range of novel substances.

On social and environmental impacts, there are important caveats in their assessment, which make it very difficult to quantitatively assess these impacts.

For **social impacts**, including **public health and safety and crime**, while not explicitly mentioned as objectives in the regulations, the ultimate purpose of controlling drug precursors trade is to contribute to the fight against illicit drugs, with impacts on public health and healthcare systems[132]. The aim of preventing drug producers from getting their hands on drug precursors is to disrupt the drug production and supply. A disrupted drug precursors supply should subsequently lead to a more complex drug production and thus to potentially a reduced drug availability. This should have a positive impact on public health and healthcare systems.

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[130] The analysis carried out by the Commission with the support of a project group of Member State authorities is included in Annex 8.

[131] An overview of the methodology is provided in Annex 4.

[132] For a lack of quantifiable data, it is therefore not possible to carry out a sensitivity analysis. A Sensitivity analysis would require a quantifiable causal relation between the independent variable (in this case "effective enforcement") and the dependent variable ("illicit precursors flow").

The extent and robustness of such indirect impact is however difficult to prove and even more difficult to quantify as a lot of external factors may influence the drug production and availability. Europol reported that criminal networks are highly adaptable, innovative and resilient to global crisis, instability and political and economic changes[133]. This reiterates a well-articulated policy precept that policing drug markets can, at best, shape and manage these markets[134].

Evaluating the societal effectiveness of enforcing prohibitions on drugs depends on whether one is examining the marginal effects of enforcement or the aggregate effects of prohibition. It also depends on the relative maturity of drug markets. Enforcement against emerging drug markets may severely curtail, or at least delay their development, with a potentially significant societal gain in terms of limitation, or delayed onset, of health and social costs that derive from drug use[135].

However, as pointed out by the EUDA, illegal drugs affect societies as whole. There is addiction and youth criminality, public health effects and social costs for communities Directly, or businesses are undermined by corruption or criminal practices. The overall effects of drugs exacerbate other complex policy problems, such as homelessness or the management of psychiatric disorders[136].

A general concern is that drug use is, to some extent, associated with behaviours that can represent health risks, such as overdoses, mental health problems and infectious diseases. The mortality rate due to overdoses in the EU in 2022 is estimated at 22.5 deaths per million population aged 15 to 64 (at least 6 392 overdose deaths involving drugs occurred in 2022, increasing from 6 166 in 2021). In addition, cohort studies show that all-cause mortality is much higher among people who use drugs. Furthermore, in 2022, the number of new HIV notifications linked to injecting drug use increased to 968, compared with 662 the previous year. Data from treatment programmes in Greece indicated that 26 % of people who inject drugs tested positive for HCV-RNA. While mortalities mostly occur in older age groups, young adults have a large share in the estimated drug use across all drug categories.[137]Research by the EUDA shows that it is not possible to quantify the impact of the drug precursors policies on public health, because the impact is indirect, data are incomplete or have quality and coverage limitations[138].

Drug production has an **environmental impact,** apart from the effects of the cultivation of drugs, especially the production of synthetic drugs and the dumping of toxic waste can lead to considerable environmental damage. However, there is limited knowledge about this despite signals of increasing cocaine processing and production of synthetic cathinones. The environmental impact of MDMA production in Europe is significant, with each kilogram of MDMA generating approximately 58 kilograms of toxic waste. Overall, MDMA production in the European Union potentially generates between 1000 and 3000 tonnes of chemical waste

[133] Europol, Decoding the EU's most threatening criminal networks, 2024.
[134] Evaluating Cocaine Market Interventions: How External Shocks and Disruption of Criminal Networks Impact the Cocaine Trade and Social Outcomes, Final Report, Monitoring and Support Project for the Global Illicit Flows Programme (MASIF)
[135] Ibid.
[136] European Drug Report 2025, p. 11.
[137] European Drug Report 2024.
[138] Ibid.

each year. Production sites are also prone to accidents, explosions and fires due to the volatile chemicals involved – posing significant risks to surrounding communities[139].

In this sense, it is not feasible to provide a quantitative estimate of the environmental costs of illicit drugs manufacturing in the EU and of the estimated savings that the policy options could deliver. Overall, it can be assumed that the environmental benefits would be roughly proportional to the reduction of the production of illicit drugs.

Fundamental rights impacts are not considered significant. The objectives of the intervention as presented in Section 4.2 are ***consistent with EU fundamental rights and, specifically,*** the freedom to conduct business set out in the EU Charter of Fundamental Rights. This freedom is not absolute, but restriction could be set out insofar it is needed to provide for high level of human health protection in the definition and implementation of all the Union's policies.

6.1. Option 1: Technical adaptations

- **Economic impacts**

Public Authorities

The guidance on mixtures would enable national authorities to take inspiration when dealing with individual cases but, of course, it would not be binding thresholds leading to uniform interpretations across the EU.

EUDA requested 1 FTE and EUR 182 000 for the repository for the period of the first two years.[140] The voluntary adoption of IT systems at national level (i.e. de-centralised) following EU guidance received mixed feedback in the targeted survey of public authorities[141]. Many national administrations thought that Member States who already have an IT system in place should be able to continue using their national system (14 out of 25). Yet, asked about their preference for the set-up of any digital system not a single authority suggested a de-centralised system. From a cost perspective, the direct one-off investment cost of such guidance would be borne by the Commission and be limited to the staff costs (one or two staff members for a matter of weeks). This is not a significant cost. However, **benefits of this measure are also likely to be marginal as a fragmentation of IT systems between various Member States would persist**. This could to some extent be mitigated by the provisions of the Interoperable Europe Act[142].

Economic operators

As the burden reduction measures of Option 1 concern internal trade only, benefits are limited to operators in the internal market. Furthermore, this option creates discrepancies between

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[139] EUDA, European Drug Report 2025, p. 24.; Thomas L. ter Laak, Erik, 'Environmental impact of synthetic drug production: analysis of groundwater samples for contaminants derived from illicit synthetic drug production waste', *EMCDDA Background Paper,* p. 6.

[140] Calculations provided by EUDA.

[141] See Annex 2 for more details.

[142] Regulation (EU) 2024/903 of the European Parliament and of the Council of 13 March 2024 laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act), *OJ L, 2024/903, 22.3.2024*

internal and external trade requirements. It could therefore rather confuse than streamline the existing drug precursor rules.

The guidance on mixtures would provide **negligible and uncertain cost savings** in comparison to the baseline scenario. Member States would remain free to follow the guidance or not. So, the potential of divergent interpretations is not fully removed.

In the targeted survey, economic operators estimate that closing the loophole on users' obligations is expected to come with a limited to moderate increase of administrative costs of 5 %-20 %. However, half of the MS authorities in the targeted consultation[143] and some 43% of economic operators call for aligning these obligations[144].

It is difficult to predict the exact cost impact of moving designer precursors to Category 2A for internal trade, but it is likely to be negligible. Currently, there are 401 active licenses for scheduled designer precursors in the EU, and 105 individual entities licensed. These entities do not benefit if they are also active in external trade. Also, if these operators also have other Category 1 substances in their portfolio, they would still need to fulfil the stricter requirements of Category 1. They would still have to secure their premises. In addition, in the targeted survey 74 % of large firms and 56 % of SMEs[145] confirmed that they made such investments regardless.

In the same vein, changing reporting requirements for internal trade but not for external trade would likely benefit only a small number of businesses. Based on the assumption that about 30 % of businesses are active in internal trade only – this would lead to a 30 % reduction of reporting burdens[146].

Figure 10: Reporting costs for operators

Cost (million EUR)		Baseline	Option 1
Reporting	SME	2.57	1.80
	large firm	0.64	0.45

Source: the study (see Annex 4 for more details on assumptions and calculations based on standard costs model)

Making use of the existing empowerment to have the customer declaration in electronic form will not change the requested content of the declaration. It will therefore continue to be necessary for individual transactions. This will lead to a reduction of printing and sending paper but not to a substantive reduction of requirements.

