Council of the European Union

Brussels, 18 December 2025
(OR. en)

17046/25
ADD 4

Interinstitutional File:
2025/0384 (COD)

UD 318
CORDROGUE 161
COMER 195
ENT 295
ENFOCUSTOM 228
CODEC 2183
IA 240

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	4 December 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2025) 398 annex
Subject:	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

Delegations will find attached document SWD(2025) 398 annex (part 2/2).

Encl.: SWD(2025) 398 annex (part 2/2)

EUROPEAN
COMMISSION

Brussels, 3.12.2025
SWD(2025) 398 final

PART 2/2

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}

Table of Contents

ANNEX 1: PROCEDURAL INFORMATION

1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

Lead DG: Directorate-General for Taxation and Customs Union (DG TAXUD), Directorate A - Customs

Co-lead: DG Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), Directorate: Directorate F – Ecosystems I: Chemicals, Food, Retail

This impact assessment corresponds to the initiative with the Decide reference PLAN/2022/1454, revision of the EU drug precursors legislation.

This initiative is also part of the 2025 CWP, under the header 'Security', with COM proposal planned by Q4 2025.

2. ORGANISATION AND TIMING

The call for evidence feedback period ran from 10 May till 7 June 2023.

The public consultation period ran from 17 April till 10 July 2024.

An inter-service steering group was convened and chaired by DG TAXUD and DG GROW. The following Directorates-General participated: SG, LS, BUDG, CNECT, DIGIT, EEAS, ENV, GROW, HOME, JRC, JUST, OLAF, SANTE and TAXUD and the agencies EUDA. The ISSG met 8 times. The last meeting on the final draft impact assessment report was held on 9 April 2025

3. CONSULTATION OF THE RSB

The RSB was consulted in an informal upstream meeting on 27 May 2024. This impact assessment was submitted to the RSB on 5 May 2025. The meeting with the RSB took place on 4 June 2025.

Following the opinion of the RSB from 4 June 2025, changes were made to the IA in order to reflect the recommendations of the Board. A summary of the RSB's recommendations and how these have been addressed is provided below.

Summary of the RSB findings and how the comments have been addressed:

Opinion of the RSB	**How the comments have been addressed**
1. The report should provide evidence to substantiate whether uneven implementation and enforcement contribute to the problem, including the extent to which traffickers exploit vulnerabilities for precursor trafficking. It should better account for the variations in illicit market challenges, both in terms of magnitude and types of challenges, across Member States,	Section 2.2.3 has been revised to use the evaluation as the basis for the problem statement. Footnotes have been added to clarify the supporting evidence regarding uneven implementation and the exploitation of paths of least resistance by criminals. Variations in drug situations across Member States are now illustrated in Annex 10, under the section 'The EU Drug and Drug Precursors Market.' Additionally, Annex 4

	assessing the rationale, costs and benefits of the different approaches, including the more stringent ones. In addition, the report should make use of the full evaluation and expand on its findings to support and substantiate the identified problems and drivers.	has been further developed to explain the methodology for cost and benefit calculations.
2.	The report should provide more robust evidence substantiating to what extent administrative requirements can be streamlined or removed while at the same time ensuring an adequate level of risk protection. It should also provide a more nuanced picture of the mixed stakeholder views on the existence of the problem.	The report has been updated in section 2.1.2 to better highlight the nuanced stakeholder views on existing administrative burdens. The analysis of the impacts has been extended to include how especially digitisation should reduce burdens while not as such reducing the levels of control.
3.	The options chapter has an overly complex structure. The report should clearly describe the key novel measures such as innovative scheduling. It should better explain the reasoning and necessity behind the new set of categories. This should be done keeping in mind both general objectives. The differences between policy options should be more clearly outlined.	Figure 8 has been replaced to better highlight the rationale for each of the policy options, the respective key policy measures, and the differences of each of the policy options. The detailed description of the policy options explains that the existing categories, and notably the obligations attached to each category have been streamlined based on the perceived risk of the category concerned (objective 1) while simplifying obligations to the extent possible (objective 2).
4.	The report should elaborate on the expected evolution of the social impact under the baseline scenario, including the anticipated change in illicit trade or manufacturing and clarify whether the baseline is static or dynamic for the purpose of comparing the impacts of the options.	Section 5.1 has been revised to explicitly highlight the dynamic nature of the baseline. Additionally, a new paragraph has been added to Section 6 to describe the social impact under the baseline scenario.
5.	The report should clarify the measures for the envisaged IT system for drug precursors and related costs.	A new section 2.9 has been added in Annex 4 to identify the measures to be taken in the short and medium term.
6.	The report should clearly state the appraisal period used to determine and compare the benefits and costs. Where applicable, one-off costs should be	Figures 21 and 23 have been amended to clearly indicate the three-year appraisal period. All one-off costs in these tables

annualised to allow for final comparison of options.	have been annualised in accordance with the Standard Cost Model formula.
7. The report should transparently outline the methodology used to calculate the expected percentage reduction in illicit trade for each option, with a clear explanation of the underlying assumptions and calculations. Similarly, it should provide a detailed explanation and substantiation behind the estimated 60% reduction in the availability of precursors for illicit drug manufacturing.	Section 3 of Annex 4 has been redrafted to provide a more detailed explanation of the methodology used for the social impact assessment. The limitations and caveats of the estimated 60% reduction have been better highlighted.
8. The report should provide a clearer comparison of the options to strengthen the assessment of effectiveness and proportionality. It should assess to what extent the two comprehensive options can be considered equal in terms of social impacts, considering the difference in ambition and scope. It should also clarify the costs for authorities and economic operators for each option taking into account the scope and other factors in implementation and enforcement.	Figures 21 and 23 have been amended to ensure consistency and a uniform interpretation. All one-off costs have been annualised using the parameters detailed in the footnotes. Additionally, a paragraph has been added to Section 6.3 explaining the rationale behind the similar impact attributed to Options 2 and 3.
9. The report should discuss how reliably it can assess the proportionality of the proposed interventions given that it is unclear to what extent the proposed measures will result in desired social impacts (reduced health detriments and crime etc.); and also unclear to what extent they will have impacts in terms of reduced rates of innovation in the industries concerned.	Section 3 of Annex 4 has been redrafted to provide a more detailed explanation of the methodology used for the social impact assessment and its limitations. The report has been updated to reflect the findings on innovation.
10. The report should clearly qualify what it will take to measure success. The monitoring framework should include indicator(s) on social and economic benefits building on the methodology behind the estimates related to the reduced availability of precursors.	Figure 24 has been updated to highlight the key indicators for success and to indicate what would be considered a successful outcome of the intervention.

3. EVIDENCE, SOURCES AND QUALITY

The Evaluation of the drug precursors regulation identified the key areas for the revision.[1] It was supported by a study by an external contractor.[2]

This impact assessment is also supported by a new study undertaken by another external contractor, who carried out dozens of interviews, analysed data from public and targeted consultations and complemented this through desk research. Annex 4 provides more details on the analytical method applied to collect the evidence supporting this impact assessment.

[1] Report from the Commission to the European Parliament and the Council on the Evaluation of the EU drug precursors regulations, COM(2020) 768.
[2] This study was not published at the time.

ANNEX 2: STAKEHOLDER CONSULTATION (SYNOPSIS REPORT)

1. OVERVIEW OF STAKEHOLDER CONSULTATION ACTIVITIES

The Stakeholder Consultation Synopsis Report (the 'Report') summarises the key findings from the consultation activities carried out in the framework of the *Impact Assessment* The consultation involved six main activities with complementary scope and objectives, and specifically:

- ***In-depth interviews.*** 78 in-depth interviews with three main stakeholder groups were conducted, namely:
    - National Authorities: 25 interviews were conducted with various national authorities from the EU and third countries (Switzerland and Norway), including licensing bodies, customs agencies, law enforcement, and policy-making entities.
    - Economic Operators (EO): 50 interviews were carried out with different EO such as chemical manufacturers, distributors, industry and research entities, and trade associations.
    - Other Stakeholders: This category included entities with an institutional profile, i.e. INCB, EMCDDA, and EUROPOL.
    - The interviews covered two main themes, i.e. enhancing precursor control and simplifying/reducing regulatory burden, analysed across two dimensions: analysis of the problem and exploration of solutions. Depending on the focus, the interviews contributed either to the qualitative analysis, which informed policy discussions, or to the quantitative analysis, supporting the Standard Cost Model exercise.

  NGOs and civil society organisations active in the field of fight against illicit drugs and prevention of drug abuse were invited to participate in the interview programme but they declined due to their limited knowledge of the technical aspects of the legislation under analysis. Similarly, ecommerce platform representatives opted to not participate in the interview programme.

- ***Targeted survey of Member States competent authorities ("MS survey").*** The targeted survey of MS authorities consisted of a detailed questionnaire including factual questions on the national legal and operational framework, quantification of the policy problem, regulatory burden and efficiency improvements, etc. It was sent to representatives of competent authorities who are part of the Drug Precursors Expert Group (DPEG). The survey was disseminated both via CIRCA BC and directly by the Consultant to authorities that have been previously involved in the in-depth interview programme. Specifically, 27 authorities corresponding to 19 Member States were directly contacted by the Consultant, while the reminder, corresponding to 8 MS, received the survey through CIRCA BC. The targeted survey of MS competent authorities was launched on 25 March. The initial deadline was set for the 3 May, however, due to the slow response rate registered in the initial weeks, a two-week extension was granted – i.e. until 17 May. On the expiration date, the status of responses was as follows:
    - a total of 29 questionnaires were received, corresponding to 37 authorities and 21 MS (as it was allowed for different national authorities to send separate questionnaires);
    - no feedback was received from 5 MS (namely Bulgaria, Lithuania, Luxembourg, Slovakia, Croatia);

- one MS (Estonia) declined the invitation to submit the questionnaire.

- ***Targeted survey of Economic Operators ("EO survey").*** The survey was launched on 18 April through an ad hoc online tool, which links were distributed (i) directly to 65 EOs, (ii) through industry associations (CEFIC and FECC), and (iii) via a notice on CIRCA BC. This 'cascading' approach was made necessary by the fact that the list of licensed / registered operators in the EU DP database could not be shared with the Consultant for confidentiality reasons. The survey, initially open until 24 May, was extended to 14 June to increase responses. Finally, 81 valid questionnaires were completed, including 43 from SMEs. However, 759 additional respondents accessed but did not complete the survey. Factors affecting participation included:
  - The extended and overlapping nature of the revised survey, leading to potential consultation fatigue;
  - concurrent running with a Public Consultation, possibly confusing some respondents;
  - an initial problem with the survey link on CIRCA BC, which may have caused a loss of momentum.

- ***Public Consultation (PC).*** Published on the *Have Your Say* portal from 17 April to 10 July 2024, this component of the stakeholder consultation strategy was open to any interested subject, i.e. institutions, companies and individual citizens, regardless of the level of familiarity and expertise in the subject matter. Its purpose was to gather stakeholders' feedback on the functioning of the current EU rules and provisions for the control of trade and use of drug precursors, as well as on possible options and measures to address challenges and shortcomings. The validated replies to the consultation, after the data cleansing process, amounted to 53.[3] In particular, the survey gathered feedback from 18 Member States, with a particularly high participation from the Netherlands (11 replies), Germany (8 replies) and Belgium (7 replies). The majority of respondents (51 %) belonged to the business environment (22 companies, 5 business associations), followed by public authorities (15 replies), and individuals (7 replies). Other few questionnaires were received from one NGO, one environmental organisation and two respondents self-qualified as 'others' that could actually be associated to a business environment. Of the 22 businesses that took part in the consultation, 15 were SMEs. Overall, the participation rate was likely affected by the concurrent implementation of two 'targeted' consultations on the same subject, one addressing specifically MS authorities and the other addressing economic operators.

- ***Call for evidence (CfE).*** At the beginning of the review process, a call for Evidence was published on the on the 'Have your say' webpage. In total 14 responses were received, of which, 3 from businesses (and business organisations), 5 from public authorities and the rest from individual citizens. [4]

- ***Workshop.*** Two stakeholder workshops were carried out, namely:
  - The first of the two workshops envisioned in the proposal was carried out on 14 November 2023. The workshop took place in hybrid mode (i.e. it was conducted

[3] The total replies to the PC amounted to 58. However, the data cleansing process revealed that five almost identical questionnaires were received from the same multinational company, which according to the Better Regulation qualifies as a 'coordinated campaign' and were therefore counted as one. One further entry has been excluded from the analysis as the submitted questionnaire resulted largely incomplete.

[4] See: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13579-Drug-precursors-EU-legislation-revised-rules-_en

both in presence in Brussels and online) with the objective of discussing and 'validating' the policy problems identified by the Consultant as well as gathering insights on policy options and measures to be reviewed during later stages of the Assignment. Overall, 109 external participants took part in the workshop, with 12 participants attending in Brussels and 97 participants online. The main stakeholder categories represented amongst the participants were: national authorities, industry associations, economic operators, and academic experts.

- The second workshop took place on 19 September 2024, in online mode. Overall, 114 participants attended the workshop. A short poll was conducted at the beginning of the workshop to collect anonymous data on the type of stakeholders and their country/location. Based on responses received, stakeholders included 23 public authorities, 34 businesses representatives (of which 8 from SMEs, 7 from EU industry associations, 4 from national industry associations, while the remaining 59 participants did not reply / did not belong to any of these categories. The objective of the workshop was to present the external impact assessment study carried out by the Contractor, and discuss, integrate and validate results.

The following sections present the results of consultations in relation to the two main objectives of the proposed revision of the drug precursors Regulations, namely:

- Objective #1 - to ***reduce the availability of drug precursors*** for illicit drug manufacturing; and
- Objective #2 - to ***facilitate legitimate trade and use of drug precursors***, both in the Internal Market and in relation to external trade.