Similarly, economic operators clearly indicated their support for an EU-integrated digital solution[147], meaning by conversion that setting up guidelines for voluntary implementation of

[143] 14 out of 28 authorities who replied to this question.
[144] 29 out of 68 who replied to this question.
[145] the remainder of SMEs most commonly responded "don't know" 4/16, but a few said their costs would increase either moderately 2/16 or significantly 1/16).
[146] The exact share at an individual company level of their shares of internal or external trade would have to be assessed. This is impossible. The 30 % reporting burden reduction is therefore likely to be a slight underestimation.
[147] For example, in the targeted survey economic operators, 41 out of 73 respondents expect savings ranging from 10 % to over 75 % (with 20 respondents anticipating 'high' or 'very high' savings, i.e. from 50 % to more than 75 %) from the availability of information on licensing / registration of other operators – this would require a more centralised digital solution.

national IT systems is less appreciated by the private sector. This option's benefits for economic operators depend on how many Member States would follow the guidance and cannot be reasonably estimated. In any case, economic operators would still need to interact with a diverse set of systems. Furthermore, this option does increase coherence with relevant customs rules (which require digitised procedures). Not all Member States may have the business case to digitise their procedures given the rather limited volumes concerned[148]. It is also more difficult to rationalise processes or automate exchanges without a system that is not centrally developed and managed. This option contributes lightly to the 'digital by default' principle.

As a result, Option 1 is likely to have a **limited impact on competitiveness, including for SMEs**. It does not drastically alter the status quo in which businesses conduct their trade. By extension, it does not have any relevant impact on international trade.

Research and innovation

As Option 1 does not alter the current approach (baseline) to traditional drug precursors use in research, this option has a **negligible impact on research and innovation**. Marginal improvements are to be expected for designer precursors scheduled in the internal market rules, as transactions with low quantities needed for research could be exempted from the registration requirement. As most designer precursors are produced outside of the EU, their import for research purposes would require a license.

- **Social impacts**

Option 1 is expected to have a positive contribution on Member States' capacity to detect and prevent crime. The proposed EUDA repository will improve competent authorities' knowledge and capacity to detect emerging threats. Additional benefits derive from the shortening of scheduling time, even if limited to about one month. Previous experience shows that the rapidity of response plays a major role in curbing the availability of precursors. Incidents with the MDMA precursors PMK glycidic acid and PMK methyl glycidate have occurred since 2013, but these substances were eventually scheduled in late 2020. Since then, annual seizure amounted to 8 000 kg, while after scheduling they dropped dramatically, down to 51 kg in 2023. Conversely, designer precursors like EAPA and MAMDPA, which were first seized in 2020 and 2021 respectively and were scheduled in 2022, did not have time to establish and develop: in 2023 MAMDPA's seizures amounted to around 500 kg – nearly one-tenth than in 2021 – while EAPA was no longer seized.[149] A shorter reaction time is therefore expected to have an impact – albeit limited - on the availability of designer precursors for illicit drug production (see also Figure 6).

Monitoring loopholes such as exempting users from notification obligations are closed, and stronger engagement of precursors 'users' is secured. However, the de minimis exemption to facilitate research and innovation might encourage illicit small-scale shipments and a possible shift to e-commerce, which is more difficult for authorities to control. The risk would remain limited: an abusive shipment of 1 g of pseudoephedrine would add shipment costs that would

[148] Data from the European drug precursor database indicate that slightly less than 60 % of operators – whether licensed or registered – are based in Germany (24.2 %), Spain (21.3 %) and France (13.4 %), and at the other end of the spectrum four Member States have under 5 licensed or registered operators.
[149] See Figure 6.

largely exceed the price of the good itself, however it would create a legal loophole. Pseudoephedrine is typically used is small-scale kitchen laboratories.

The updated guidance on tackling suspicious transactions would enable economic operators to better identify suspicious transactions and contribute to improving businesses' cooperation in addressing the threat of designer precursors.

On the other hand, Option 1 does not envisage ad hoc measures addressing the proliferation of designer precursors and does not strengthen existing tools concerning unscheduled designer precursors addressing suspicious transactions involving non-scheduled precursors (the catch-all clause). By largely relying on the current legal framework and on voluntary efforts, Option 1 cannot be expected to make a real difference on the illicit trade of precursors and on drug-related crime.

Therefore, indirect effects on public health are also expected to be negligible under this policy option. Benefits should not be overestimated, as option 1 relies largely on voluntary implementation by authorities and operators.

- **Environmental impacts**

As described above, it is difficult to reasonably assess the difference in environmental impacts between the policy options. However, as the impact on illegal drug manufacturing is expected to be limited, illegal waste disposal is also not expected to be reduced significantly. There continues to be a risk that criminals will eventually rely on more remote chemical derivatives that create more toxic waste.

Figure 11: Summary of impacts of Option 1

Impacts		Rating
Economic	Facilitation of legal trade	0
	Costs / savings for economic operators	0
	Costs / savings for MS authorities	-1
	Cost / savings for Commission	0
	Research and innovation in the chemical sector	-0
	Digitalisation of the EU system	0
	SME competitiveness	0
Social	Impact on control / prevention of illicit trade	+1
	Drug-related health impact	+1
Environmental	Impact on toxic waste disposal	0

Legend: Impact ratings: +3 = highly positive; +2 = positive; +1 = moderately positive; 0=neutral/modest impact; -1 moderately negative; -2 = negative; -3 = highly negative; N/A=not applicable

6.2. Option 2: Comprehensive Review

- **Economic impacts**

Public authorities

Option 2 is expected to facilitate public authorities' tasks and the enforcement of rules. It should overall reduce their administrative costs for reporting, licensing as well as import/export authorisations. The enforcement costs associated with the introduction of a ban on designer precursors and for IT infrastructure should be offset by the reduction in other administrative burdens.

The ban on designer precursors is likely to imply **moderate additional costs** to public authorities, but this will depend on the scope of the ban. Those authorities who provided a prediction in the targeted survey assume that their burden would increase between 10 % and 50 % in comparison to the baseline. The burden is assumed to increase with a larger scope of substances banned. National authorities' feedback on the proactive scheduling approach suggests a preference for moderate rather than a wide extension. Indeed, only 6 respondents out of 27 would be in favour of extending the proactive approach as much as possible, while for 13 authorities the extension should be limited or none. At the final workshop, national authorities raised the need for a clear identification of the substances. Otherwise, in their view, there would be a lack of legal certainty and authorities would not be able to enforce the rules in practice. As it is not possible to quantify this cost, it cannot be directly offset against other cost savings in licensing and registration.

The **streamlining of the legal texts is expected to have a limited impact on public authorities**. It will not change obligations as such but make them more easily readable and understood. 4 out of 22 respondents to the survey of public authorities who provided feedback on this proposed measure anticipated a limited or no change in burden. It is expected that there would be some administrative effort in the short term, offset by the long-term improvement in clarity. At the same time, binding rules on thresholds for mixtures were welcomed, as they reduce ambiguity and aid compliance. For public authorities, the benefit of such rules would be that they would not need to spend effort determining nationally the best approach for mixtures.

The **biggest economic impact for authorities is expected by the introduction of a centralised IT system** that would streamline all administrative procedures linked to drug precursors. For the vast majority of public authorities consulted (70 %, 17/24), e-license and e-registrations are expected to reduce administrative burden either moderately (25-50 % of costs, 13/24), or substantially (more than 50 % of current costs, 4/24).

Setting up an IT system that would digitise internal trade is estimated to cost the Commission about EUR M 1.575 in one-off cost. This would include evolutive maintenance of the system during its first years of existence.[150]

For external trade, in addition to the costs for the Commission detailed in ***Figure 12***, national authorities would also face adjustment costs to make any necessary connections, to revise standard operating procedures and for training, as well as recurrent costs for maintenance and updates, and ongoing support for users (EUR 1.38 million per year).[151]

Figure 12: Costs for the Commission to develop and maintain the external trade IT system

Cost estimate (million EUR)	Time horizon	Details
0.9	2026-2027	Pre-inception activities, business analysis, digitalisation policy and business architecture input, coordination and work with external stakeholders (notably the Project Group with Member States), digitalisation legal input during the preparation of internal COM legal

[150] See Annex 8 for more details. This would be in addition to the baseline cost of EUR 430 000 for developing function 3 of the existing database.
[151] Again, the Impact Assessment for the Single window environment for customs is used as a benchmark given that the approach would be similar.

Cost estimate (million EUR)	Time horizon	Details
		proposals, cooperation during the co-legislation phase and preparation for the next phases to build the solutions (e.g. COM IT Governance).
17 - 25 (2.83-4.16 per year)	2028-2033[152]	Core digitalisation work (i.e. technical specifications, development of system).
2.3 per year	2034+	Yearly maintenance cost could be expected once implementation is complete.

Source: European Commission

Public authorities can also expect **costs savings from the digitalisation of processes**.

Removing annual reporting to the Commission would be appreciated by national authorities as they have a significant burden to compile and validate data across multiple formats for many entities (at the higher end, a country like Germany has close to 1 000 entities reporting data on legitimate trade). Instead of national authorities reporting to the Commission, the data to be submitted to the UN would be generated by the digital solution. Authorities could use time saved to conduct targeted spot checks and perform ex-post compliance checks. The administrative cost saving by automating the annual reporting is estimated at EUR 3.2 million[153]. Risks due to this removal would be mitigated through the ex-ante nature of quantities to be included in licenses and registrations and the automatic checks via quantity management in external trade.

It was assumed that replacing the current quarterly incident reporting with a **real-time reporting obligation for analytical purposes would be cost-neutral** if integrated and linked to the existing UN based incident reporting system PICS.[154] However, at the final workshop, this measure was met with criticism by national authorities for introducing new and duplicate reporting obligations for Member States. This is so because the current PICS only concerns incidents that are of international interest, while other incident reporting needs to be in summary form at UN level. Nevertheless, in the event interoperability with PICS is enabled, ***the administrative costs for reporting would be roughly halved***, in monetary terms to EUR 240 000 EU-wide, per year.[155]

Similarly, as shown in Figure 13 cost savings for public authorities are expected when relying on the digital system to process licensing and registrations and to automatically issue import and export authorisations based on the quantity management functionality.

[152] This timeline assumes that the updated regulation(s) on drug precursors come into force mid /late 2027 (assuming the Impact Assessment presented at the Regulatory Scrutiny Board in Jun. 2025, possible adoption by the College by Q4 2025, followed by at least 18 months of co-legislation).

[153] See Annex 4

[154] As regards connection of Union systems to UN systems (PEN and PICS), in the case of both options, this would be subject to the approach which UN services would take to interoperability with a Union system. It is not possible to estimate currently their appetite for this or their cost-benefit perspective. Therefore, while the Hub could in principle be used for exchange of information with the UN systems, the potential additional cost in this option is not assessed. The systematic exchange of information may also be subject to a prior international agreement.

[155] The annual administrative costs for national authorities were estimated based on survey feedback. As the survey question included also the efforts required to report legal trade figures, the average number of days reported – i.e. approx. 40, based on 14 authorities that provided an estimate – was divided by two, assuming the two reporting tasks (incidents and legal trade) have the same weight.

Figure 13: Expected administrative cost savings for national authorities in Option 2 (licences, registrations, authorisations and reporting)

Action	Baseline	Option 2	
	Costs (million EUR)	Costs (million EUR)	Cost savings (million EUR)
To issue new license/registration (one-off)	1.3	0.8	0.5
To renew license/registration (annually)	0.23	0.15	0.09
To issue import authorisation (annually)	0.2	0	0.2
To issue export authorisation (annually)	6.7	0	6.7

Source: the study (see Annex 4 for more details on assumptions and calculations based on standard costs model)

Economic operators

Option 2 equally provides for a reduction of administrative and compliance costs for economic operators through the digitisation and streamlining of procedures for drug precursors. As for public authorities, additional costs linked to the introduction of specific controls for designer precursors depend on the scope of the measures but should be mitigated by the overall reduction in costs for the economic operators concerned.

The ban of designer precursors is largely supported by economic operators (35 out of 70 agree with this solution, and only 6 disagree), and is clearly preferred over an extension of the current practice of requesting a licence for scheduled designer precursors (24 'strong' agreements against 15). There is a **lighter burden associated with the ban** (prior notification instead of licence). The surveyed economic operators expect the ban to increase cost by nil to +15 %.[156] Concerning **the prior notification of transactions** in these substances, the frequency of such instances is difficult to predict. However, for perspective, in 2018-2022, declared licit uses of designer precursors amounted to around 70 kg/year, i.e. 0.002 % of total declared licit use for Category 1 substances. Imports and exports amounted to some 52 transactions/year – i.e. 2 % of total yearly transactions involving Category 1 substances. So, extending the notification obligation to other substances is not expected to have relevant impact on burden.[157]

While designer precursors do not have known legal use (except research)[158], economic operators, especially those that produce or sell a broad range of specialty chemicals, need nevertheless to continuously check their portfolio to provide for legal compliance ('due diligence tasks').These tasks are already performed whenever a new substance is added to the regulations, so ***the ban would not require to introduce a new procedure but to extend checks to a larger number of substances that do not always have clear identifiers***.

As described above, the cost of the regulations is directly related to the number of substances in a given company's portfolio. The due diligence costs also depend on the scheduling method. It is straightforward for companies to conduct due diligence check when a newly scheduled

[156] Compared to the baseline situation. The dynamic baseline changed as the Commission started to schedule proactively during the impact assessment. Therefore, here the baseline refers to a situation where this had not yet taken place.

[157] Additionally, the burden reduction benefits of using the EU central portal for notifications should be considered, as discussed in Section 6.2.7.

[158] The annual legal trade reports from the EU drug precursors database affirms that there is no legal trade for these substances. Currently, only105 operators hold a license for designer precursors for research purposes and each of them also possesses a license for the corresponding scheduled key precursor.

substance is identified through a CAS number, as most chemical companies already use it as portfolio identifier. More substantial effort is required to check substances identified through the derivative description (i.e. substances designated by adding terms like '*and its esters'* or '*and its carbamates'* to the definition of scheduled substances). In this case, checks cannot be automated but require chemical expertise and manual work (as substances may appear under various chemical names). Similar considerations apply to the designation of substances through chemical formula. Qualitative feedback indicates that, in the absence of CAS number, alternative identifiers would be SMILES strings[159] (mentioned by nine companies), InChI / InChI Key (mentioned by two companies) [160], MDL number, Pub-Chem Number (mentioned by one company).

According to the estimate collected, the due diligence for a new substance requires only 1-2 hour per substance if the CAS number is provided, while it may rise to 7-12 hours in case of the other identification methods discussed. As the precise models were not available at the time of the consultations, a number of assumptions are needed to estimate the ***extent of due diligence costs that the proposed ban would impose on economic operators***:

- it is assumed that the time input required to conduct due diligence on listed designer precursors will be in line with what is currently required for new scheduled substances with a CAS number, i.e. ***1.5 hour*** (on average). It is reasonable to estimate that bulk scheduling is less burdensome than one-by-one scheduling, when the substances concerned are derivatives of the same core molecule.

- From a single company perspective this is a ***one-off cost***, however, from the regulation perspective it is a recurrent cost, as new substances are continuously added to the regulation, and businesses need to conduct due diligence checks whenever they start producing or selling new families of chemicals.

- The number of ***affected companies*** cannot be precisely estimated; however, it can safely be assumed that all companies that are licensed to deal with precursors falling under Category 1 - i.e. ***approx. 1 200 companies*** - regularly conduct due diligence checks.

Assuming an average cost of labour of EUR 35.65 / hour, the aggregate 'one-off' impact on administrative costs for businesses (EU-wide) would result in EUR 7.7 million.

The EUDA has confirmed the availability of easily accessible automated chemical structure search tools. Currently, it appears that not all economic operators make use of such tools. This concerns SMEs in particular.[161] In an additional follow up survey by the Commission, those that did use a specific software reported one-time costs from EUR 0 to 4 000 for their use[162] . To provide for a level playing field for SMEs, the EUDA could be invited to develop such a

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[159] SMILES stands for "Simplified Molecular Input Line Entry System," and translates a chemical's three-dimensional structure into a string of symbols that is easily understood by computer software.

[160] InChI is an international chemical textual identifier developed by the International Union of Pure and Applied Chemistry (IUPAC). Differently from CAS number, the InChI is non-proprietary, can be computed from structural information (it is not 'assigned') and is human readable. It contains more information than SMILES. InChI Key is the condense machine-readable string version of InChI.

[161] According to the follow-up survey, SMEs reported higher due diligence costs due to less accessible IT tools.

[162] An additional follow-up survey was conducted to gain a clearer understanding of the due diligence costs associated with family scheduling.

tool and make it accessible to everyone [163]. This initiative will help SMEs to reduce their due diligence costs.

Concerning, the simplification of procedures, more than half of the 60 economic operators responding to the survey considered **consolidating the two regulations into a single act as cost-neutral**[164]. Disaggregating the responses from SMEs, roughly the same proportion expect no relevant change in their costs. In a similar vein, streamlining definitions and aligning them to other pieces of legislation is not expected to have any impact. Concerning mixtures, economic operators had mixed approaches, some advocated for flexibility while others would welcome clear rules.

Economic operators were supportive of an integrated EU digital solution. Most economic operators who responded to the survey expected cost savings of varying degrees. Adjustment costs for economic operators should be low given that the IT system would be developed by authorities. The economic operators who responded to the survey had mixed views on whether IT investments would be required (35 out of 77 anticipated such costs, and 32 viewed them as unlikely or were unsure). Much more probable, also in accordance with operators, is that they would entail the costs of familiarisation with the new system and adapting internal procedures (48 out of 78 operators were of this view).