In the following section, the results of specific questions posed in the targeted surveys and the public consultation are ***reported with reference to the number of respondents to the specific question***, which might be lower than the number of overall participants to the survey, as (i) some questions were conditional to the response to a previous question, (ii) some respondents opted to skip certain questions that were not mandatory.[5]

2. REDUCTION OF THE AVAILABILITY OF DRUG PRECURSORS FOR ILLICIT DRUG MANUFACTURING

Feedback on the policy problem

➢ PROLIFERATION OF DESIGNER PRECURSORS

According to the results of the ***MS survey***, illegal activities connected to drug precursors have been growing in recent years in the EU, and MS authorities appear not entirely satisfied with the effectiveness of the EU policy in this respect (13 respondents expressed moderate / high satisfaction against 7 who expressed moderate/high dissatisfaction and 9 expressing a neutral view or answered 'don't know'). According to survey results, various MS registered a worsening in drug precursor trafficking in the past five years. In particular, while illegal import/export have largely remained in balance - i.e. with almost the same number of respondents (5-6) reporting a worsening or an improvement - the illegal circulation of precursors within the EU market and domestic production of illicit drugs in MS have reportedly worsened, with respectively 7 and 5 surveyed authorities reporting a substantial or moderate increase, against only one reporting a decrease. Specifically, the MS authorities surveyed underlined the relevance of the 'designer precursors' problem (confirmed by 20 out of 27 authorities who replied to this question, against only 2 respondents that did not consider it an issue).

[5] "Don't know" replies are nonetheless considered in totals.

Regarding specifically designer precursor-related challenges, the majority of MS authorities (13 out of 23 respondents to this specific question) considers the identification of these substances as problematic. In fact, 20 respondents (out of 27 who responded to this question) noted that the current scheduling approach is unfit to tackle the specific challenges posed by these substances. As stated by one interviewed authority, "*criminals remain various years ahead of authorities in scientific research on new precursors*".

According to MS survey results, one of the most severe issues hampering the control of designer precursors relates to the weak and scarce implementation of the 'catch-all clause'[6], with 16 out of 23 respondent authorities considering it as a relevant problem, of which 10 qualifying it as 'very relevant'. The fact that under EU law no provision for seizure or imposition of other sanctions for offences related to designer precursors are envisaged is perceived as a 'very relevant' or 'relevant' issue by 15 MS authorities. During interviews some national authorities also affirmed that other aspects of the 'catch-all clause' are problematic, for instance, from enforcement perspective, the 'sufficient evidence' concept for triggering enforcement action is – according to one interviewee – "*too vague and subject to interpretation*". Another authority interviewed underlined that it is "*difficult to prosecute and sanction offences related to rather undetermined substances*" – making reference to the fact that the non-scheduled designer precursors subject to the catch-all clause generally lack clear identifiers, such as the Chemical Abstracts Service (CAS) or a univocal Combined Nomenclature (CN) code.

Criticism of the 'catch-all clause' was also raised in the ***Call for Evidence*** by some national authorities. In particular, one custom and one law enforcement authorities who participated in the CfE highlighted the poor effectiveness of the clause, advocating for enhanced measures to halt unlisted substance flows.

Participants to the ***EO survey*** generally consider the current EU regulatory framework as highly or moderately effective in preventing and tackling the diversion of controlled substances that are used in industrial processes (55 respondents out of 81, against 12 that consider it poorly effective). This is also due to the fact that the EU framework is deemed by EO as generally able to facilitate the level of cooperation between economic operators and competent authorities (32 out of 81 respondents) – particularly in terms of information exchange on suspicious transactions – and putting into place rapid and clear information and operational guidance on drug precursors at the EU level (36 out of 81 respondents). Nevertheless, EO are less positive on the EU framework ability to prevent and tackle the trafficking of designer precursors (i.e. for 38 respondents it is moderately / highly effective, while 20 consider it poorly effective). More in detail, most of the criticism for the effectiveness of the EU policy on the illicit trade of designer precursors came from the sub-set of SMEs (8 out of 42 SMEs who responded to this question had a negative view).

The lack of a clear identification (i.e. via unique identifier) of designer precursors is reportedly a source of concern for EOs, as it might create legal uncertainties for legal trade. As a major industry organisation put it down in its response to the PC: "*Grouped/family scheduling can create legal uncertainty and exorbitant compliance costs for economic operators. In particular, clearly identifying which items produced or used by a company fall under the scope of the regulation would be technically unfeasible if scheduling is based on the chemical structure of substance group*."

The proliferation of designer precursors is viewed as a major problem also by the majority of participants in the ***PC*** (32 out of 52 who respondent to this question) – especially public

[6] Non-scheduled precursors are subject to voluntary monitoring as well as to enforcement measures that can be adopted at MS level under the so-called 'catch-all' clause. In summary, the clause requires MS to prohibit the import or export of non-scheduled substances, where there is 'sufficient evidence' that those substances are intended for illicit drugs manufacturing, and more generally allows MS to adopt control and monitoring measures (e.g. obtain information on orders and operations involving non-scheduled precursors and enter business premises to obtain evidence of suspicious transactions).

authorities (14 out of 15). The results of the ***PC*** also confirmed widespread concerns about the adequacy of the scheduling procedure for designer precursors, with 42 out of 52 respondents considering it as too slow (i.e. a 'major' or 'moderate' problem) – especially among MS authorities (totality of 14 respondents), less so among EOs (20 out of 28).

- **OTHER ISSUES REGARDING ILLICIT TRADE OF DRUG PRECURSORS**

The illicit online trade of drug precursors is a growing concern for all stakeholder groups. According to PC results, 66 % of respondents (35 out of 53) identified the dark web as a major problem, with significant issues also reported concerning social networks and regular e-marketplaces (26 and 22, respectively).

The majority of ***MS authorities surveyed*** (16 out of 27 who replied to this question) agreed that the tools and measures for monitoring the online trade of drug precursors are insufficient, and 10 MS authorities (out of 25 who responded to this question) reported a worsening of illegal online trade in the past five years. As emerged from authorities' qualitative feedback (interviews and survey open questions) the illicit online trade problem consists of four components: (i) the lack of resources to effectively inspect the amount of chemicals that enter the EU (also considering that traffickers use postal services to import scheduled and non-scheduled substances, which are frequently misdeclared), (ii) the legal and technical obstacles to monitor darknet, (iii) the lack of legal means to place platforms operating from third countries under control, and (iv) the absence of control on the intra-EU trade. Furthermore, none of the surveyed MS reported having adopted specific legislation to enhance control over the online trade of precursors, but one respondent indicated the existence of dialogue with the main online platforms, to facilitate identification of suspicious transactions.

According to the majority of ***EO surveyed***, illegal online trade of drug precursors in their respective countries is a major/moderate problem (28 respondents, against 13 for whom it is a minor / not a problem). No relevant difference is observed in the responses of SMEs compared to large companies.

The difficulties stemming from online trade were also pointed out in the context of the ***Call for Evidence.*** National authorities who participated to the CfE noted significant enforcement difficulties with monitoring the online trade of drug precursors, particularly due to lack of resources and technical obstacles.

The results of consultations largely confirmed that there are differences in how MS implement and enforce the measures envisaged in the drug precursors framework. The majority of ***surveyed MS*** (15 out of 27 who replied to this question) acknowledged that the uneven implementation of drug precursor regulations creates paths of 'least resistance' that could be exploited by criminal organisations. In addition, insufficient enforcement capacity was identified as a relevant issue by 11 MS authorities surveyed. As elaborated by MS authorities who participated in the Workshops, capacity issues regard, inter alia, the lack of reference standards for forensic purposes established at EU level, and the lack of detection equipment available to customs officers at EU entry points.

Another frequently mentioned issue regards the criteria established in the EU Regulations for exempting mixtures from the scope of controls. And the different in national interpretations of these criteria. In fact, for 30 ***surveyed EO*** (out of 67 who responded to this question), the subjective nature of exemption criteria for mixtures is a relevant problem (for 16 a 'major' one, while for 14 a 'moderate' one). In this respect, a representative of a global cosmetic production company interviewed noted that both drug precursors and dual-use regulations address mixtures, but while dual-use substance thresholds are clearly defined, drug precursor regulations allow MS authorities to set their own thresholds. As stated in the contribution to the PC submitted by a major trade association: "*We see the need for an increased harmonisation*

of legal requirements, implementation practices and guidelines at EU level. The adequate handling of drug precursors is a joint European issue. Where one European legislation exists, the aim should be one European approach to interpreting and implementing it. This should progressively lead to establish a common approach towards internal as well as external trade in listed substances, including a fully harmonised voluntary listing".

These concerns were also supported by national authorities: in fact, 10 ***MS authorities surveyed*** (out of 25 who responded to this question) rated the clarity of the rules governing mixtures as 'partly' or 'highly unsatisfactory'. Nine of these respondents highlighted that the lack of clear and specific EU rules regarding drug precursor mixtures leads to ambiguity, legal uncertainty, and inconsistency in how MS interpret and apply regulations. Furthermore, two of them also noted that the mixtures catalogue is not updated frequently enough to cover all relevant substances and mixtures.

The issue of controlling equipment used in the illicit manufacturing of drugs emerged as a significant concern across various stakeholder groups. According to the results of the ***PC***, the majority of respondents (26 out of 47 who responded to this question) considers the lack of control over equipment, such as tableting and encapsulating machines, as 'problematic'.

A relative majority of ***EO surveyed*** expressed a positive opinion on the current cooperation between authorities and the industry (33 out of 80 positive replies, against 22 negative replies, one did not reply). As the ***MS survey*** showed, MS authorities are comparatively less satisfied in this respect. For 12 out of 28 authorities who replied to this question the extent of collaboration is insufficient, while 8 of them disagrees with this opinion. Dissatisfaction appears related, in part, to the variability in the notifications of suspicious transactions across countries. While authorities are generally satisfied with the quality of notification (9 out of 19 who responded to the question) but less so with the quantity (6 satisfied vs. 5 dissatisfied). Regarding the factors hindering better notifications, more than half of the authorities agree that operators often lack awareness or the ability to detect suspicious transactions, and an equal number agree that operators are reluctant to notify due to the perceived hassle (in both cases 14 out of 25 respondents).

Feedback on policy solutions

- **PROLIFERATION OF DESIGNER PRECURSORS**

The results of the ***PC*** registered particularly high consensus on three possible approaches to address the problem of designer precursors, namely (i) strengthening early warning mechanism and exchange of information among national authorities (49 out of 53 respondents, of which 44 'strongly' agreed); (ii) promoting awareness-raising and cooperation with legal economic operators (50 out of 53, of which 34 'strongly' agreed); and (iii) adopting EU-level provisions enhancing MS authorities' capacity to monitor and prosecute irregular transactions involving designer precursors (47 out of 53, of which 33 'strongly' agreed).

Similar findings emerged from ***MS survey results***. In fact, strengthening the EU early warning system and improving information exchange was supported by 25 out of 27 MS authorities (of which 19 'strongly' agreeing). Similarly, 22 out of 26 MS authorities endorsed promoting awareness and cooperation with the private sector. Additionally, there was strong backing for adopting EU-level provisions to enhance monitoring and prosecution capacities. More in detail, 19 out of 25 MS authorities displayed support for expediting the scheduling process for designer precursors, while slightly higher support was expressed for the introduction of a 'fast-track' temporary scheduling mechanism (21 out of 26). However, also the automatic scheduling of substances that correspond to the definition of "designer precursors" and the idea to explore other ways to shorten the duration of the scheduling process received a fairly large support (20 and 19 out of 25, respectively). Surveyed MS authorities recognise the importance of extending

proactive scheduling to cover derivatives of controlled substances, although expressing larger support for a 'moderate' rather than a 'wide scope' extension of controlled substances. Indeed, only 6 respondents (out of 27 who replied to this question) would be in favour of extending the proactive approach as much as possible, while for 13 authorities the extension should be limited or none. Another policy measure strongly supported by targeted survey participants is the establishment of a binding list of designer precursors to prohibit their use (14 out of 26 who replied to this question).[7]

At the same time, survey results show that agreement increases if such 'outright ban' is accompanied by appropriate exemptions to prevent disruptive side-effects on research activities. The inclusion of a 'de minimis' threshold, in order to facilitate the legal trade of small quantities, was supported by 21 out of 27 MS authorities who replied to this question, while the 'special licenses' to authorise legal trade / use of designer precursors under specific circumstances (e.g. for research purposes) was supported by 20 out of 26. For MS authorities the major benefits of this approach would regard the 'facilitation of enforcement activities' ('major impact' for 10 out of 22 who replied to this question) and the overall 'reduction in the availability of precursors' ('major impact' for 9 out of 22 respondents). On the downside, the results of the survey indicate that an increase of enforcement costs is expected. In fact, based on the estimates provided by 18 MS authorities, an increase comprised between 10 % and 50 % is expected. Finally, publishing an extensive list of designer precursors for voluntary monitoring purposes also registered positive feedback, with 21 out of 26 respondents to this question supporting this approach.

From an enforcement and prosecution perspective, MS authorities showed varying degrees of support for the measures proposed to strengthen the catch-all clause. Specifically:

- 18 out of 25 respondents to this question agreed that the catch-all clause provisions should be immediately applicable without the need for preliminary adoption of specific national measures. However, a few dissenting views were also registered (seemingly in relation to the additional human resources and enforcement costs that it would require to MS).
- Adopting the provision of false information (mislabelling / misdeclaration) as a criterion for the identification of suspicious transactions of non-scheduled substances was also largely supported by MS authorities (22 out of 26 agreed, of which 16 'strongly').
- On the other hand, more tepid support (albeit mostly positive) was registered for a criterion based on the establishment of a positive list of relevant non-scheduled substances. The automatic labelling as 'suspicious' to certain transactions based on the substance involved appears disproportionate and – according to a respondent – might negatively impact on the willingness of legal operators to engage in the trade of them.
- Finally, the possibility of introducing temporary detention for investigation purposes of non-scheduled substances suspected of illicit use received mixed but generally positive feedback. Of those who responded to this question, nine strongly agreed, 11 partly agreed, and 3 were neutral. This reservation seems linked to the need to ensure proportionality and avoid disruption of legal trade, and the administrative and enforcement costs involved.