On average, large firms expected cost savings of around 35-36 % for license applications (new or renewal) and 28-29 % for registrations (new or renewal), while SMEs estimated savings at 21-22 % in all cases. As large firms had higher estimated costs on average to begin with, they stand to make higher savings.

Figure 14 highlights the expected cost savings related to introduction of e-licences and self-registration, as well as the removal of the reporting obligation.

An estimated 600 operators who are currently required to register for Category 2 but only trade internally would be exempt from self-registration compared to the baseline. An estimated additional 100 operators trading in Category 4 would be expected to self-register for external trade.

The **elimination of annual reporting requirements** by economic operators would be supported and is in line with the Commission's goal of reducing reporting requirements. The figure likely underestimates the reality since the estimation for the number of entities is derived from the information in the European drug precursors database, which does not include Category 4.

[163] In accordance with the follow-up survey, SMEs reported higher due diligence costs due to less accessible IT tools.
[164] 35 out of 60 respondents anticipate "No Relevant Change" (+/- 5 %) in their costs.

Figure 14: Expected administrative cost savings for economic operators in Option 2 (license, registrations and reporting)

		Baseline	Option 2	
		Cost (million EUR)	**Cost (million EUR)**	**Cost saving (million EUR)**
New license/ registration	SME	0.65	0.44	0.25 (one off)
	large firm	0.09	0.05	
License/ registration renewal	SME	0.21	0.14	0.07 (annual)
	large firm	0.02	0.01	
Reporting	SME	2.57	0 (no reporting)	3.21 (annual)
	large firm	0.64		

Source: the study (see Annex 4 for more details on assumptions and calculations based on standard costs model)

The automation of import and export authorisations would lead to the estimated direct administrative cost-savings for economic operators in Figure 15. The risk of extending this to all economic operators is considered relatively manageable as these operators will still have to go the formalities for licences and registrations.

Figure 15: Expected administrative cost savings for economic operators in Option 2 (import and export authorisations)

	Transactions/year (2020-2023)	**Average effort (minutes)**	**Labour cost (EUR/min)**	**Annual cost savings (million EUR)**
Import	2 451	182 (3 hours)	0,59	0.27
Export	31 304	331 (5 hours)	0,59	6.15

Source: the study (see Annex 4 for more details on assumptions and calculations based on standard costs model)

Replacing the current paper-based customer declaration by an e-validation is the only measure that concerns business-to-business processes. Consulted operators were keen to modernise the procedure. In accordance with operators, the **customer declaration was particularly burdensome** because it is required for every transaction. For firms dealing with hundreds or thousands of transactions this quickly adds up. Most economic operators who responded to the survey expected **cost savings of varying degrees**, on average, 40 %, for large firms and 36 % for SMEs. In absolute terms, about 3 500 operators currently obtaining a customer declaration would save annually EUR 17.6 million by replacing the customer declaration with e-validation. The remaining cost would amount to EUR 3.5 million for SMEs and EUR 1.4 million for large firms[165].

The measures in this option do not specifically address SMEs, but as they are about reducing burdens, SMEs' bottom lines should be positively affected. Larger companies should nevertheless benefit more due to their larger number of activities and transactions.

Overall, this burden reduction should improve both SMEs and larger companies' competitiveness – also internationally. A lighter and more targeted control system should

[165] See Annex 4.

positively affect them in comparison to companies based in other markets. They would also be more flexible in the conduct of their business e.g. due to reduced waiting times in imports and exports.

Research and innovation

Stakeholders largely concur on the need to avoid unintended adverse impact on ***chemical research and innovation***. The proliferation of designer precursors has made research on new chemicals more difficult and expensive due to restrained access to certain substances.[166] Economic operators consider exemptions for legitimate R&D activities as an essential component of the revised policy on precursors. Considering that nearly one-third (10 out of 36) of surveyed companies engaged in Category 1 precursors-related activities perform research activities, this issue does not regard only universities or research entities. A chemical distributor specialised in supplying pharmaceutical laboratories with screening drug compounds reported, during an interview, that their transactions seldom exceed 5-10 mg. Therefore, a blanket ban on designer precursors without any exemptions would have a negative impact on research and innovation. Also, the scope of scheduling needs to be very clear so as not to deter research from substances that might potentially be subject to controls. This is mitigated by the possibility to use these substances if authorities are notified of their use, or by the possibility to request a license if larger quantities are required. Likewise, the 'de minimis' exemption for Category 1 substances enables companies to use them for research purposes without having to undergo the administrative procedures for a license. The expectation is that this measure will not have any economic effect on potential innovations as research access to substances is facilitated.

These exemptions should also positively affect competitiveness by facilitating innovation in comparison to the baseline.

- **Social impacts**

The impact on detection and prevention of drug precursors crime is estimated to be highly positive.

The time to detect and respond to new threats will be reduced. The **urgency procedure** will **shorten** the adoption time **by 3 months**. The **real-time seizure** reporting will allow the EUDA to **detect new trends** immediately, **speeding up** the availability of critical data to detect new threats **by 4 to 18 months**.

As data analysis and literature showed, the benefits of placing new substances under control is temporary, but **comprehensive interventions** covering several substances have **deeper effects**, as it takes longer for organised crime groups to find alternative chemicals and establish the supply chain[167]. Some of these interventions, while limited in time may still have a long-term effect for the persons concerned. It was found that the control of ephedrine and pseudoephedrine in the 1990s in the US lead to a reduction of the availability of methamphetamine. As a result,

[166] This issue was reported by 6 out of 15 economic operators who reported adverse side-effects for the industry linked to the growth in illicit trade of designer precursors.
[167] The study, Annex 6, p. 53.

less children were put in foster care[168]. This is a long-term benefit for the children concerned that will last beyond the market effects of the measures concerned[169].

A robust prediction of the effect of the proposed **ban on designer precursors** availability is, however, not feasible. Nevertheless, the analysis of incidents reported in the European drug precursors database and comparison with similar regulations, such as the rules on new psychoactive substances (NPS), provide some useful indications of possible impacts. In analogy with the national rules **using a moderate scope based on chemical formula scheduling** of new psychoactive substances, the prohibition of specific designer precursors is likely to **significantly reduce** their **circulation and use**. However, a key factor in this respect is the consistency in the regime applied in the EU and internationally, notably in alliance with the United States.

A clear ban on designer precursors will also facilitate the enforcement of rules on online marketplaces.

The same impacts for closing the loopholes on user as in Option 1 are expected.

The strengthened catch-all clause will substantially increase the competent authorities' capacity to identify and prosecute offences involving new, non-scheduled substances. Obliging the Member States to adopt necessary measures to enforce the catch-all clause for non-scheduled precursors, including the possibility to select goods for investigation purpose, was supported by most authorities surveyed (18 out of 25). Authorities largely agreed with adopting the provision of false information as a criterion for identifying suspicious transactions of non-scheduled substances (22 out of 26 agreed, of which 16 'strongly'). **Overall, the strengthening of the catch-all clause is associated with major positive impacts on the reduction in the availability of drug precursors** (12 out of 23 respondents) and on enforcement (11 out of 23).

The effects of the **ban on designer precursors and on the strengthening of the catch all** clause are expected to contribute substantially to **reduce the availability of precursors for illicit drug manufacturing.** Based on previous interventions, it could be assumed that the large scale measures introduced may lead to an estimated decrease of **around 60 %[170]** of the baseline lasting for at least two years (assuming 2020 as benchmark).

The **central digital system** should further enhance the capacity of competent authorities to **identify and stop suspicious transactions**. This system should be more robust against fraud and facilitate more targeted risk management and analysis compared to the current fractioned paper-based environment. Benefits are likely to be magnified by the planned **Customs reform** and the establishment of the new European Customs Authority and of the EU Customs Data Hub, as this would likely **boost the probability of mislabelled / mis-declared consignments to be detected** through improved risk management capabilities which will reduce the availability of drug precursors for illicit manufacture of drugs. In addition, the EU wide risk

[168] Scott Cunningham and Keith Finlay, 'Parental Substance Abuse and Foster care: Evidence from two methamphetamine supply shocks', *Economic Inquiry,* Vol. 51, No. 1, 2013, pp. 764-782

[169] Benjamin Blemings, Scott Cunningham, 'Temporary gains and permanent costs in methamphetaime precursor controls', *International Journal of Drug Policy, vol. 138, (2025), p. 3*

[170] While a quantitative projection is not possible. Annex 4 provides a qualitative assessment of the factors that would presumably lead to a substantial reduction of the availability of drug precursors for illicit drug production.

analysis capabilities will end or at least reduce significantly the paths of least resistance[171] created by the uneven enforcement by Member States.