According to ***EO survey*** results, most EO supports the strengthening of the EU early warning system (27 out of 40 who responded to this question positively assessed the measure). Strong support was registered for improving information exchange with national authorities (38 out of 41 respondents to this question). As for expediting of the scheduling process for designer precursors, this solution was supported by 40 out of 71 respondents to this question.[8] The

[7] This matter was generally not covered by CfE respondents, except by a national agency who confirmed that a targeted regulatory approach for designer precursors could be impactful.

[8] In all cases no relevant differences are observed in the responses of SMEs compared to large companies.

'outright ban' solution for designer precursors is largely approved by EOs (35 out of 70 who responded to this question agree with this solution, and only 6 disagree), with a rate of agreement moderately higher among large companies (55 %) than SME (45 %). EO survey respondents expect such solution to be associated to an increase of costs comprised between nil and +15 %. The qualitative feedback gathered from EOs (interviews, survey open questions) converges on the need for a clear and univocal identification of banned substances (ideally through CAS number or other machine-readable coding) as a pre-requisite to avoid undue increase of due diligence costs for legal trade. Similarly, as a research institutions interviewed pointed out, the pharmaceutical compounds patent practices could be taken as reference: "*pharmaceutical patents typically cover the relevant derivatives, which do not need to have specific CAS number, it is sufficient that the main compound does.*"

The proposed measures for designer precursors were discussed in the final ***validation workshop*** (workshop #2). Workshop participants confirmed approval for the 'outright ban' solution, but remarked the need to carefully addressed the following technical aspects:

- Need for clear and unambiguous identifiers, which can be 'machine-readable' to avoid excessive burden on legal trade.
- De minimis exemption should be tailored on substances and in some cases (e.g. fentanyl precursors) could be excluded.
- Need to clarify who is allowed to use the prior notification exemption clause and exclude individuals.
- Need to clarify whether the definition of operators / users will be reviewed to make sure the ban applies to 'anyone'.

➢ **OTHER ISSUES REGARDING ILLICIT TRADE OF DRUG PRECURSORS**

The results of the ***MS survey*** indicate a substantial demand for radical measures to curb illicit online trade of precursors. In particular, 20 out of 25 respondents to this question would be in favour of prohibiting the online trade of designer precursors, in order provide competent authorities with stronger legal basis for prosecution. Qualitative feedback gathered from two authorities indicate a possible demand to make online players somehow accountable for the legitimacy of transactions occurring on their marketplaces. This type of measures has been considered but eventually dropped to avoid contravening he 'conditional liability' principle of the DSA, which prevents platforms from being held liable for hosted content unless they are aware of its illegality and fail to promptly remove it (and unless is unclear for customers who the actual seller is) and – more generally – the principle of avoidance of specific product regulation on the top of the DSA.

According to the ***EO survey*** results, EOs would rather support 'soft' measures such as increased cooperation and monitoring of online platforms for the detection and removal of illegal products, including through IT tools, etc. In fact, 64 % of EO surveyed (45 out of 70 who replied to this question) believe that 'soft' measures are indeed necessary. Half of EO respondents estimated that neither a ban nor the adoption of soft measures would lead to a relevant increase in administrative costs (respectively, 30 and 28 out of 60 – many of which, however, did not express an opinion).

Among others, also some ***CfE*** respondents expressed support for expanding the reach of online platform controls and creating stronger partnerships with online marketplace operators.

Regarding the uneven ***levels of awareness and enforcement capacity*** across MS, the vast majority of ***MS authorities surveyed*** (24 out of 29) consider the provision of implementation and enforcement support to authorities as a relevant objective of the policy revision. As

confirmed also by the ***PC***, this should ideally cover (i) exchange of information and early warning; (ii) scientific and technical support; (iii) facilitation and enhancing of international cooperation; and (iv) awareness-raising and trainings (from 19 to 23 'high' or 'very high' importance out of 53 who replied to this question).

The results of consultations showed that a possible revision of the EU framework should include enhancing collaboration with private sector among its objectives. This was mentioned, inter alia, by 23 out of 53 ***PC*** respondents (actually, the near totality of those who expressed a judgment (24)). In particular:

- Based on the ***EO survey***, for half of EOs (36 out of 72 who replied to this question) there's a need for better information and support regarding EU drug precursors regulations and obligations. Many EO specifically requested clearer guidelines on how to identify suspicious transactions (41 out of 55). The need for improved consultation with both EU and MS authorities was highlighted by 41 and 43 out of 54 respondents to this question, respectively.
- Regulatory gaps: a key issue is the lighter obligations for 'users' compared to 'operators', which may be exploited by criminals. Half of the ***surveyed MS authorities*** (14 out of 28 who replied to this question) and some 43 % of ***surveyed EO***s (29 out of 68 who replied to this question) call for aligning these obligations. Similarly, the majority of respondents agreed with the need to better define the status and obligations of 'intermediaries' in the external trade, namely: 22 out of 28 ***surveyed MS authorities*** and 36 out of 67 ***surveyed EOs*** who replied to this question agreed with this proposed measure.

The main outcomes of final ***validation workshop*** on the other miscellaneous aspects of control of illicit trade of precursors have been as follows:

- Regarding online trade, there is a need to clarify who should fall in the scope of the Regulations, as problems regard mainly business-to-consumer (B2C) platform and social media.
- EOs welcome more guidance and trainings and are willing to participate in the preparation of materials.
- There is a need to clarify the added value of the proposed real time incidents reporting system, considering the system that already exist at international level (Precursors Incident Communication System – PICS.
- Participants from EFTA countries reminded that – if the Regulations are revised - the international dimension is not neglected, and agreements are found to avoid obstacle to trade.

3. FACILITATION OF LEGAL TRADE

Feedback on the policy problem

The ***EO survey*** results return mixed results on the issue of administrative burden for legal trade imposed by the Regulations. For some 36 % of targeted survey participants (29 out of 81), the drug precursors regulation (nearly) failed to prevent imposing an unnecessary burden on legal businesses, against an equal number of respondents (29 out of 81) who conversely expressed a positive judgment in this respect. In particular, 17 % (14 out of 81) of the respondents consider the EU regulatory framework for drug precursors 'not at all effective' in preventing unnecessary burden for legal business. Considering specifically SME respondents, 22 out of 42 participants to the survey displayed a favourable view of the Regulatory framework's ability to

prevent unnecessary burden, while 10 (24 %) had a negative view.[9] A specific question on the Regulations' impact on SME competitiveness showed that for 20 respondents - of which 8 SMEs[10] - out of 81 the drug precursors legislation had indeed negative effects.

The targeted survey also investigated the current level of burden for EOs connected to the main obligations of the Regulations. The results show that annual reporting and obtaining customer's end-use declarations are viewed as the most burdensome obligations (i.e. by respectively 50 and 44 out of 81 respondents). With regard to annual reporting, the estimates on time spent, range from "a matter of hours" (22 respondents out of 81) to a "matter of days" (35 respondents out of 81). The need to obtain an export authorisation was also judged as burdensome by a large share of surveyed EOs – i.e. 48 % (39 out of 81). Comparatively less burdensome are labelling obligations, license/registration obligations, and the notification of suspicious transactions to competent authorities.

The qualitative results of interviews added some depth to EO's feedback on the burden of the drug precursors Regulations. In summary:

- The variability in the estimated administrative burden due to reporting obligations is explained, according to EO interviewed, by the fact that such requirements vary across countries, and when individual transactions must be reported separately, the burden becomes more substantial.
- As for the need to obtain customer declarations, it emerged as a particularly burdensome aspect also during interviews with EO, since at present it relies on paper-based procedures. The procedure is especially burdensome for new customers from other EU countries, as sometimes the declarations are too general regarding the end-use of the substances and need to be completed again with more details, which extends the waiting times.
- Based on the interviews, the operational challenges related to import and export authorisations varied depending on factors such as the location of the company, and the origin and destination of substances. Nevertheless, the actual completion of the forms was not indicated as the most burdensome aspect; rather, it was the wait times that posed challenges. Wait times for import authorisations appeared to be longer (as much as "a couple of months") than for exports (a matter of weeks). In the case of exports, this implied storage costs pending approval. In both cases, the requirement for paper documents was indicated both as an annoyance and an obstacle.

According to the ***MS survey***, only a minority of MS authorities consider the implementation/enforcement burden cause by the Regulations as problematic. Specifically, only 3 out of 27 respondents to this question consider excessive the burden imposed on authorities, and only 5 out of 27 consider excessive the burden imposed on legitimate operators. Although most authorities find the annual reporting obligations acceptable (16 out of 27 respondents to this question), these represent a significant burden. Feedback from the targeted survey showed mixed results in terms of the level of effort devoted to annual reporting, with estimates ranging from "14 days", to weeks, months, and up to 4 FTE per year.

Participants in the ***PC*** expressed more mixed views 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. However, the majority of respondents to the PC considered the administrative burden as 'highly' or 'moderately' heavier for SMEs (28 out

[9] The remaining 10 replied "do not know".
[10] In fact, 40% SMEs had an overall positive view, but 19% had a negative view (i.e. 8) and the other 40% didn't know.

of 46 who replied to this question). With regard to import and export authorisations-related burden, PC results partly echoed those of EO targeted survey, with 23 out of 53 respondents (43 %) judging it 'very' or 'moderately' burdensome. Finally, the fragmented digital infrastructure is identified by EO as a significant contributor to unnecessary administrative burdens. As noted in an industry association position paper submitted to the PC, "*The current paper-based system is cumbersome, leads to high administrative costs for economic operators and delays the overall process, thereby reducing the effectiveness with which relevant substances can be targeted*".

This judgement was echoed in the feedback to the ***Call for Evidence.*** In fact, two trade associations emphasized the need for a harmonized, EU-wide digital application system to streamline processes and eliminate documentation inconsistencies across MS.

Beyond administrative burdens, stakeholders also pointed out other aspects of unnecessary complexity of the current policy framework, in particular the separation of rules and provisions in two acts, of which one governing intra-EU trade and the other regulating extra-EU trade. The results of the ***PC*** showed that for 35 out of 53 respondents this is perceived as a 'major' or 'moderate' problem, with no relevant differences across respondent's groups (i.e. 9 out of 15 public authorities, and 20 out of 29 EOs). According to the ***EO survey,*** the separation is problematic for 24 out of 68 respondents to this question (57 who provided an assessment) – slightly higher among SMEs (12 out of 26 who provided an assessment) than large companies (12 out of 26 who provided an assessment). According to the ***MS survey,*** the lack of consolidation is viewed as problematic for by 16 out of 28 respondents to this question.

Feedback on possible policy solutions

Many stakeholders believe that transitioning to a fully digitalised system would significantly reduce administrative burdens by streamlining processes, improving accuracy, and enabling real-time access to necessary data:

- According to ***PC*** results**,** the digitalisation of procedures is among the measures that register the highest consensus (46 out 52 respondents to this question agreed).
- This view is further corroborated by the ***EO survey***. In fact, the majority of surveyed EO are optimistic about the potential for savings, with estimates ranging from a reduction of up to 10 % to more than 75 %. Among the proposed measures, the availability of information on licensing and registration of other operators through an EU database, replacing – where relevant – the obligation to obtain a customer declaration, and the automation of reporting were seen as having the most significant impact. Specifically, the proposed measures were evaluated as follows:
    - availability of information on licensing / registration of other operators: 41 of 73 respondents to this question 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 %);
    - automatic elaboration of annual report: 33 of 73 respondents to this question foresee savings ranging from 10 % to over 75 % (with 21 respondents foreseeing 'high' or 'very high' savings);
    - licensing and registration applications: for first-time licensing applications, 25 out of 72 respondents to this question anticipate savings between 10 % and over 75 %. This increases to 26 out of 71 respondents for renewals or amendments. For registrations, 25 out of 73 respondents expect similar savings, whether for first-time applications or renewals/amendments;

- electronic submission/release of export and import authorisations*:* 23 out of 73 respondents to this question for export authorisations and 22 out of 71 for import authorisations expect savings between 10 % and over 75 %.

- As for ***MS survey***, national authorities' responses indicate broad support for digitalising drug precursors procedures and formalities, including licensing, registration, and import/export authorisations, with 14 out of 26 who replied to this question strongly supporting this initiative. Significant backing was also registered for the digitalisation of reporting obligations for EO (12 'strongly' agreeing) and the connection of a hypothetical EU digital system with international platforms (11 'strongly' agreeing). However, opinions are more varied regarding the continued use of national IT systems and whether digitalisation should build on existing EU platforms. While some respondents favour these approaches, a notable number remain neutral or uncertain. In particular, the option of maintaining national IT systems was the only one registering two negative responses (i.e. one 'partly' and one 'strongly' disagreeing), while the one on existing EU platforms registered one partial disagreement and a notable number of neutral and uncertain positions (7 responses for both 'neutral' and 'don't know'). However, surveyed authorities believe that even if digitalisation leads to significant cost savings, these are unlikely to result in a reduction of the fees charged to operators (out of 24 respondents to this question, 11 stated that a fee reduction is 'not likely' to happen, 6 responded 'maybe', and only 2 'yes').

In the ***Call for Evidence***, a main trade association expressed strong support for introducing "*digital based solutions that allow to file import and export authorizations electronically*". Moreover, the association also advocated the integration of trusted trader programs to provide real-time customs access, suggesting that the Single Window Regulation 2022/2399 offers a blueprint for ensuring interoperability across MS systems.

Regarding the complexity of the current system, large support was gathered on a possible consolidation of the two Regulations in a single act. In particular:

- The position papers received from trade associations under the ***PC*** agreed on the need to harmonise and consolidate the legal acts, since this would "*reduce complexity and better align provisions*", which would be especially beneficial for SMEs.

- The majority of authorities consulted through the ***MS survey*** (i.e. 16 out of 28 who replied to this question) find the current split as inconvenient, and various authorities interviewed expressed support for the consolidation of the two regulations into a single act.

- Consolidation was also supported by several EO interviewed, but ***EO survey*** results show that this the complexity of the current framework should not be overemphasise while 24 EOs surveyed (out of 68 who replied to this question) consider it a 'major' or 'moderate' problem, for 21 EOs this is conversely 'not a problem'.

Finally, the results of the ***validation workshop*** (workshop #2) on the one hand confirmed what authorities and EOs already expressed in previous consultations (interviews and surveys) – i.e. large support to the digitisation process and consolidation of Regulations in a single act – on the other hand mixed support emerged on a few possible implementation arrangements discussed in the workshop, i.e. the identification of substances by CUS number[11], the possible aggregation of scheduling categories (implying a change of status for some regulated substances), and the possible establishment of fixed thresholds to determine the applicability of Regulations to 'mixtures' of drug precursors with other substances.

[11] The CUS number is a univocal code assigned to the chemicals listed in the ECICS inventory. Established by DG TAXUD, the European Customs Inventory of Chemical Substances (ECICS) is a tool facilitating the identification, customs classification, and nomenclature formalisation of chemicals.

ANNEX 3: WHO IS AFFECTED ON HOW?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

With regards to Objective 1, Member States and operators will have to implement a new ban on designer precursors, based on an ad hoc list including families of derivatives of known and seized precursors that are chemically viable and easy to use, identified with sufficient precision to allow operators to conduct automated due diligence checks on their portfolios. As designer precursors do not have established industrial or commercial use legal operators would be, in principle, not affected. Still, operators will need to check their portfolios and establish internal procedures to block orders for banned substances and conduct additional legitimacy scrutiny. For MS authorities, the ban implies in an extension of the scope of existing control and monitoring rules, with implementation and enforcement efforts largely proportional to the extension of the list. Authorities will receive centralise supports to help scaling up the capacity required to detect and test newly identified substances. Other measures impacting on certain economic operators (albeit with negligible costs / cost savings) include (i) clarifications regarding the scope of application of provisions to the online environment, possibly requiring certain online platforms to either comply with existing monitoring requirements or remove precursors form their e-marketplaces, and (ii) extension of notification and record-keeping obligation to certain 'users'. Regarding MS, two relevant novelties will consist in (i) the need to adopt and implement the 'improved' catch all clause at the national level, and (ii) the removal of the obligation for quarterly reporting of incidents involving precursors, replaced with a real time notification system, under the digital platform discussed below.

With regards to Objective 2, Member States and operators will rely on a centralised EU portal to manage licenses and registrations. All operators will see a reduction in their obligations notably through the automation of authorisations for import and export and annual reporting and enjoy the possibility to fulfil the remaining obligations (licensing / registration and customer verification) digitally. Operators trading in current Category 4 will see a new obligation (the need to register) which is compensated for by the removal of previous obligations (reporting annually and requesting export authorisations). Operators trading in (current) Category 2b internally will be relieved of the need to register and verify customers for internal trade. All operators will be relieved of the 15-day wait period attached to the PEN.

2. SUMMARY OF COSTS AND BENEFITS

As per the Better Regulation Guidelines, the following tables present an overview of costs and benefits by type. This is based on the analysis presented in section 6.2 of the report.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Administrative cost reductions	Economic operators: -Reduction of costs for licenses and registrations: -EUR 251 000 (one-off) - EUR 72 000 (annual) Digitisation of customer verification brings cost reduction: - EUR 17.6 million/year import / export authorisations: - EUR 6.4 million/year) annual reporting - EUR 3.2 million/year Hassle costs saved (not possible to quantify) Public authorities: -Reduction of costs for licenses and registrations: - EUR 460 000 (one-off) - EUR 86 000 (annual) -cost reduction on import / export authorisations: - EUR 6.9 million/year - cost reduction on annual reporting: - EUR 3.2 million/year - PICS if interconnected - EUR 0.24 million/year	
Indirect benefits		
Trade facilitation	Reduced burdens and smoother, more effective control based on more robust, error-free data and protection against fraud	
Control of illicit trade	Reduced time to detect new threats and place them under control, associated to roughly 5.5 % of illicit trade reduction for concerned substances Decline in designer precursor and other non-scheduled precursors trafficking (possibly -60 % for two years according to previous experiences)	

Notes: *(1) Estimates are* ***gross values*** *relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together); (2) The* ***comments*** *column states which stakeholder group is the main recipient of the benefit;(3) For reductions in regulatory costs, the* ***comments*** *column describes how the saving arises (e.g. reductions in adjustment costs, administrative costs, regulatory charges, enforcement costs, etc.;).*

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
	Direct adjustment costs	N/A	N/A	Negligible	Negligible	N/A	N/A
	Direct administrative costs	N/A	N/A	Due diligence cost: EUR 7.7 M		digitisation: EU: EUR 26.6 M (up to 2033) MS: EUR 8-9 M (up until 2033)[12]	Scheduling designer precursors: non-monetizable (est. +10 % of baseline) digitisation: EU: EUR 3.3 M annually (2033 onwards) MS: EUR 1.1 M (2033 onwards)[13]
	Direct regulatory fees and charges	N/A	N/A	N/A	N/A	N/A	N/A
	Direct enforcement costs	N/A	N/A	N/A	N/A	EUDA Library: EU: EUR 182 000 for 2026-2027.	Online enforcement: non-monetizable (est. +30 % of the baseline) EUDA Library: EU: 1FTE
	Indirect costs	N/A	N/A	N/A	N/A	N/A	N/A

The below OIOO calculations are based on the figures presented in the SWD (See Annex 4 for explanation).

[12] Note these figures are based on estimates from the Commission and include connecting with the customs environment. Lower estimates were obtained where functionalities solely for the internal market were concerned.
[13] Ibid.

III. Application of the 'one in, one out' approach – Preferred option(s)			
[EUR million]	**One-off**	**Recurrent** (nominal values per year)	**Total**
Businesses			
New administrative burdens (INs)	Due diligence cost: 7.7[14]		7.7
Removed administrative burdens (OUTs)	New registrations: -0.25[15]	Renewal of registration: -0.072 E-verification: -17.6 Import/export authorisation: -6.4 Annual reporting: -3.2	-27.5
Net administrative burdens*	7.45	-27.29	-19.84
Adjustment costs**	Negligible	Negligible	
Citizens			
New administrative burdens (INs)	N/a		
Removed administrative burdens (OUTs)			
Net administrative burdens*			
Adjustment costs**			
Total administrative burdens***	7.45	-27.29	-19.84

(*) Net administrative burdens = INs – OUTs;
(**) Adjustment costs falling under the scope of the OIOO approach are the same as reported in Table 2 above. Non-annualised values;
(***) Total administrative burdens = Net administrative burdens for businesses + net administrative burdens for citizens.

[14] The notification requirement for legitimate transactions involving banned precursors is not expected to impose relevant new burden, since most of the transactions involving these substances will likely fall under the de minimis exemptions (currently, the large majority of declared legal use of designer precursors involves quantities smaller than 1g) and, by analogy with notification of suspicious transactions, the act of notification requires minimal effort. Finally, and for similar reasons, the expanded obligations for 'users' are not associated to relevant increase of burden, as (i) the occurrence of thefts is rare (overall 38 cases reported between 2012 and 2023) and the burden of notification is minimal; (ii) record-keeping is a typical business-as usual requirement; and (iii) industrial 'users' are often already subject to the obligations of the Regulations as 'importers'.
[15] EUR 250 977 or EUR 16 870 annualised (or EUR 0.002 M).

3. RELEVANT SUSTAINABLE DEVELOPMENT GOALS

Table – Overview of relevant Sustainable Development Goals – Preferred Option

Relevant SDG	Expected progress towards the Goal	Comments
GOAL 3: GOOD HEALTH AND WELL-BEING	The Preferred Option is expected to contribute to Target 3.5 "*Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol*" and specifically to the prevention of abuse by making it more difficult for criminal organisations to procure drug precursors for illicit drugs manufacturing activities. The impact is indirect and cannot be quantified, due to numerous intervening factors and the absence of valid models for prediction.	By increasing control and facilitating investigation and seizures of illicit precursors the intervention will contribute disrupting the supply chains that support clandestine laboratories across the EU, with ensuing impact on the availability and the price (hence demand) of illicit drugs. Among other things, the extent and the nature of impacts depend on enforcement aspects, and possible changes in OCG modus operandi to continue supplying the EU market. The impact on health and society depends also on the trends in specific drugs demand (e.g. the development of synthetic opioids market).
GOAL 9: INDUSTRY, INNOVATION INFRASTRUCTURE	The Preferred Option is expected to contribute to Target 9.5 "*Enhance scientific research, upgrade the technological capabilities of industrial sectors in all countries, in particular developing countries, including, by 2030, encouraging innovation and substantially increasing the number of research and development workers per one million people and public and private research and development spending*".	One of the goals of the proposed intervention is to minimise the adverse effect of drug precursors control on legitimate research activities and innovation.
GOAL 16: PEACE, JUSTICE AND STRONG INSTITUTIONS	The Preferred Option is expected to contribute to Target 16.4 *"By 2030, significantly reduce illicit financial and arms flows, strengthen the recovery and return of stolen assets and combat all forms of organized crime."* and specifically to tackling OCG involved in illicit drugs trafficking. The impact cannot be quantified, due to numerous intervening factors and the lack of reliable data on illicit trade volumes and routes.	Fighting illicit drugs trafficking is not a direct objective of the Regulations and falls outside of its legal basis. Nonetheless, a stronger EU system for drug precursors control can lead to improvement in detection, investigation, and prosecution of illicit trade, thus affecting OCG activities.

ANNEX 4: ANALYTICAL METHODS

1. DATA COLLECTION

- An **external contractor conducted a study** from September 2023 to March 31, 2025, utilizing specific data collection and analytical tools to enhance the relevance of assessed impacts.
- Extensive public and targeted consultation activities were carried out, with the data analysed in different ways and fed into the impact assessment. The activities and analytical methods are described in Annex 2: stakeholder consultation.

Additionally:

- Innovative scheduling methods were explored in-depth with input from **EUDA, JRC, ECHA, and Member States' experts**. **S**ee also Annexes 7.

- Future potential supportive activities for the EUDA were developed in collaboration with the **EUDA and the Commission services**. Cost estimates for these activities were prepared by the EUDA.

- The digitization process and potential simplifications were evaluated with **relevant Commission services**, including those overseeing **Customs Reform** and the **datahub**, in consultation with **Member States' experts**. Cost estimates for external trade digitization provided are documented in Annex 8.

- Relevant Commission services were consulted regarding the control of online markets.

- The sector analysis was performed by the Commission services.

2. STANDARD COST MODEL

This section summarises the standard cost models that were used to calculate the administrative burden.

2.1. GENERAL PARAMETERS

Number of affected entities

The number of affected entities is based on the number of entities that hold a license or registration. In various options /measures, the number of entities is a sub-set of the total or requires estimation. The table below indicates the number of entities per category as used throughout the cost model.

Number of economic operators – affected entities		
Category	**Number of entities**	**Comments**
Estimates based on the drug precursors database		
1	1 201	
2a	689	
2b	1 696	
3	726	for external trade only
1 – 3	3 986	unique entities
1	105	For designer precursors
Estimates		
4	100	a) for external trade only
2	600	b) trading internally only
3	363	c) trading internally only

Estimates

a) For category 4, the number of affected entities is estimated to be up to 100. There is no data source for the number of economic operators trading externally only in category 4, i.e. for whom annual reporting would be an additional requirement. Based on the survey of economic operators, a quarter traded in category 4 (i.e. 1 000), but 90 % of them were already licensed/ registered for trade in categories 1-3, and of the 10 % who were not (effectively 2 survey responses). Applying the same logic – of the approx. 4 000 entities already registered, 1 000 trade in category 4, but only 10 % (around 100 additional operators) trade just in category 4, some of whom may only trade internally and would therefore be exempt, but it is not possible to know how many since the sample is small. We therefore estimate that up to 100 may be captured by this requirement.
b) The DP database is confidential and there is no information in the Surveillance data which would enable us to estimate how many operators trade in a particular category. A public source of information on listed suppliers of category 2 substances is the ECHA maintained database of registered suppliers for REACH. For those with active licenses and with publicly available information, the study team reviewed websites for a sample to assess the likelihood of trade in third countries[16]. Roughly 70 % were. Taking this as our reference would mean that around 600 operators would not be required to register (also implying that information on their use of drug precursors would not be maintained in the system) but this estimate is not necessarily reliable.
c) For the number of entities trading internally in category 3 substances[17], our estimate is extrapolated by looking at the survey responses: 61 of the firms responding to the survey trade in category 3 substances and 48 of them indicated they export substances, and 41 indicated they import substances. Although this has limitations[18], we could assume that

[16] There are some caveats to note, this exercise covered a sample of substances and firms are required to register only if they trade in volumes of at least one metric tonne, so any firms trading in smaller volumes are not required to register.
[17] The REACH database has gaps (hydrochloric acid / hydrogen chloride is not covered by REACH) and for other Category 3 substances the number of entities is in the hundreds and given it would be incomplete, the exercise would be disproportionate. For ephedrine and pseudoephedrine, the fact that the ECHA database only requires registration for importers / manufacturers for >1 tonne per year means that the information is limited (for example, there is just 1 registered supplier each for ephedrine and pseudoephedrine, and the same for a sample of their salts).
[18] There are several reasons why the survey responses might not be indicative: operators who trade in exclusively in Category 3 substances (which comprised only 9 survey respondents), and only do so within the EU (one of the 9 survey respondent who

most entities dealing with category 3 substances are more likely than not to export or import them, i.e. that around two thirds do so. So, for the purposes of the measure, we divide the current number of registrations by two and multiple by three.