Recent seizures of designer precursors in Liège Airport amounting to 2.5 tonnes in March 2024 only made possible by the implementation of the ICS 2 (Import Control System) are a good example of the benefits of performing joint risk analysis. This system allows for Member States, for the first time, to perform joint risk analysis still in specific situations and on a limited set of data. The ICS 2 is only a first step towards an EU wide risk analysis for all consignments where other data sources can be integrated working with advanced analytics and managed by the EU Customs authority.

The scientific literature[172] on the impact of precursors regulation suggests that a reduction in the illicit trade of precursors can lead to public health benefits, in particular a reduction in the demand for treatments related to the use of synthetic drugs. However, the extent of such impact can hardly be estimated, due to the numerous and decisive confounding factors.

- **Environmental impacts**

As described above, cascading benefits can be expected in the area of environmental impact, as the decline of illicit drug manufacturing activities in the EU would reduce the amount of chemical waste illegally disposed, and the costs of cleaning dumps, laboratories and storage sites. On the other hand, eventually criminals will adapt and have recourse to chemical alternatives which may well have detrimental effects on the environment and human health. It is not feasible to reasonably compare the impacts of the various options in this field.

Figure 16: Summary of impacts of Option 2

impacts		Rating
Economic	Facilitation of legal trade	+2
	Costs / savings for economic operators	+2
	costs / savings for MS authorities	+2
	Cost / savings for Commission	-2
	Research and innovation in the chemical sector	0
	Digitalisation of the EU system	+3
	SME competitiveness	+2
Social	Impact on control/prevention of illicit trade	+3
	Drug-related health impact	+2
Environmental	Impact on toxic waste disposal	+1

Legend: Impact ratings: +3 = highly positive; +2 = positive; +1 = moderately positive; 0=neutral/modest impact; -1 moderately negative; -2 = negative; -3 = highly negative; N/A=not applicable; ?=impact conditional to other factors / conditions.

6.3. Option 3: Comprehensive Review with stronger controls

- **Economic impacts**

Public authorities

[171] EU drug precursors policy is unevenly implemented or enforced across EU countries, creating ***paths of 'least resistance' that Organised crime groups can exploit*** for trafficking designer precursors into and across the EU.
[172] See Annex 4, section 3.1 on the reduction in the availability of precursors for illicit drugs manufacturing.

Option 3 puts greater emphasis on objective 1 than objective 2. Therefore, a **substantially greater burden is placed on national authorities to enforce Option 3**.

As the ban of designer precursors would comprise around 300-400 substances, some of them listed individually, others using innovative ways of scheduling, the increase in cost would be towards the larger end of the predicted 10 % to 50 % increase indicated by the targeted survey. As highlighted for option 2, only 6 respondents out of 27 would be in favour of extending the proactive approach as much as possible, while for 13 authorities the extension should be limited or none. At the final workshop, national authorities raised the need for a clear identification of the substances. Otherwise, in their view, there would be a lack of legal certainty and authorities would not be able to enforce the rules in practice. Such risks would be aggravated by the larger number of substances scheduled by option 3. Like for option 2, as these costs cannot be quantified, it was impossible to offset them against other burden reduction measures in licensing and registration[173].

A relative majority of authorities expects that this will lead to an increase of implementation burden[174] as it would require, in accordance with a respondent: '*more extensive monitoring and enforcement efforts, necessitating significant additional resources*. The analysis of authorities' estimates on the expected impact on enforcement costs indicates a ***limited to moderate increase, likely comprised between 0 % and 35 %***.

For public authorities and the Commission, the costs of digitisation are the same as in Option 2. Thus, national authorities would likely incur an annual cost of EUR 1.38 million for digitisation. Equally, they would benefit from the removal of annual reporting obligations, administrative costs related to import and export authorisations as well as the streamlining of incident reporting.

On licensing and registration, the savings are marginally lower than in Option 2 due to the larger number of substances that would be subject to licensing and registration requirements for internal trade. However, national authorities would benefit from an available list of economic operators dealing in these bulk materials.

Figure 17: Expected administrative cost savings for public authorities in Option 3 (license, registrations)

License/ registration	Baseline	Option 3	
	Cost (million EUR)	Cost (million EUR)	Cost saving (million EUR)
New	1.3	0.9	0.4 (one-off)
Renewal	0.23	0.2	0.1 (annual)

Source: the study (see Annex 4 for more details on assumptions and calculations based on standard costs model)

In comparison to the baseline, there is an overall reduction in the cost of licensing and registration formalities to be carried out by authorities, but authorities will need to broaden their

[173] For further details, please refer to Annex 2.

[174] Specifically, 7 respondents expect an increase of which 4 a 'major' one, against 4 expecting a moderate reduction. Qualitative feedback indicates that the reduction of burden would stem from a 'reversal of proof' provision, requiring operators to demonstrate the legitimate use of non-scheduled precursors. This hypothetical provision was however dropped at a later stage as not consistent with the mandate and principles of the EU policy concerned.

enforcement and inspection activities for a much larger scope of substances. Depending on the resources and expertise available, especially in the context of extended scheduling, the enforcement of controls may become less targeted and as a result less effective. These costs may in fact exceed the enforcement costs of inspections identified in the baseline.

Economic operators

As in Option 2, **legitimate economic operators also benefit from a simplification and standardisation of the framework**, through streamlined obligations that can be automated / require less manual intervention from authorities (i.e. e-license applications, self e-registration, authorisations for external trade and annual reporting) This makes obligations easier to comply with and to comply with and reduces administrative (compliance) costs, but cutting hassle costs for authorised economic operators (AEO) / equivalent only. This would possibly reduce the risk of diversion further but would lead to a double requirement of control – licenses and registrations and an additional AEO status to benefit from trade facilitation.

The establishment of a separate category for designer precursors with an ad hoc license requirement is not expected to make any relevant change. More operators might need to request special licences due to the larger scope but the burden of obtaining a license is generally considered as manageable – i.e. between EUR 165 and EUR 300 per license/company, EUR 232 on average - and the introduction of e-licensing is expected to further reduce burdens. The aggregated administrative one-off costs would be EUR 22 060[175].

However, like for public authorities, the **larger scope of substances scheduled under Option 3 will increase economic operators' administrative costs for checking portfolios**. As highlighted under Option 2, the due diligence costs for operators are difficult to calculate and are subject to several assumptions. Based on these assumptions, scheduling an additional 300-400 substances could result in a total one-off cost of EUR 20.5 million.

While savings are expected from **digitisation**, the stricter rules on the control of substances imposed by Option 3 directly translate into reduced cost savings and sometimes increased costs for economic operators.

For internal trade, Option 3 would extend the requirement for self-registration for substances of the new Category 2 also. This would affect an additional 363 operators[176].

The **stricter controls of current Category 2A substances would impose substantial additional burdens on trade**. Feedback at the workshop and written feedback received subsequently confirmed significant concerns on the extension of the licensing requirements for companies operating with Category 1 substances to Category 2A, **especially for SMEs**.

Figure 18: Expected administrative cost savings for operators in Option 3 (license and registrations)

	Baseline	Option 3

[175] The study, p. 91.
[176] Self-registration would be required for all substances, and the process would be the same regardless of whether an operator was already registered for other substances.

License/ registration		Cost (million EUR)	Cost (million EUR)	Cost saving (million EUR)
New	SME	0.65	0.52	0.16 (one-off)
	large firm	0.09	0.6	
Renewal	SME	0.21	0.17	0.04 (annual)
	large firm	0.02	0.12	

Source: the study (see Annex 4 for more details on assumptions and calculations based on standard costs model)

There are currently 689 firms registered to trade in Category 2A substances. Based on industry feedback their costs would increase to comply with the licensing requirements, among others[177]. Yet, a proportion of those trading in Category 2A currently already trade in Category 1, and it can be assumed that those trading also in Category 1, would already fulfil the criteria and have limited additional costs. Discounting these operators, the number of firms who would have new obligations is estimated to be 498 based on the European drug precursors database. To meet these obligations, **a significant potential cost would be the need to secure their premises against unauthorised removal and theft**. 74 % of large firms confirmed that they made such investments regardless and 56 % of SMEs[178]. Securing premises is estimated to imply EUR 2.7 million one-off adjustment costs and EUR 1.5 million annual cost but the estimate is likely to be above the real costs.

As only AEO benefit from lifting the PEN wait period, **hassle cost for non-AEO will increase**, with a more detrimental effect on their competitiveness as it will reduce their ability to process business transactions in a timelier manner. It is not possible to calculate potential numbers of non-AEO or a proportion of SMEs. Yet, SMEs are likely to be less well represented given the efforts of certification.

Also, under Option 3 an **additional 700 operators would need to verify their customers** which could be a significant burden when the numbers of transactions are high. This measure would imply an estimated annual cost of EUR 12.5 million for SMEs, and EUR 5.2 million for large firms. The overall cost saving in comparison to the baseline would be EUR 4.7 million.[179]

Figure 19: Expected administrative annual cost savings e-validation

	Baseline	Option 3 (Category 1 and 2)	
	Cost (million EUR)	Cost (million EUR)	Cost saving (million EUR)
SME	15.6	12.5	4.7
Large firm	6.9	5.2	

Source: the study (see Annex 4 for more details on assumptions and calculations based on standard costs model)

Overall, Option 3 has a lower economic benefit and introduces new administrative and hassle costs for businesses. These additional costs are likely to affect SMEs rather than larger firms as

[177] For instance, additional needs for training, additional communication with suppliers, special arrangements for the disposal of substances and so on.
[178] The remainder of SMEs most commonly responded "don't know" 4/16, but a few said their costs would increase either moderately 2/16 or significantly 1/16).
[179] Calculation based on the study. See Annex 4.p.

they are not as well placed to benefit from economies of scale through existing licenses or the AEO status. These measures also have a much more limited effect on facilitating trade within the single market as well as internationally. Benefits for competitiveness are therefore more mitigated.

Research and Innovation

The administrative burdens introduced by the option, while enhancing controls are also likely to create obstacles to research, the acquisition of samples by national laboratories and other legitimate activities. In this sense this option might eventually affect capacity to innovate (innovation competitiveness), although not in a significant way (as special license for legal trade of designer precursors will be possible). By not enabling exemptions for small quantities of the new Category 1, research on the substances will come with higher administrative costs and burdens.

In the same vein, the automatic labelling as 'suspicious' of certain transactions based on the beefed-up catch-all clause was also regarded critically. In accordance with a respondent, this might negatively impact on the willingness of legal operators to engage in the trade of such substances even if they are not included in the legislation, thus eventually hampering research and innovation involving such substances. It was not possible to quantify the effects of these measures for innovation and research.

- **Social impacts**

The impact on control and prevention of illicit trade is estimated to be highly positive.

As the measures to improve the time to detect and respond to new threats are the same as for Option 2 the impact will be the same.

The effects of the ban on a wider scope of designer precursors and the mandatory investigation by competent authorities on the strengthening of the catch-all clause are expected to strongly reduce the availability of drug precursors for illicit drug manufacturing and will increase the competent authorities' capacity to identify and prosecute offences involving non-scheduled substances. A robust prediction of the effect of the proposed measures on designer precursors availability is, however, not feasible.

It is assumed that, as the scope of the ban would be wider the more difficult it would be for criminals to create and use designer precursors that are not yet scheduled.

As data analysis showed, the benefits of placing new substances under control is temporary[180], but comprehensive interventions covering several substances have deeper effects, as it takes longer for organised crime groups to find alternative chemicals and establish the supply chain. As the number of substances is significantly higher than with Option 2 the impact on drug precursors availability is expected to be magnified. The combined measures related to

[180] Literature documented in the study. Here, due to the larger number of scheduled substances, therefore, the overall number of seizures of unscheduled substances should also be reduced in this option.

scheduling and the ban on designer precursors are estimated to contribute approximately a 60 %[181] of the reduction in the availability of precursors used in illicit drug manufacturing.

In addition, threshold exemptions will further close the legal loopholes that criminals can abuse to obtain designer precursors.

The mandatory registration of Category 2 operators, including automated reporting, will increase the capacity of competent authorities to monitor legal trade and detect diversion.

As with Option 2, the central digital system should further enhance the capacity of competent authorities to identify and stop suspicious transactions. This system should be more robust against fraud and facilitate more targeted risk management and analysis compared to the current fractioned paper-based environment. Benefits are likely to be magnified by the planned Customs reform and the establishment of the new European Customs Authority and of the EU Customs Data Hub, as this would likely boost the probability of mislabelled / mis declared consignments to be detected through improved risk management capabilities which will reduce the availability of drug precursors.

The scientific literature[182] on the impact of precursors regulation suggests that a reduction in the illicit trade of precursors can reasonably lead to a disruption of drug supply and reduction of drug availability, which in return may have public health benefits, and in particular linked to a possible reduction in the demand for treatments related to the use of synthetic illicit drugs. On the other hand, and in line with possible consequences for the environment, the recourse to more toxic substances may lead to higher health risks for those producing and consuming the drugs. However, the extent and robustness of such impact can hardly be estimated, due to the numerous confounding factors that play a decisive role on success.

- **Environmental impacts:**

Similarly, cascading benefits can be expected in the area of environmental impact, as the decline of illicit drug manufacturing activities in the EU would reduce the amount of chemical waste illegally disposed, and the costs of cleaning dumps, laboratories and storage sites. On the other hand, if criminals resort to more remote chemical derivatives, this may in fact increase the chemical waste produced by illegal drug production. It is not feasible to quantify these impacts as the volume of illicit drug production in the EU is unknown.

Figure 20: Summary of impacts of Option 3

Impacts		Rating
Economic	Facilitation of legal trade	-2
	Costs / savings for economic operators	0
	Costs / savings for MS authorities	+1
	Cost / savings for Commission	-2
	Research and innovation in the chemical sector	-1
	Digitalisation of the EU system	+3
	SME competitiveness	-1
Social	Impact on control / prevention of illicit trade	+3
	Drug-related health impact	+2?
Environmental	Impact on toxic waste disposal	+1?

[182] See Annex 4, section 3.2 on the impact on drugs availability.

Legend: Impact ratings: +3 = highly positive; +2 = positive; +1 = moderately positive; 0=neutral/modest impact; -1 moderately negative; -2 = negative; -3 = highly negative; N/A=not applicable; ?=impact conditional to other factors / conditions.

7. How do the options compare?

7.1. Effectiveness

The purpose of the effectiveness evaluation is to determine how well the proposed options would achieve both objectives at the same time and in a satisfactory manner, i.e. taking into account the trade-off that exists between them.

Option 1 will help reduce the time for a newly detected substance to be placed under control and will improve national authorities' knowledge. Similarly, the EUDA repository will strengthen economic operators' awareness, and engagement. However, this option will fall short of expectations regarding the proliferation of designer precursors. Also, it is not very effective in facilitating trade as the success of the soft measures will depend on their uptake and only limited improvements for internal trade can be done by delegated or implementing acts.

Option 2 will prove effective against the proliferation of designer precursors and the trafficking of non-scheduled substances. If well implemented, the real-time seizure reporting and urgency procedure will reduce significantly the time to detect and respond to new threats, while enabling authorities to target controls more specifically on those substances that are at a higher risk of being used in illegal drug production. Option 2 will also help closing the existing monitoring gap regarding potential diversion occurring at the level of final users of precursors. Overall, this is expected to help reduce the availability of precursors used in the manufacturing of illicit drugs (especially synthetic drugs) and allows to align with the United States' family scheduling. Economic operators' awareness, and engagement will improve. The regulatory framework is effectively simplified and streamlined. The development of an EU portal provides for the modernisation of the control system, alongside the provisions for digital verification of customers in the internal trade of Category 1 substances. The burden of the EU control system for legal trade is reduced through the lifting/automation of various requirements. These should offset the slight increase in authorities' enforcement costs for the additional substances scheduled. These changes should contribute to effectively facilitating trade and promoting the competitiveness of the sector without affecting the overall control framework for drug precursors. Option 2's impacts are more balanced considering the two objectives with a comparatively stronger focus on facilitating legal trade.

Option 3 will largely deliver the same results as Option 2. It is expected to maximise Objective #1 of the intervention, i.e. the reduction in the availability of precursors used in the manufacturing of illicit drugs. Given the greater number of scheduled substances, than in option 2, there should be more seizures of scheduled rather than un-scheduled substances. It is, however, not possible to predict to what extent this would effectively lead to a greater reduction of drug precursor supplies for illicit drug production. Given that it would be more costly to enforce option 3 due to the larger number of substances to be screened and higher control burdens on legitimate businesses, some Member States did not support excessively broad scheduling of substances as they may not be in the position to cope with the required effort. There is a substantial risk of leading to sub-optimal enforcement. This may pose problems for effectiveness. As with Option 2, Option 3 sees the Regulatory framework streamlined and the processes modernised. However, the extension of obligations for Category 1 substances to also cover Category 2A, and to cover internal trade of now Category 3 substances stands to create considerable additional burden for affected firms. Option 3's impacts are addressing both

objectives, but the balance between reducing illegal trade without unduly affecting legitimate activities is more heavily skewed towards controls.