Proportion of SMEs

There is no perfect 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

Time spent and time saved for each obligation

Estimates are based on feedback from economic operators through the survey disaggregated for large firms (38 operators identified themselves as large), and SMEs (42)[19]. To calculate the estimated time and savings, weighted averages were used to generate values for a typical firm, even if in practice the situation can vary significantly in view of the many configurations possible. The survey was launched before the options were confirmed meaning that some assumptions have been made that, for example, where operators were asked to what extent a digital solution for customer verifications could lead to cost-savings, the answers have been used to estimate the cost-savings from a digitisation of the current process.

Estimations for costs /cost savings for public authorities largely draw on the same methods and datasets with the exception of estimates are based on feedback from public authorities through the survey disaggregated for large firms. Time spent was reported as open text. For the estimation of time saved through the digitisation of licenses and registration, the modal value is reported as a percentage saving. For the estimation of saving through the lifting of the requirement for authorisations, a weighted average of time spent is used to estimate the current cost. For the estimation of saving through the automation of annual reporting, examples of the variation in the reported time spent are given but deducing an average was challenging given the vast ranges reported.

Labour costs

The average hourly wage of EUR 35.65 per hour or EUR 0.59 per minute (which is used for the calculation of savings).

dealt exclusively with Category 3 neither imported or exported), would currently only be required to submit data for annual reporting upon request, so would have limited engagement with the regulatory framework.

[19] As mentioned above, since just 4 of the SMEs were micro sized firms, the estimated effort / saving for micro-sized firms is elaborated separately through a case study

2.2. LICENSE AND REGISTRATION

For economic operators

	SME				Large firm			
	New		Renewal		New		Renewal	
Obligation	**License**	**Registration**	**License**	**Registration**	**License**	**Registration**	**License**	**Registration**
Paper-based formality (baseline)								
No. of affected entities	1 105	2 862	1 105	2 862	96	249	96	249
Time spent (hours)	4.7	4.6	6.0	3.7	8.5	6.9	4.3	4.2
Labour cost (EUR)	35.65	35.65	35.65	35.65	35.65	35.65	35.65	35.65
Times/year	1	1	0.33	0.33	1	1	0.33	0.33
Recurrency	one off	one off	annual	annual	one off	one off	annual	annual
Total cost (EUR)	183 822	467 658	79 218	125 843	29 000	61 073	4 890	12 323
	651 480		205 061		90 073		17 214	
Digitised formalities								
Proportion of costs saved	21 %	22 %	22 %	22 %	36 %	29 %	35 %	28 %
New time spent (hours)	3.7	3.6	4.7	2.9	5.4	4.9	2.8	3.0
OPTION 2								
No. of affected entities	1 105	2 292	1 105	2 292	96	199	96	199
Total cost (EUR)	145 219	292 077	61 790	78 595	18 560	34 720	3 179	7 104
	437 296		140 386		53 280		10 283	
Savings (EUR)	*214 184*		*64 675*		*36 793*		*6 930*	
OPTION 3								
No. of affected entities	1 563	2 462	1 563	2 462	136	214	136	214
Total cost (EUR)	205 435	313 769	87 412	84 432	26 256	37 299	4 497	7 632
	519 204		171 844		63 555		12 129	
Savings (EUR)	*132 277*		*33 217*		*26 518*		*5 085*	

Number of affected entities are category 1 license holders and category 2 and 3 registration holders to which the proportion SME/large firm has been applied. Under **option 2**, the affected entities include category 1 for e-licenses, and category 2, 3, and 4 for self e-registration. However, 120 entities appear in more than one category and should only be counted once. Additionally, self e-registration applies solely to external trade. This brings the total number of affected entities for self e-registration to 2 491. For **option 3**, the affected entities for e-licenses include category 1 and 2a licensees and registration holders. Since 191 operators hold both a category 1 license and a category 2a registration, they should be counted only once. This results in 1 699 affected entities for e-licenses. For self e-registration, the affected entities are category 2b, 3, and 4 registration holders and the category 3 that trades only internally. Among them, 209 operators hold multiple registrations and should be counted as one. This brings the total number of affected entities for registration to 2 676.

Recurrency may be first time license or registrations in which case they are a one-off cost, but they may also be renewed and typically this needs to be done every three years but does vary. We assume that a third of licenses / registrations require renewal every year. While the number of licenses / registrations being requested / renewed depends on an operator's activity, the

responses to the survey show that typically operator indicator this is an obligation fulfilled every few years.

For public authorities:

Obligation	License / registration	
	New	Renewal
Paper-based formality (baseline)		
No. of affected entities	3 986	3 986
Time spent (hours)	9	5
Labour cost (EUR)	35.65	35.65
Times/year	1	0.33
Recurrency	one off	recurring
Total cost (EUR)	1 278 908	236 835
Digitised formalities		
Proportion of costs saved	38 %	38 %
New time spent (hours)	6	3
OPTION 2		
No. of affected entities	4 086	4 086
Total cost (EUR)	819 371	150 521
Savings (EUR)	*459 537*	*86 313*
OPTION 3		
No. of affected entities	4 449	4 449
Total cost (EUR)	892 164	163 894
Savings (EUR)	*386 745*	*72 941*

The baseline number of **affected entities** are the number of license and registration holders in the EU drug precursors database. Under **option 2**, the affected entities are the number of license and registration holders in the EU drug precursors database and category 4 operators, making the total number of affected entities for 4 086. For **option 3**, the affected entities are the number of license and registration holders in the EU drug precursors database, the category 3 trading only internally and the category 4 operators., making the total number of affected entities for 4 449.

2.3. DIGITAL CUSTOMER VERIFICATION

For economic operators

Type of EO	SME	Large firm	Total
Paper-based customer declaration (baseline)			
No. of affected entities	3 183	277	3 460
Time spent (hours)	3.6	2.1	

Labour cost (EUR)	35.65	35.65	
Transactions (frequency/ year)	38	336	
Total cost	15 596 083	6 907 544	22 503 627
Digitised formalities (e-Validation)			
Proportion of costs saved	36 %	40 %	
New time spent (hours)	2.3	1.3	
OPTION 2			
No. of affected entities	1 105	96	1 201
Total cost (EUR)	3 464 674	1 438 606	4 903 280
Savings (EUR)	*12 131 409*	*5 468 938*	*17 600 347*
OPTION 3			
No. of affected entities	4 001	348	4 349
Total cost (EUR)	12 546 102	5 209 406	17 755 508
Savings (EUR)	*3 049 981*	*1 698 138*	*4 748 119*

For the number of affected entities, not all operators trading in categories 1 and 2 will need to verify their customers. If their customers or suppliers are ALL outside the EU, this requirement won't be relevant. The DP database does not have this level of detail, nor does the survey of operators. As such, we have assumed that most operators have some relevant EU supply chain and we have not applied a discount for this for the baseline estimates, nor attempted to estimate the sub-set of relevant entities in the estimation for the options. Nevertheless, the number of relevant entities differs for options 2 and 3, based on the revised categories. **For option 2,** only entities trading in category 1 would be covered by the obligation. **For option 3,** all entities currently licensed or registered plus those not registered for Category 3 (because they are only required to register for internal trade).

2.4. IMPORT/EXPORT AUTHORISATION

Under option 2 and 3 import and export authorisation will not be needed as they will be replaced by quantity management.

Fore economic operators:

BASELINE – economic operators	Import	Export	
Transactions (year)	2 451	3 1304	
Time spent (hours)	3	5.5	
Labour cost (EUR)	35.65	35.65	
Total cost (EUR)	265 047	6 147 232	6 412 279

For public authorities

BASELINE – public authorities	Import	Export	Total
Transactions (year)	2 451	31 304	
Time spent (hours)	2	6	
Labour cost (EUR)	35.65	35.65	
Total cost (EUR)	174 756	6 695 926	6 870 682

Number of affected imports / exports or transactions: The most accurate information on the number of transactions for imports and exports is derived from the Surveillance data. These data contain precise information on the number of imports requiring authorisations (since this is simply the number of transactions for Category 1 imports). For exports, it is more complicated. The surveillance data contain information on the number of transactions (per Category) and country of origin / destination, but they do not contain information which transactions involve simplified procedures. Further, the data are not precise. There are some transactions (c.60 000 annually) which may contain drug precursors, but the CN code is not sufficiently detailed to allow for a precise estimate. To estimate exports, the Surveillance data was analysed in parallel with a survey of Member States[20] and an estimates average for the number of imports / exports requiring authorisations was generated, for the last four years 2020-2023. Essentially, the estimate is generated by multiplying the Member State estimate by a factor of 3.6[21] and checking this against the relevant transactions for exports to check its appropriateness.

[20] The survey of Member States asked for an estimate of the number of transactions requiring import and export authorisations. These data show under-reporting but when analysed together with the Surveillance data allow for a robust, if conservative, estimate for both import and export authorisations to be generated.

[21] Imports authorisations were under-reported by this factor, so we assume exports were underreported by a similar factor

2.5. ANNUAL REPORTING

Under option 1, reporting obligations will be reduced, while under options 2 and 3, they will be lifted. The assumptions for the 30% reduction in burden cost under option 1 are fully detailed in section 6.1 of Part I of the Impact Assessment. The table below outlines the assumptions used to calculate the current reporting costs, which represents the cost reductions under options 2 and 3 once these reporting obligations would be lifted.

	SME (92 %)	**Large firm (8 %)**	**Total**
No. of affected entities	3 759	327	4 086
Time spent (hours)	19.15	55.2	
Labour cost (EUR)	35.65	35.65	
Cost per entity (EUR)	683	1 968	
Times/year	1	1	
Total cost (EUR)	2 566 342	643 261	3 209 602

The **number of affected entities** may be underestimated. For instance, operators trading in category 4 are required to submit data annually, but they are not registered in the database. The estimated detailed in section 2.1 was used. Operators trading in category 3 are required to submit information "upon request" (and are likely to provide information for other substances already) we have included them in the total number of affected entities. We have assumed that operators are required to fulfil the obligation once a year, but that is a minimum. In some cases, it may be more frequent.

The **recurrency** is by definition annual, however some Member States do require reporting at shorter intervals to facilitate the validation of the data. Information for category 3 is only required "upon request", but Member States might have different rules.

Public authorities are assumed to have an equivalent benefit to economic operator as they will have to process the same number of reports.

2.6. DUE DILIGENCE COSTS:

	Option 2	**Option 3**
a) Average time input for the 'due diligence' on new substance (hours)	1.5	1.5
b) Estimated number of affected companies	1 200	1 200
c) Number of substances (gross)	150	350
d) Number of substances net of 'dynamic baseline' assumptions	120	320
e) Average labour cost (EUR)	35.65	35.65
f) Total costs (EUR) (a * b * c * e)	**7 700 400**	**20 534 400**
g) Total costs – annualised (EUR) (over 3 years)	517 588	1 380 234
h) Costs – annualised per company (EUR)	431	1 150

As mentioned, the stated objective of the ***innovative scheduling approach*** is to ensure a streamlined identification of the substances that will be placed under control combining different scheduling methods in the way that ensures the maximum of efficiency and no risk of

ambiguity. In this sense, the scheduling of families of derivatives can be employed only for certain families that ensures an appropriate delimitation of scope (e.g. esters, sulfonamides, acetals). Chemical formula description can be used for certain designer precursors that have the same core structure and certain specific variables. Substance-by-substance scheduling would remain necessary in all cases where the other approaches appear unsuitable. It is worth highlighting that the EUDA library will help the identification of concerned substances thus mitigating constraints due to technical complexity. Furthermore, it is reasonable to estimate that bulk scheduling is less burdensome than one-by-one scheduling, when the substances concerned are just virtual derivatives of the same core molecule. All in all, it is therefore 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)

The number of affected economic operators corresponds with the number of category 1 licensees, taking into account that designer precursors are modified category 1 substances. It should be noted that, currently, only 100 operators have a license for ATS related designer precursors, the main concern for the EU. All of them, have a category 1 license.

The number of substances correspond with the scope of each option. Based on the current scheduling trend, it is assumed that no less than 30 new substances would be scheduled by 2029 under the dynamic baseline.

2.7.SPECIAL LICENSE FOR DESIGNER PRECURSORS

Type of EO	**Large firm**	**SME**
No. of affected entities	8.4	96.6
Time spent (hour)	4.3	6.0
Labour cost (EUR)	35.65	35.65
Times/year	1	1
Recurrency*	one off	one off
Total cost (EUR)	1 283	20 778
	22 060	

The **affected entities** are those having licenses for designer precursors.

The **time spent** is assumed to be equivalent to the estimated time to renew a license. The estimate time is based on the survey responses.

The recurrency is one off, subsequent renewals are business as usual (the precursors at stake are already subject to license)

2.8. ADJUSTMENT COSTS FROM CONSOLIDATION OF CATEGORIES

Under option 3, current category 2a registration holders will need to secure their premises. Below table details the calculation method.

Type of EO	**Large firm**	**SME**
No. of affected entities	39.84	458.16
Average one-off investment cost (EUR)	7 400	5 331
Average annual cost operational and maintenance costs (EUR)	4 440	2 800
Total one-off (EUR)	294 816	2 442 451
	2 737 267	
Total recurring (annual) (EUR)	176 890	1 282 848
	1 459 738	

The **affected entities** are the category 2a registration holders, in so far that they do not hold a category 1 license. In the latter, they are already subject to this obligation and will not suffer additional adjustment costs. 191 of the 689 category 2a registrations holders, hold also a license for category 1, bringing the number of affected entities to 498.

2.9. DIGITALISATION

After adoption of the proposal on monitoring and controlling of drug precursors the process of interinstitutional negotiations between co-legislators will start. In parallel with this process the responsible body in charge of digitalisation will start business analysis in order to compose Project Initiation request and Business Case for submission to ITCB. In parallel to this work the Commission shall start drafting implementing acts on details of IT solution and data elements and its formats to be exchanged to be adopted based on business analysis. The Commission shall also negotiate and adopt agreement on bilateral arrangement with third parties such as UN/INCB on data exchange together with Annex on technical arrangements.

Depending on the decision of ITCB on the alternative for development of the solution and delivery model COM will chose between outsourcing the work from an external contractor, or developing in-house (e.g. by DG SANTE/DG Trade etc).