7.2. Efficiency

A greater 'efficiency' – in the sense of a need for reducing implementation and administrative costs and burden – is indeed one of the purposes of the intervention. In this section, the impact of the proposed option on costs (i.e. cost savings) are combined with those expected from measures addressing illicit trade, for an aggregate comparison of the overall costs and benefits balance (see also Annex 3). However, not all impacts can be quantified or monetised, especially benefits. Therefore, an aggregate monetary impact cannot be fully predicted. This particularly so for the enforcement costs (inspections and controls) of authorities that do not pertain to the regular implementation of licensing and registration formalities. They cannot be quantified precisely as authorities were only able to provide estimates in percentage bands.

Figure 21 presents the respective benefits and costs from the intervention envisaged under the two main objectives, and aggregate efficiency conclusions.

Figure 21: Comparison of options regarding the 'efficiency' criterion assessed over a period of 3 years, with costs/cost savings annualised.

<table>
<tr><th>Option 1</th><th>Option 2</th><th>Option 3</th></tr>
<tr><td colspan="3">Objective #1 - Benefits</td></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td></td><td colspan="2">Substantial decline in designer precursors and other non-scheduled precursors trafficking (about -60 % for two years based on similar previous measures) (+++)
More robust supply chain control system (qualitative) (+)</td></tr>
<tr><td colspan="3">Objective #1 - Costs</td></tr>
<tr><td colspan="3">EUDA repository costs (1FTE [183] + 182000 EUR one-off [184]): EUR 0.252 million</td></tr>
<tr><td rowspan="3">Baseline</td><td colspan="2">Due diligence administrative costs for operators linked to the ban of designer precursors (EUR):
2.72 million[185] (-) 7.25 million[186] (---)</td></tr>
<tr><td></td><td>One-off costs for operators to obtain special license for designer precursors: EUR 0.01[187] (-)</td></tr>
<tr><td>Moderate additional costs (est. +10 %) for MS to implement the ban (-)</td><td>Substantial additional costs (est. +50 %) for MS to implement the ban (--)
Moderate enforcement costs increase for MS from the need to decide if to follow up on every transaction that meets 'suspicion' criteria (up to +35 %) (-)</td></tr>
<tr><td>Alignment of obligations for users: limited to moderate increase of administrative costs (5 %-20 %) (-)</td><td colspan="2"></td></tr>
<tr><td colspan="3">Objective #2 - Benefits</td></tr>
</table>

[183] 1 FTE: EUR 188,000 EUR/year according to the Legislative financial and digital statement.
[184] Annualised according to the standard cost model formula: "= total cost*(years/100)/(1-((1+years/100) ^-3))"
[185] Annualised according to the standard cost model formula above with total cost = EUR 7.70 million.
[186] Annualised according to the standard cost model formula above with total cost = EUR 20.53 million.
[187] Annualised according to the standard cost model formula above with total cost = EUR 0.022 million.

<table>
<tr><th>Option 1</th><th colspan="2">Option 2</th><th>Option 3</th></tr>
<tr><td rowspan="11">Negligible benefits (if any) expected without change to legal framework or Mandatory EU centralised system

Minor benefits for reducing burden on internal trade, but the overall coherence of rules is further reduced (0)

30 % cost reduction on annual reporting
1 million/year (+)

1 million/year</td><td colspan="2">Quicker and more efficient processes that are more harmonised and less prone to error</td><td>Benefits akin to Option 2 but diminished to a lesser extent due to extension of obligations to Category 2A substances and internal trade in current Category 3 substances</td></tr>
<tr><td colspan="3"><u>Reduced compliance costs for economic operators</u> compared to baseline (EUR):</td></tr>
<tr><td colspan="3">Reduction of costs for licenses and registrations (EUR):
- 0.09 million[188] (one-off) (+)
- 0.072 million (recurring)
- 0.09 million[189] (one-off) (+)
- 0.072 million (recurring)</td></tr>
<tr><td colspan="3">Digitisation of customer verification brings cost reduction (EUR):
- 17.6 million/year (+++)
- 17.6 million/year (+++)</td></tr>
<tr><td colspan="3">100 % cost reduction on import / export authorisations
- 6.4 million/year) (+++)
- 6.4 million/year) (+++)</td></tr>
<tr><td colspan="3">100 % cost reduction on annual reporting
- 3.2 million/year (++)
- 3.2 million/year (++)</td></tr>
<tr><td colspan="3">Hassle costs saved (qualitative) (++)
Hassle costs saved (qualitative) (++)</td></tr>
<tr><td colspan="3">Public authorities benefit from more efficient processes compared to baseline (EUR):</td></tr>
<tr><td colspan="3">Reduction of costs for licenses and registrations compared to baseline (EUR):
- 0.16 million[190] (one-off) (+)
- 0.086 (recurring)
- 0.16 million[191] (one-off) (+)
- 0.086 (recurring)</td></tr>
<tr><td colspan="3">100 % cost reduction on import / export authorisations
- 6.9 million/year (+++)
- 6.9 million/year (+++)</td></tr>
<tr><td colspan="3">100 % cost reduction on annual reporting
- 3.2 million/year (++)
- 3.2 million/year (++)</td></tr>
<tr><td colspan="3">Possible EUR 240 000 savings for national authorities, if the new incident platform is interconnected with PICS (+)</td></tr>
<tr><td colspan="4">Objective #2 - Costs</td></tr>
<tr><td rowspan="2">Potential costs incurred by MS who engage with interoperability requirements and invest in their national systems (-)</td><td colspan="3">Adjustment costs borne primarily by the Commission (EUR):
6.01 – 8.84 million[192] (one off)
3.3 million/year

MSs bear costs of approximately a third (EUR):
3.1 million [193](one off)
1.1 million/year</td></tr>
<tr><td colspan="3">Registration costs for category 4 economic operators: EUR 0.01 million.</td></tr>
</table>

7.3. Coherence

All policy options are consistent with the EU's international obligations towards the UN and follow their recommendations to address designer precursors. Options 2 and 3 reduce certain reporting activities to the UN which has so far been done on a voluntary basis by the EU.

While Option 1 improves the enforcement of rules and synergies with the EUDA, options 2 and 3 go further in contributing to the objectives of EU drug policy. By extending scheduling and

[188] Annualised according to the standard cost model formula above with total cost = EUR 0.25 million
[189] Annualised according to the standard cost model formula above with total cost = EUR 0.25 million
[190] Annualised according to the standard cost model formula above with total cost = EUR 0.46 million
[191] Annualised according to the standard cost model formula above with total cost = EUR 0.46 million
[192] Annualised according to the standard cost model formula above with total cost = EUR 17-25 million
[193] Annualised according to the standard cost model formula above with total cost = EUR 8.9 million

introducing a separate category of drug precursors, they strengthen the application of the Framework Decision on combatting drug trafficking and should also reduce the amount of drug precursors available for illegal drug production.

Concerning general customs policy, Option 1 does not have any positive impacts apart from the baseline, while under Option 2 and 3 the IT system, including the real-time seizure reporting, and use of CUS numbers should improve interoperability and risk management.

Finally, concerning the digital by default principle, option 1 can make some small contribution through guidance, but options 2 and 3 have a much larger impact through the full digitisation of all procedures. In addition, the digitisation has the benefit of enabling a drastic reduction of reporting requirements for both national authorities and economic operators – while respecting UN reporting obligations.

7.4. Subsidiarity and proportionality

Option 1 moderately complies with subsidiarity and proportionality principles. However, the 'technical approach' appears weak considering EU competence in this area and, in some cases, the proposed measures are disproportionately limited compared to objectives. They entail limited implementation costs, but these correspond to more limited benefits also. Given the EU's competence to act on both internal and external trade, these benefits appear to be unduly limited. Member States and economic operators showed a moderate support of Option 1.

Option 2 has the benefit of removing some of the disparities of implementation between Member States and therefore facilitating trade. It is proportional in the sense that measures are targeted to a limited number of designer precursors, thus increasing benefits on tackling illegal trade without unduly hampering legal trade and innovation. Costs can be considered proportional to the risk despite a reduction on controls notably on bulk materials. Member States showed support to the measures proposed in Option 2 and considered them to be well-balanced. Economic operators equally welcomed stricter rules if legal trade is safeguarded.

Option 3 shares many of the benefits of Option 2. Also, the option does consider risks but rather favours controls. In this sense, the wide scope of designer precursors scheduled as well as the increased controls of other precursors such as bulk materials may lead to some burdens that are not entirely proportionate to the risk of diversion. This is corroborated by the fact that authorities also associated this policy option with an increased cost of enforcement that could potentially be considered disproportionate enough to no longer be implemented effectively.

Ranking of options

The results of the comparison are summarised in Figure 22.

Figure 22: Summary of comparison ratings

	Option 1	**Option 2**	**Option 3**
Effectiveness	low	high	high
Efficiency	low	moderate	low
Coherence	moderate	high	high
Subsidiarity	moderate	high	high
Proportionality	low	moderate	low
Summary	moderate/low	high/moderate	moderate

8. Preferred option

The results of comparison indicate that Option 2 is the approach that would best address the policy problems identified and maximize the achievement of both objectives. It addresses the risks of diversion in a targeted manner while balancing these with a burden reduction for legal trade through the introduction of modern digital procedures.

8.1. REFIT (simplification and improved efficiency)

The preferred option would lead to significant simplifications of the rules, namely:

1) A merger of the two regulations into a single regulation, removing the unnecessary differences, aligning and updating definitions and identifiers (i.e. the use of the CUS number instead of CN code) to make it easier to follow the rules.
2) A lower of the number of categories of scheduled substances, from 5 to 3.
3) A revision and modernisation of procedures for legal trade, the development of a central web portal allows for digital applications for license (new Category 1) and self e-registration for external trade (new Category 2) and the automation of authorisation for imports and exports based on quantity management as well as the lifting of the PEN wait period, the aggregation of data on legal trade for annual reporting to the UN on legal use, and the digitisation of the process of requesting and verification of customers.
4) An introducing a de minimis rule for mixtures, i.e. thresholds that are objectively defined to create a standardised approach that does not differ across Member States, nor rely on the expert judgment of operators.
5) An exemption of small quantities to enable research and innovation.

The above should lead to reduced administrative costs for operators and public authorities. The benefits accruing from the consolidation of the two regulations and the introduction of the de minimis rule for mixtures are difficult to quantify since they relate to the time spent understanding the rules and how to comply with them (i.e. they are a complementary action for the compliance with the actual obligations themselves). Based on the feedback there is an expectation that the measures envisaged to simplify would (over time) lead to a reduction in the time needed to understand the rules. Meanwhile, the cost savings from digitalisation and automation of processes (alongside the revision of substance categorisation) are estimated in section 6.2 based on the methodology in Annex 4 and summarised below.

8.2. Application of the 'one in, one out' approach

The proposed option would entail the removal of administrative costs associated with reduced obligations for certain substances to better facilitate trade where risks are low, and the introduction of new administrative costs related to new obligations to support enhanced control (where risks are high, or the additional administrative cost is negligible). Figure 23 lists one by one which administrative costs are removed (OUTs) under the proposal, and which are introduced (INs). The preferred option would lead to net administrative costs lower than the baseline. Specifically, the net benefits of the proposed option for economic operators would amount to approximately EUR 25.27 million per year.

Figure 23: Overview of administrative costs (and corresponding obligations) added or removed, assessed over a period of 3 years, with costs annualised

Administrative costs OUT (Obligations removed)	Cost (M EUR)	Administrative costs IN (New obligations)	Cost (M EUR)
		• Due diligence for the implementation of the ban on designer precursors	2.72
• New registrations	0.09		
• Annual renewal of registrations	0.07		
• Annual administrative costs for e-verification	17.6		
• Annual administrative costs for import and export authorisations	6.4		
• Annual administrative costs for reporting	3.2		

9. How will actual impacts be monitored and evaluated?

This Section provides a list of indicators that can be embedded in plans for future monitoring and evaluation of the regulatory framework and, in particular, of the interventions proposed under the preferred Option 2. An evaluation of drug precursor rules should be carried out no later than 10 years after the entry into application of the revised rules. This would enable the Commission to analyse a period of approximately five years of practical implementation of the rules.

It needs to be recognised, however, that especially indicators used for illegal drug supply concern a clandestine activity in which many factors intervene. They will therefore not necessarily always accurately reflect the effects of policy and would have to be assessed in the overall context of drug policy indicators[194].

The monitoring framework includes two lists of indicators, i.e. output and impact indicators.

Output indicators in Figure 24 connected to the operational objective of the intervention supported, where available, by the baseline situation, as a point for comparison for future evaluations.

[194] In accordance with to Singleton et al, interpretation and comparative analysis can be difficult. "Examples of limitations of these data sources include: the extent to which they reflect operational priorities rather than market changes; question marks over the robustness of and consistency in data collection methods, and issues around the timeliness of data availability." Singleton et al., "Drug supply indicators: Pitfalls and possibilities for improvements to assist comparative analysis", International Journal of Drug Policy, 2018.

Figure 24: Provisional list of output indicators for future monitoring and evaluation of operational objectives

Operational objective	Output Indicator	Key indicator	Baseline	Goal	Tentative source
Objective #1					
To reduce the time to schedule a new precursor	Reduction of # of months from first detection to adoption of response measure	No	14 months	10 months	Drug precursors database
To reduce illicit trade of precursors	Reduction of annual volume of seized scheduled precursors	Yes	2 100 incidents, corresponding to approximately 541 tonnes of precursors seized in 2023	60% reduction	Drug precursors database
	Lower share of designer precursors amongst seizures	Yes	88 % of seizures of key precursors included designer precursors	60 % reduction	
	Reduced volume of ed non-scheduled precursors seized by MS	Yes	194 tonnes (average 2021-2023)	60% reduction[195]	
To increased engagement of economic operators	No of notifications of suspicious transactions	Yes	324 notifications 1900 seizures	Better ratio of suspicious transactions vs. seizures	public consultation
	No of notifications from online platforms	Yes	N/A	Higher number of notifications	

[195] Due to the larger number of scheduled substances, less substances should fall outside of the scope of the regulations and therefore, the overall number of seizures of unscheduled substances should also be reduced. This would also indicate that illegal drug producers find it more difficult to have recourse to new substances.

Objective #2					
Simpler regulatory framework	Cost of formalities for economic operators	Yes	Licenses and registrations: - EUR M 0.74 (one-off) - EUR M 0.23 (annual) Customer declaration: -EUR M 22.5 Import/export autorisations: - EUR M 6.4 (annual) Annual reporting: - EUR M 3.2	Reduction of costs for licenses and registrations: -EUR M 0.25 (one-off) - EUR M 0.07 (annual) Digitisation of customer verification cost reduction: - EUR M 17.6 (annual) Import / export authorisations: - EUR M 6.4 (annual) Annual reporting: - EUR M 3.2 (annual)	Public consultation
	Cost of formalities for public authorities	Yes	Licenses and registrations: -EUR M 1.3 (one-off) -EUR M 0.23 (annual) Import/export authorisations: -EUR M 6.9 (annual) Annual Reporting: -EUR M 3.2	Reduction of costs for licenses and registrations: - EUR M 0.46(one-off) - EUR M 0.086 (annual) Cost reduction on import / export authorisations: - EUR M 6.9 (annual) Cost reduction on annual reporting: - EUR M 3.2 (annual)	Public consultation

Impact indicators in Figure 25, related to the broader objectives of the intervention. At this level, the extent of the impact that is attributable to the policy will have to be carefully considered, through appropriate qualitative / quantitative methodologies. Both EUDA's work on data collection as well as the EU Drugs Action Plan are based on several indicators that monitor the situation of illegal drugs in the EU. The impact of drug precursor measures on these indicators is largely indirect. Nevertheless, any policy on drug precursor controls also needs to be assessed and analysed in the overall framework of EU drug policy.

Figure 25: Provisional list of impact indicators for future monitoring and evaluation of the broader objectives

Objectives	**Impact Indicator**	**Tentative source**
Objective #1		
Reduction in the illicit drugs manufacturing in the EU	No. of clandestine laboratories dismantled per year, per type of (synthetic) drugs	Drug precursors database
	MS authorities' estimate on the illicit drug production trends in the EU	Public consultation
Reduction in the illicit drugs market	Prevalence of drugs uses in Europe, per type of (synthetic) drugs Sewage analysis score in Europe, per type of (synthetic) drugs Indexed price and purity, retail	Annual EUDA Drug report
Public health impact	Treatment entrants in Europe, per type of (synthetic) drugs	
Environmental Impact	N/A (not possible to establish direct link)	
Objective #2		
Smooth trade of legal drug precursors	Evolution of use of drug precursors within the EU (volume)	Drug precursors database