As a first activity related to the development of DP eLicencing system and based on the experience gained from other EU projects for the issuance of digital certificates, a prototype for the issuance module shall be prepared, followed by a piloting activity.

COM will organize a Conformance tests (CT) campaign in cooperation with MSs. All necessary information and documentation for the CT campaign (Integration Guide for Member States, CT Plan, CT Organization Document) will be provided and organizational meetings will be organized prior to the campaign.

To ensure the smooth implementation of the requirements the EU Commission will:

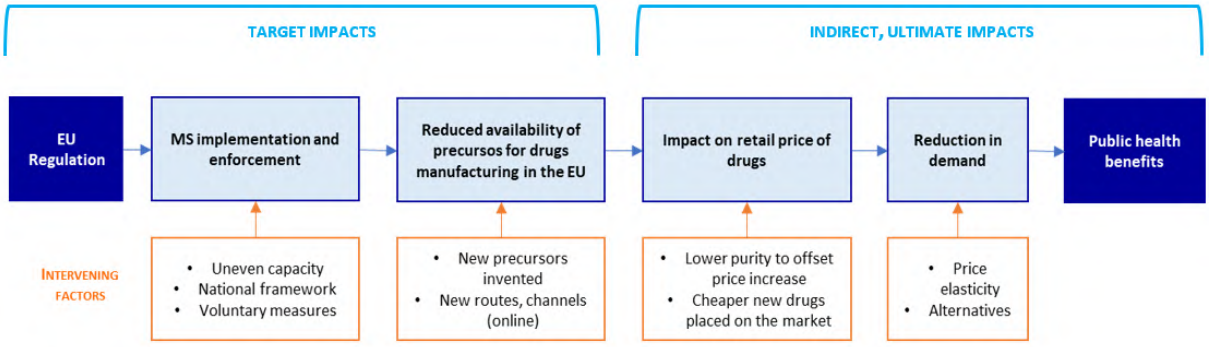
- Create a dedicated team to manage the specifications (functional and technical ones) and the implementation of the system, facilitating the collaboration between all stakeholders.
- Create guidelines for the implementation (functional and technical specifications) of the needed services for interaction with the DP eLicencing system by the EU MSs.
- Develop and maintain the common components of the system needed for the issuance and the exchange of certificates with a central repository, and an administrative cooperation.

- Extend the functionalities of EU CSW-CERTEX for the new domain of drug precursors and interaction with the EU MS National customs systems.
- Maintain (in technical means) a central registry of authorised users, including EOs of EU MSs and partners from partner countries.
- Extend the existing platforms used in the EU for the authentication, authorisation and connection of users from the partners of partner countries.
- Provide the relevant guidelines (i.e., user manuals, GUI help desk procedures, and training materials) for the DP eLicencing system GUI.
- Discuss, elaborate and provide the needed information guidelines (e.g., specifications, connectivity instructions, training materials) to international partners to be connected via machine-to-machine interface such as INCB.
- Provide trainings for the users of the system, including operators, officials of MS medcine and customs authorities.
- Provide the GUI (user interface) of the system in all EU languages. The platform will be able to support other languages for the future needs, apart from Latin and Cyrillic alphabet
- Provide a centralised 3rd level IT support in English. The central support from EC will be provided only to national service desks of customs authorities, not for businesses. Technical Support will be provided by DG DIGIT.

3. LIMITATIONS IN QUANTIFYING IMPACT ON CRIME, HEALTH AND ENVIRONMENT.

The approach to determining the impact on crime and the ultimate health and environmental implications of revising the EU drug precursors regulation is a multi-faceted process. This initiative is expected to indirectly affect illicit drug manufacturing and markets, thus yielding social benefits such as reduced crime and enhanced public health. However, realizing these benefits involves a complex impact chain with external factors influencing each stage.

The impact chain:



The ultimate aim is to make it more difficult for criminal organizations to obtain drug precursors. By disrupting illegal drug manufacturing, the regulation could potentially decrease the availability of illicit drugs, with resulting benefits like reduced drug-related health issues. Nevertheless, these effects depend on effective law enforcement and the adaptive behaviour of illicit market actors.

3.1. REDUCTION IN THE AVAILABILITY OF PRECURSORS FOR ILLICIT DRUGS MANUFACTURING

Regarding policy revision effects, methodological limitations make it difficult to quantify changes in precursor availability. The extent of illegal activities is largely unknown, so qualitative assessments rely on law enforcement indicators such as seizure volumes and trends. These indicators, though informative, are not directly correlated with the underlying illegal activities due to variations in national legal frameworks, enforcement capacities, and other factors.

The impact on illicit drug supply, theoretically affected by precursor availability, similarly presents measurement challenges. Reliable supply data is lacking, and the metrics for demand, including surveys and wastewater analysis, have inherent limitations. Furthermore, the illicit drug trade is not solely linked to EU consumption, as products are frequently exported, and local users may consume imported drugs. Substitution behaviours among users and other factors like social attitudes also influence demand, complicating the establishment of significant correlations between precursor control and drug supply.

Literature[22] and EU experience provides mixed results on regulatory interventions, revealing that comprehensive, large-scale measures often yield better results than small-scale measures. For instance, following the EU's scheduling of a significant number of new precursors in July 2020, there was a notable and sustained decline in seizures compared to previous rounds that targeted fewer substances. Moreover, the speed with which new designer precursors are regulated plays a vital role; slow regulatory response can give drug manufacturers time to find alternative, non-regulated precursors[23]. Consequently, while regulatory efforts disrupt the illicit trade temporarily, continuous advancements and prompt intervention are necessary to maintain effectiveness.

- **Scheduling precursors**
  The analysis of the impact of EU scheduling on the availability of designer precursors shows significant, albeit varying, trends. Data for nine designer precursors, scheduled at different times, reveal key insights[24]:
  - **General reductions post-scheduling:** There is a consistent reduction in both the number and volume of seizures after scheduling. The data indicates that the number of cases typically halved following scheduling (down ~47% over 12-36 months), while the volume of seizures decreased even more significantly, dropping to 9% over 36 months. This suggests a substantial impact on the circulation of designer precursors.
  - **Variability across substances:** Some substances, like APAA and PMK glycidic acid, saw near disappearance post-scheduling, while others like BMK glycidic acid and PMK

[22] for instance: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7370931/; Petruželka, Benjamin, and Miroslav Barták. 2020. "The Identification of Precursor Regulation Impact on the Methamphetamine Market and Public Health Indicators in the Czech Republic: Time Series Structural Break Analysis." International Journal of Environmental Research and Public Health 17 (21): 7840. https://doi.org/10.3390/ijerph17217840; Australian Institute of Criminology, The price elasticity of demand for illicit drugs: A systematic review, Trends and Issues in crime and criminal justice October 2020.; In 2023, the number of death related to synthetic opioids amounted to nearly 75,000 in the United States. Source: https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2024/20240515.html ;

[23] Bouchard, M. and Ponce, C., 'Structuring adaptations: Resilience, restrictive deterrence, and the Cunningham precursor control papers', *International Journal of Drug Policy,* Vol. 138, (2025), pp. 1-4.

[24] **APAAN** - Scheduled in November 2013; **BMK glycidic acid** - Scheduled in July 2020; **PMK glycidic acid** - Scheduled in July 2020; **APAA** - Scheduled in July 2020; **BMK methyl glycidate** - Scheduled in July 2020; **PMK methyl glycidate** - Scheduled in July 2020; **MAPA** - Scheduled in July 2020; **DEPAPD** - Scheduled in November 2022; **PMK ethyl glycidate** - Scheduled in November 2022.

ethyl glycidate remained resilient. APAAN continues to be seized despite regulations since 2013, due to mislabelling practices by smugglers, highlighting the role of detection capabilities over regulatory status.

- **Impact on amphetamine and methamphetamine precursors:** Between 2020 and 2022, seizures fell from around 10 tonnes to 2 tonnes quarterly, an estimated 60% reduction in trade volume that would have occurred without intervention. These results were partly due to the scheduling of substances like MAPA and APAA, confirming the temporary impact of scheduling.
- **Role of consistency and substitution:** The effects of prohibition are not uniform, as some substances persist in trade despite controls. This underscores the importance of consistent application of regulation across the EU and internationally. Benefits from scheduling are often temporary, as new precursors emerge, necessitating broader bans for lasting impact.

Response time

The timely regulation of designer precursors plays a crucial role in controlling illicit drug manufacturing. Key points and quantified impacts from the analysis of the EU drug precursors database include:

- **Delay in scheduling impacts:** Substances such as APAA circulated for seven years before being scheduled, resulting in sizable seizures of 57,000 kg. After scheduling, this figure dropped to just 62 kg in three years. PMK methyl glycidate saw seizures decline from 44,000 kg before scheduling to a mere 50 kg afterward.
- **Significance of timeliness:** Hypothetical scenarios indicate scheduling within 2 years of first detection could result in a 90% reduction in illicit trade, and an 80% reduction with a 4-year delay. **Timely regulatory actions post-2020 reflected a 60% reduction in illicit trade volume**, underscoring substantial benefits from prompt interventions.
- **Improving Response Time:** Current scheduling, taking 10-17 months, can be shortened:
    - Reducing the scrutiny period by 1 month will reduce the overall scheduling time by 5-10%, potentially resulting in a 1-3% reduction in illicit trade.
    - Introducing an urgency procedure for delegated acts concerning new scheduled substances will potentially save up to three months, reducing the scheduling time by 15-30%. The anticipated benefit of these options is a reduction in illicit trade amounting to approximately 3%.
- **Proactive scheduling benefits:** Faster regulation, akin to scheduling substances before illicit use is evident, can significantly reduce circulation. The impacts, though temporary, can disrupt illegal supply chains and are potentially multiplied by international cooperation, raising control levels globally.

These findings underline the complexity of assessing and counteracting illicit drug precursor trades, highlighting the essential need for nuanced approaches tailored to current patterns of illegal activity and rapid adaptation by criminal networks.

3.2. INDIRECT IMPACT ON DRUGS AVAILABILITY

The primary goal of controlling drug precursors is to disrupt illicit drug markets and mitigate public health issues, rather than focusing solely on precursor availability. Key insights from the literature[25] analysis include:

- **Market Availability and Price:**
  - Controlling precursors can lead to temporary drug unavailability due to enforcement actions, although effects may be short-lived.
  - Changes in illicit drug prices and purity can occur as producers adapt by finding new precursors or altering product composition.
  - Studies show limited evidence of precursor control significantly impacting drug price or purity, with few exceptions like the early U.S. regulations.
- **Impact Limitations:**
  - Methodological challenges make it difficult to correlate regulation with drug market trends, such as using seizures as market proxies or dealing with varied data on price and purity.
  - Illicit drug demand is weakly price-elastic, meaning price changes have less impact on demand. Demand is also influenced by broader socio-cultural factors.
- **Public Health Outcomes:**
  - The public health impact of precursor control varies, influenced by drug toxicity, use patterns, and healthcare system performance.
  - Literature reviews show mixed outcomes from precursor regulations, with some interventions correlating with decreased treatment needs and others having no significant effect or opposite results.
  - Case studies, like Mexico's 2008 ban and Canada's 2003-2004 regulations, illustrate diverse health impacts.
- **Complexity of Estimating Benefits:**
  - While enhanced control of designer precursors might reduce treatment demand for synthetic drug use, predicting effectiveness is challenging due to confounding factors.
  1. Direct correlations between precursor policies and public health metrics (like drug-related mortality) remain underexplored and complex to establish.

Overall, the effectiveness of precursor regulation on disrupting drug markets and improving public health is not straightforward, involving multiple confounding factors and varied regional impacts.

[25]The study included in the review: Berbatis, Sunderland, and Dhaliwal 2009; Brandenburg et al. 2007; Callaghan et al. 2009; J. Cunningham 2013; J. K. Cunningham et al. 2010; J. K. Cunningham, Callaghan, and Liu 2015; J. K. Cunningham et al. 2012; J. K. Cunningham and Liu 2008; J. K. Cunningham, Liu, and Callaghan 2013; 2016; J. K. Cunningham and Liu 2003; 2005; J. K. Cunningham, Liu, and Callaghan 2009; J. K. Cunningham, Liu, and Muramoto 2008; J. K. Cunningham et al. 2013; S. Cunningham 2015; S. Cunningham, Finlay, and Stoecker 2015; d'Este 2021; Delcher et al. 2017; Dobkin 2009; 2014; Dobkin, Nicosia, and Weinberg 2014; Ferris et al. 2016; Freylejer and Orr 2023; Jones 2022; Mazerolle et al. 2017; D. C. McBride et al. 2011; D. McBride et al. 2009; McGuffog 2012; Nonnemaker 2011; Office for Health Improvement & Disparities 2023; Petruželka and Barták 2020; Ponicki et al. 2013; Strang 2012; Sudakin and Power 2009; Wing Lo 2020); Australian Institute of Criminology, The price elasticity of demand for illicit drugs: A systematic review, Trends and Issues in crime and criminal justice October 2020.; In 2023, the number of death related to synthetic opioids amounted to nearly 75,000 in the United States. Source: https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2024/20240515.htm

3.3. ENVIRONMENTAL IMPACT

In 2019, a pioneering study by the EUDA assessed the environmental costs of synthetic drug production, particularly in Belgium and the Netherlands[26]. Key findings include:

- **Environmental Impact of Production:**
    - Synthetic drug production involves hazardous techniques and chemicals, leading to significant environmental damage due to unsafe waste disposal.
    - Producing 1 kg of MDMA generates 6-10 kg of waste, while amphetamine production produces 20-30 kg of waste. This waste is often illegally dumped, causing environmental and public health risks.
- **Additional Impact from Designer Precursors:**
    - Designer precursors exacerbate environmental harm as they require conversion to key precursors in 'conversion laboratories', generating more chemical waste.
- **Current Data and Costs:**
    - Recent data identified 234 illegal dumping sites in the EU, with most located in Belgium (41) and the Netherlands (153).
    - Cleanup costs in these two countries are estimated at EUR 5.7 million, implying nearly EUR 7 million EU-wide. These costs only cover detected sites; the true number of clandestine operations is unknown.
- **Challenges in Quantification:**
    - The study highlights the difficulty in providing precise estimates of the environmental costs due to the clandestine nature of operations.
    - Environmental benefits of improved regulation would likely correlate with reductions in illicit drug production, particularly where designer precursors are involved.

In conclusion, while the financial and environmental costs of illicit drug manufacturing are substantial, accurately quantifying them and predicting savings from regulatory measures remain challenging due to the secretive operations of illicit drug labs.

[26] Claessens, M., Hardyns, W., Vander Laenen, F. and Verhaeghe, N. (2019), An analysis of the costs of dismantling and cleaning up synthetic drug production sites in Belgium and the Netherlands, EMCDDA, Lisbon;EMCDDA Papers, Drug precursor developments in the European Union, 2019 ; https://www.euda.europa.eu/publications/european-drug-report/2024/drug-supply-production-and-precursors_en

ANNEX 5: COMPETITIVENESS CHECK

1. OVERVIEW OF IMPACTS ON COMPETITIVENESS

Dimensions of Competitiveness	Impact of the initiative (++ / + / 0 / - / -- / n.a.)	References to sub-sections of the main report or annexes
Cost and price competitiveness	+	Aggregate impacts of Option 2 Annex 4, section 2 for final estimates of benefits and costs in Option 2 with inclusion of Category 4.
International competitiveness	0	Impacts of Option 2
Capacity to innovate	0	Impacts of Option 2
SME competitiveness	+	Impacts of Option 2, Annex 6

2. SYNTHETIC ASSESSMENT

The preferred option implies significant savings (as summarised in Annex 3.2). Economic operators stand to save EUR 19.8 million annually. However, as these do not have a direct effect on products' costs, it can only be assumed that there might be a trickle-down effect that would increase the **cost and price competitiveness** of the chemical industry concerned.

We do not expect a trickle-down effect of increased enforcement costs onto operators. Fees or charges of public authorities must be based on actual services rendered, not merely on administrative activities that authorities are required to perform as part of their responsibilities.

The preferred option is designed to reduce the compliance costs of legal traders through simplification, digitalisation and rationalisation (streamlining) of redundant / inefficient procedures. In turn this should contribute (indirectly) to a modest impact on **international competitiveness**. It is worth noting that the EU has limited room for manoeuvre given that obligations facing economic operators have their origin in international obligations. But it also means that operators outside the EU face similar obligations and hence that EU businesses are not at a competitive disadvantage provided the controls are relevant, proportionate and efficient.

The **capacity to innovate** would remain largely unaffected by the control measures applied to designer precursors, thanks to small quantity exemptions – designed to facilitate non-commercial transactions like the acquisition of samples, reference standards etc. for research or forensic use – and the establishment of a light 'prior notification' mechanisms to allow for occasional legitimate transactions involving banned substances, typically or R&D purposes. The preferred option also entails to limit the scope of the ban, thus minimising the risk of disruption on industrial research and innovation activities.

SMEs may save less than large firms on a case-by-case basis (by virtue of undertaking certain obligations less frequently) but overall, the contribution to their bottom line should be positive given that specific obligations are entirely removed and others are made faster and more efficient. Additionally, the simplification of the regulatory framework is expected to be beneficial to SMEs who are less likely to have dedicated staff dealing with compliance.

3. COMPETITIVE POSITION OF THE MOST AFFECTED SECTORS

As explained in more detail in Annex 10, drug precursors drug precursors are chemical substances diffused in the quasi-entirety of the chemical industry. While drug precursor rules regulate legal trade, they also affect precursors that have no known legal use which would be outside the scope of sectorial analysis. The obligations imposed by the regulations do not influence economic operators' variable costs but represent overhead costs only. With the above caveats, the manufacturing of basic and other chemical products is the industrial sector that is most relevant for drug precursors sectorial analysis.

Within the EU, the chemical industry is one of the most important sectors of manufacturing, as it:[27]

- represents about 7 % of total EU manufacturing by turnover (2018);
- provides 1.2 million direct jobs, displaying a labour productivity 77 % higher than EU's manufacturing average (2020) and paying wages 48 % higher than EU's manufacturing average (2022);
- displays the 2nd-largest capital spending in the global chemical industry, which has constantly represented over 15 % of the EU chemical industry's value added during the last two decades (19.5 % in 2023);
- is currently (since 2021) spending about EUR 10 billion annually on R&I, which amounts to 6 % of the sector's value added;
- generates trade surpluses of over EUR 40 billion annually (EUR 50 billion in 2024), ranking 4th among all EU industrial sectors.

While there are 29,000 companies operating in the EU chemical industry, meaning that the number of SMEs runs in the tens of thousands, their relevance for the drugs precursors is tenuous and strictly theoretical. In fact, none of the building blocks and of the critical intermediates required for manufacturing the scheduled drug precursors can be produced in small companies.

Besides, one of the most important contribution the SMEs are making reputedly making to the economy overall is in terms of employment. Yet, over 2/3 of people employed in the EU chemical industry work in large companies.

A distinct characteristic of the chemical industry is that it requires energy not just in order to power its production processes, but in fact mainly as feedstock for obtaining all of its building blocks. This makes it the highest industrial final energy consumer in the EU and the industrial sector displaying the highest energy intensity (in terms of % of revenues). This has had severe consequences following the increase in energy prices energy prices triggered by the Russian aggression of Ukraine launched in 2022.

Indeed, the competitive position of the EU on the global cost curves for the chemical industry's main building blocks has massively deteriorated. As chemical products are intensively traded internationally, the EU chemical industry's important erosion of international competitiveness translated itself in a corresponding deterioration of all its main indicators.

[27] Based on Eurostat and Cefic

Over the last two years, the EU chemical industry's capacity utilisation rate was 6 percentage points lower than its long-term (20 years) average. In fact, the state of capacity utilisation in the EU chemical industry is so morose that the most realistic prospect of seeing it improving consists of closures of existing capacities.

Following a deterioration of the business confidence sentiment in the EU chemical industry over the last quarter of 2024, a recovery can be noticed since January 2025 but the indicator is still negative. The last time this indicator was in positive territory is May 2022.

ANNEX 6: SME TEST

Overview of impacts on SMEs

Relevance for SMEs
This initiative is relevant.

1. IDENTIFICATION OF AFFECTED BUSINESSES AND ASSESSMENT OF RELEVANCE
Are SMEs directly affected? *(Yes/No)* **In which sectors?**
Drug precursors have important legitimate uses in several industrial processes. In particular, precursors are largely used in the following industries: pharmaceuticals, flavouring and fragrance, fertilisers, battery manufacturing, cosmetics, plastics, dyes and inks, textiles, oil refinery, water treatment, food additives, explosives, and rubber production. The legal use of precursors in the EU exceeds 10.6 million tonnes per year, while aggregated export to third countries amounts to approximately 2.6 million tonnes per year. Economic operators including SMEs are part of this supply chain and therefore an important stakeholder to consider. The legislative framework governing Drug Precursors provides for the registration and licensing of operators involved and sets up documentation and labelling requirements. Operators are obliged to notify the competent authorities of any suspicious transactions. The system is supposed to operate in a spirit of cooperation between authorities and industry/economic operators. The planned revision of the Drug Precursors Regulations will thus have an impact on operators, including SMEs.
Estimated number of directly affected SMEs
According to Eurostat's structural business statistics, the SMEs account for 92 % of enterprises active in the manufacturing of basic and other chemical products – i.e. the industrial sectors that are most relevant for drug precursors production – of which the majority (68 %) are micro enterprises with less than 10 employees. The exact share of SMEs actually involved in the manufacturing of drug precursors is unavailable, but according to national public authorities consulted the proportion of SME operators in this specific field is likely in line with the above estimate of 92 % that applies to the entire chemical sector. The survey of operators conducted in the context of the study indicated that for the responding SMEs (of which there were 43 out of 81) the approximate share of their company's turnover that relate to drug precursors was less than 5 % in around half of cases (the most common response for SMEs).
Estimated number of employees in directly affected SMEs
Not available
Are SMEs indirectly affected? *(Yes/No)* **In which sectors? What is the estimated number of indirectly affected SMEs and employees?**
No.

2. CONSULTATION OF SME STAKEHOLDERS
How has the input from the SME community been taken into consideration?
The complexity affects operators involved in the legal trade of drug precursors, especially smaller businesses (SMEs and micro-enterprises), which are disproportionately affected in cases where specialised or dedicated resources are required to navigate the burdensome

requirements. As such, the options prioritised simplifying the legal framework and streamlining the obligations on economic operators including through a more modern (digital) approach.

Are SMEs' views different from those of large businesses? *(Yes/No)*

The impact assessment effectively consulted different SMEs such as chemical manufacturers, distributors, industry and research entities, and trade associations through complementary consultation tools providing quantitative data supplemented by qualitative results. The input collected through these consultations informed both the definition of the policy problems and their solutions highlighting where results for SMEs diverge from the results for large companies. The main findings were as follows:

- **Proliferation of designer precursors:** According to survey results, on issues such as an 'outright ban' on designer precursors and support measures to make the scheduling process faster, SMEs are even less concerned than large companies about this issue.
- **Facilitation of legal trade**: The consultation confirmed the absence of a systematically more negative assessments in relation to the burden on business by SMEs compared to other businesses. SMEs had a more favourable view of the Regulatory framework's ability to prevent unnecessary burdens and SMEs were not disproportionately of the view that the Regulation had a negative effect.
- The separation of legal texts was perceived as problematic by EOs and slightly more so among SMEs than large companies.

3. ASSESSMENT OF IMPACTS ON SMEs[1]

What are the estimated direct costs for SMEs of the preferred policy option*?*

Qualitative assessment

Impact of outright ban on designer precursors and other main measures to address illicit trade of precursors (objective 1).

The benefits of measures addressing illicit trade of precursors regard legitimate EOs (and SMEs) only indirectly (e.g. reputational effects).

According to surveyed EOs (and SMEs) the other possible measures for enhancing control of illicit trade of precursors are not going to impose relevant new burden.

Impact of measures for the simplification and modernisation of the current system (Objective 2).

Costs and benefits of the proposed trade facilitation measures was examined differentiating between SMEs and large enterprises. While SMEs were included as a separate target group for the analysis of costs and benefits, the external study treated micro-sized enterprises via a qualitative case study approach to illustrate the difficulties in generalising the results for such varied enterprises.

The preferred option stands to reduce administrative costs and hassle costs for all type of businesses including SMEs.

Quantitative assessment

Objective 1:

Regarding costs, the proposed 'outright ban' for designer precursors would be implemented through a list of prohibited substances, and this would require EOs to accurately verify that none of the banned substances is actually in their portfolio (including under a different chemical name). This due diligence activity would regard primarily operators engaged in the production and trade of specialty chemicals – i.e. an estimated 1,200 companies, of which 1,100 SMEs (according to the above Eurostat-based proportion).

According to the estimate collected, the due diligence for a new substance requires a one-off 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 method tested, with no relevant differences between SME and large enterprises. Assuming an average cost of labour of EUR 35.65 / hour, the administrative costs linked to the addition of a new substance to the EU schedule currently range from EUR 36 to EUR 320 per company[28]. Further checks might be necessary in case a company's portfolio changes. The number of substances to be added to the list of banned designer precursors will have to be established in an appropriate forum. The additional costs for EOs (and SMEs) will depend on the number of banned substances, and in this sense the preferred option will involve a lower number of substances i.e. only derivatives of known and seized precursors that are chemically viable and easy to use. It also envisages exemptions to the ban, to avoid adverse effects on Eos' (and SMEs') research and innovation activities.

Objective 2:

In the preferred option, there is an overall reduction in the number of operators facing the more stringent requirements (including SMEs). Licensing, registration as well as import and export authorisation requirements are simplified, while reporting obligations are removed entirely. The e-verification would cost SMEs approximately EUR 3.4 million.

What are the estimated direct benefits/cost savings for SMEs of the preferred policy option[29]?

Qualitative assessment

The preferred option largely focusses on streamlining the requirements for economic operators. And would benefit SMEs.
A consolidation of categories would alleviate the obligations for operators, and, by virtue of their volume and the relative impact on their turnover, it would benefit SMEs in particular.

Quantitative assessment

The following measures benefit SMEs directly:

- The introduction of e-licenses and self e-registration: SMEs would save around 21-22 % of the existing costs of applying for the first time for a license or registration through the digitisation of the procedure. They would save 22 % of the annual (renewal) costs for the same.
- Digitalisation of customer verification: SMEs would save around 36 % of the annual current costs associated with verifying customers for internal trade through the digitisation of the procedure.
- Automation of import / export authorisation processes: All operators (including SMEs) would save 100 % of costs associated with annual reporting and applying for import / export authorisations.

[28] This cost would be repeated every time new substances are scheduled at EU level.
[29] The direct benefits for SMEs can also be cost savings.

What are the indirect impacts of this initiative on SMEs? *(Fill in only if step 1 flags indirect impacts)*
N/A

4. **MINIMISING NEGATIVE IMPACTS ON SMES**
Are SMEs disproportionately affected compared to large companies? (*Yes/No)* **If yes, are there any specific subgroups of SMEs more exposed than others?**
SMEs represent the vast majority of companies affected by drug precursor rules. However, as drug precursors are used throughout the entire chemicals industry, it is not possible to identify any subgroups that are more exposed than others.
Have mitigating measures been included in the preferred option/proposal? (Yes/No)
The preferred option, and especially the general simplification of rules, is designed to benefit especially SMEs and it does not contain specific mitigating measures targeting only SMEs.

CONTRIBUTION TO THE 35 % BURDEN REDUCTION TARGET FOR SMES
Are there any administrative cost savings relevant for the 35 % burden reduction target for SMEs?
SMEs stand to benefit from the overall burden reduction of the preferred option which amounts to a reduction of EUR 19.8 million.

ANNEX 7: INNOVATIVE WAYS OF SCHEDULING

1. USE CASE OF DESIGNER PRECURSORS USED FOR THE MANUFACTURING OF AMPHETAMINE TYPE STIMULANTS (ATS)

This section is based on the work of a group of experts from EUDA, JRC, CLEN, Belgium and the Netherlands.

This Annex describes different ways of listing substances for the purpose of scheduling for regulatory purposes. Precursors used for the production of amphetamine type stimulants (ATS) where designer precursors are a common phenomenon are used as a case study.

Usually, criminals use relatively simple modifications and rely on derivatives that are easily converted into the original precursor that is subject to controls.

The objective of scheduling designer precursors is to be able to capture the scope of those substances that are attractive to serve as designer precursors.[30]

There are different techniques to spell out such a scope in legislation. Below sections illustrate 3 possible techniques to schedule around 100 substances:

1. an extensive list of possible ATS designer precursors
2. Describing the possible ATS designer precursor as families of derivatives or related chemicals
3. Describing the possible ATS designer precursor based on a chemical formula

1. Scheduling an extensive list of possible ATS designer precursors

This is a straightforward approach: based upon scientific advice a large list with potential designer precursors is added to the Regulation.

The substances are identified substance-by-substance by including their name.

An example from the Netherlands would be the following:

Precursor voor	Naam	Andere benaming
BMK		
BMK	propyl 2-fenyl-3-oxobutanoaat	PAPA
BMK	isopropyl 2- fenyl-3-oxobutanoaat	iPAPA
BMK	butyl fenyl-3-oxobutanoaat	BAPA
BMK	isobutyl fenyl-3-oxobutanoaat	iBAPA
BMK	tert-butyl fenyl-3-oxobutanoaat	tBAPA
BMK	azijnzuur-2-fenyl-3-oxobutaanzuuranhydride	n.n.b.
BMK	ethyl 3-fenyloxiraan-2-methyl-2-carboxylaat	ethylester van 'BMK-glycidezuur'
BMK	propyl 3-fenyloxiraan-2-methyl-2-carboxylaat	propylester van 'BMK-glycidezuur'
BMK	isopropyl 3-fenyloxiraan-2-methyl-2-carboxylaat	isopropylester van 'BMK-glycidezuur'
BMK	butyl 3-fenyloxiraan-2-methyl-2-carboxylaat	butylester van 'BMK-glycidezuur'

[30] Bearing in mind that this will continue to be a moving target.

Precursor voor	Naam	Andere benaming
BMK	isobutyl 3-fenyloxiraan-2-methyl-2-carboxylaat	isobutylester van 'BMK-glycidezuur'
BMK	tert-butyl 3-fenyloxiraan-2-methyl-2-carboxylaat	tert-butylester van 'BMK-glycidezuur'
BMK	3-ethylpentaan-3-yl 3-fenyloxiraan-2-methyl-2-carboxylaat	n.n.b.
BMK	2-benzyl-2-methyl-1,3-dioxolaan	4362-18-9
BMK	2-benzyl-2,4-dimethyl-1,3-dioxolaan	6282-34-4
BMK	2-benzyl-2,4,5-trimethyl-1,3-dioxolaan	n.n.b.
BMK	2-benzyl-2,4,4,5,5-pentamethyl-1,3-dioxolaan	n.n.b.
BMK	(2,2-dimethoxypropyl)benzeen	26163-01-9
BMK	(2,2-diethoxypropyl)benzeen	71094-32-1
BMK	1-fenylprop-1-en-2-ylformiaat	n.n.b.
BMK	1-fenylprop-1-een-2-ylacetaat	24175-87-9
BMK	4-fenyl-3-oxobutaanzuur	25832-09-1
BMK	N-acetyl-2-fenyl-3-oxobutaanamide	122664-30-6
BMK	azijnzuurfenylazijnzuuranhydride	n.n.b.
BMK	natrium 1-fenyl-2-hydroxy-2-propaan-2-sulfonaat	BMK bisulfiet adduct
BMK	diethyl (fenylacetyl)propaanedioaat	20320-59-6, DEPAPD
Amfetamine		
amfetamine	(9H-fluoreen-9-yl)methyl (1-fenylpropaan-2-yl)carbamaat	N-FMOC-amfetamine
amfetamine	tert-butyl (1-fenylpropaan-2-yl)carbamaat	N-tBOC-amfetamine
amfetamine	N-(1-fenylpropaan-2-yl)acetamide	N-acetylamfetamine, 14383-60-9
amfetamine	trifluormethyl (1-fenylpropaan-2-yl)carbamaat	n.n.b.
amfetamine	2,2,2-trifluor-N-(1-fenylpropaan-2-yl)acetamide	N-TFA-amfetamine, 62840-99-7
amfetamine	N-(1-fenylpropaan-2-yl)formamide	N-formylamfetamine, 15302-18-8
amfetamine	prop-2-een-1-yl (1-fenylpropaan-2-yl)carbamaat	N-Alloc-amfetamine
amfetamine	N-(1-fenylpropaan-2-yl)benzamide	N-Bz-amfetamine, N-benzoylamfetamine, 1795-95-5
amfetamine	benzyl (1-fenylpropaan-2-yl)carbamaat	N-Cbz-amfetamine
amfetamine	4-methyl-N-(1-fenylpropaan-2-yl)benzeen-1-sulfonamide	N-Tosyl-amfetamine, 34542-12-6
amfetamine	4-nitro-N-(1-fenylpropaan-2-yl)benzeen-1-sulfonamide	n.n.b.
amfetamine	4-broom-N-(1-fenylpropaan-2-yl)benzeen-1-sulfonamide	n.n.b.
amfetamine	N-(trifenylmethyl)-1-fenylpropaan-2-amine	n.n.b.
amfetamine	1-fenyl-N-(1-fenylpropaan-2-yl)methanimine	2980-02-1
amfetamine	2-(1-fenylpropaan-2-yl)-1H-iso-indol-1,3(2H)-dion	n.n.b.
amfetamine	2-acetamido-1-fenylpropylacetaat	n.n.b.
amfetamine	1-fenyl-2-formamidopropylformiaat	n.n.b.
amfetamine	dimethyl N-(1-fenylpropaan-2-yl)fosforamidaat	n.n.b.
amfetamine	diethyl N-(1-fenylpropaan-2-yl)fosforamidaat	n.n.b.
amfetamine	difenyl N-(1-fenylpropaan-2-yl)fosforamidaat	7761-65-1
amfetamine	N-(1-fenylpropaan-2-ylideen)hydroxylamine	fenylaceton-oxime, 13213-36-0
amfetamine	N-methoxy-1-fenylpropaan-2-imine	n.n.b.
amfetamine	2-methyl-N-(1-fenylpropaan-2-yl)propaan-2-sulfinamide	n.n.b.
amfetamine	1-[2-(fenylsulfanyl)fenyl]propaan-2-amine	127876-67-9
amfetamine	1-chloor-1-fenylpropaan-2-amine	107912-52-7
amfetamine	(2-nitro-1-nitrosopropyl)benzeen	n.n.b.
amfetamine	1-azido-3-fenyl-2-methylpropaan-1-on	n.n.b.
amfetamine	(2-azidopropyl)benzeen	823189-05-5
amfetamine	[(1-fenylpropaan-2-yl)imino]methaansulfonzuur	n.n.b.

Precursor voor	Naam	Andere benaming
amfetamine	3-fenyl-2-methylpropaanamide	7499-19-6
amfetamine	4,4,5,5-tetramethyl-N-(1-fenylpropaan-2-yl)-1,3-dioxolaan-2-imine	n.n.b.
amfetamine	5-fenyl-4-methyl-1,3-oxazolidin-2-on	125133-96-2
amfetamine	(2-isocyanatopropyl)benzeen	22084-42-0
(meth)amfetamine	(2-chloorpropyl)benzeen	10304-81-1
(meth)amfetamine	(2-broompropyl)benzeen	130232-93-8
(meth)amfetamine	(2-joodpropyl)benzeen	29527-87-5
Metamfetamine		
metamfetamine	(9H-fluoreen-9-yl)methyl methyl (1-fenylpropaan-2-yl)carbamaat	N-FMOC-metamfetamine
metamfetamine	N-methyl-N-(1-fenylpropaan-2-yl)benzamide	N-Bz-metamfetamine, N-benzoyl-metamfetamine
metamfetamine	tert-butyl methyl(1-fenylpropaan-2-yl)carbamaat	N-tBOC-metamfetamine
metamfetamine	N-methyl-N-(1-fenylpropaan-2-yl)acetamide	N-acetylmetamfetamine, 27765-80-6
metamfetamine	trifluormethyl methyl(1-fenylpropaan-2-yl)carbamaat	n.n.b.
metamfetamine	2,2,2-trifluor-N-methyl-N-(1-fenylpropan-2-yl)acetamide	N-TFA-metamfetamine
metamfetamine	N-methyl-N-(1-fenylpropaan-2-yl)formamide	N-formylmetamfetamine, 42932-20-7
metamfetamine	methyl methyl(1-fenylpropaan-2-yl)carbamaat	N-Moc-metamfetamine
metamfetamine	prop-2-een-1-yl methyl(1-fenylpropaan-2-yl)carbamaat	N-Alloc-metamfetamine
metamfetamine	N-methyl-N-(trifenylmethyl)-1-fenylpropaan-2-amine	n.n.b.
metamfetamine	benzyl methyl(1-fenylpropaan-2-yl)carbamaat	N-Cbz-metamfetamine
metamfetamine	N,4-dimethyl-N-(1-fenylpropaan-2-yl)benzeen-1-sulfonamide	N-Tosyl-metamfetamine, 74810-23-4
metamfetamine	N-methyl-4-nitro-N-(1-fenylpropaan-2-yl)benzeen-1-sulfonamide	N-Ns-metamfetamine
metamfetamine	4-broom-N-methyl-N-(1-fenylpropaan-2-yl)benzeen-1-sulfonamide	N-Bs-metamfetamine
PMK	(2H-1,3-benzodioxol-5-yl)acetonitril	4439-02-5
De 3,4-methyleendioxy-gesubstitueerde derivaten van de hierboven opgesomde BMK precursoren, waaronder		
PMK	ethyl 2-(2H-1,3-benzodioxol-5-yl)-3-oxobutanoaat	n.n.b.
PMK	propyl 2-(2H-1,3-benzodioxol-5-yl)-3-oxobutanoaat	n.n.b.
PMK	isopropyl 2-(2H-1,3-benzodioxol-5-yl)-3-oxobutanoaat	n.n.b.
PMK	butyl 2-(2H-1,3-benzodioxol-5-yl)-3-oxobutanoaat	n.n.b.
PMK	isobutyl 2-(2H-1,3-benzodioxol-5-yl)-3-oxobutanoaat	n.n.b.
PMK	tert-butyl 2-(2H-1,3-benzodioxol-5-yl)-3-oxobutanoaat	n.n.b.
PMK	propyl 3-(2H-1,3-benzodioxol-5-yl)-2-methyloxiraan-2-carboxylaat	propylester van 'PMK-glycidezuur'
PMK	isopropyl 3-(2H-1,3-benzodioxol-5-yl)-2-methyloxiraan-2-carboxylaat	isopropylester van 'PMK-glycidezuur'
PMK	butyl 3-(2H-1,3-benzodioxol-5-yl)-2-methyloxiraan-2-carboxylaat	butylester van 'PMK-glycidezuur'
PMK	isobutyl 3-(2H-1,3-benzodioxol-5-yl)-2-methyloxiraan-2-carboxylaat	isobutylester van 'PMK-glycidezuur'
PMK	tert-butyl 3-(2H-1,3-benzodioxol-5-yl)-2-methyloxiraan-2-carboxylaat	tert-butylester van 'PMK-glycidezuur'
PMK	5-[(2-methyl-1,3-dioxolaan-2-yl)methyl]-2H-1,3-benzodioxol	n.n.b.
PMK	5-[(2,4-dimethyl-1,3-dioxolaan-2-yl)methyl]-2H-1,3-benzodioxol	n.n.b.
PMK	5-[(2,4,5-trimethyl-1,3-dioxolaan-2-yl)methyl]-2H-1,3-benzodioxol	n.n.b.
PMK	5-[(2,4,4,5,5-pentamethyl-1,3-dioxolaan-2-yl)methyl]-2H-1,3-benzodioxol	n.n.b.
PMK	5-(2,2-dimethoxypropyl)-2H-1,3-benzodioxol	90176-89-9
PMK	5-(2,2-diethoxypropyl)-2H-1,3-benzodioxol	n.n.b.

Precursor voor	Naam	Andere benaming
PMK	natrium 3-(2H-1,3-benzodioxol-5-yl)-2-hydroxypropaan-2-sulfonaat	PMK bisulfiet adduct
De 3,4-methyleendioxy-gesubstitueerde derivaten van de hierboven opgesomde amfetamine- en metamfetamineprecursoren, waaronder		
MDMA	tert-butyl [1-(1,3-benzodioxol-5-yl)propaan-2-yl]methylcarbamaat	N-tBOC-MDMA, 1228259-70-8
MDMA	N-[1-(1,3-benzodioxol-5-yl)propaan-2-yl]-N-methylacetamide	N-acetyl-MDMA
MDMA	trifluormethyl [1-(1,3-benzodioxol-5-yl)propaan-2-yl]methylcarbamaat	n.n.b.
MDMA	N-[1-(2H-1,3-benzodioxol-5-yl)propaan-2-yl]-2,2,2-trifluor-N-methylaceetamide	N-TFA-MDMA, 158097-59-7
MDMA	N-[1-(1,3-benzodioxol-5-yl)propaan-2-yl]-N-methylformamide	N-formyl-MDMA,154148-22-8
MDMA	methyl [1-(2H-1,3-benzodioxol-5-yl)propaan-2-yl]methylcarbamaat	N-Moc-MDMA
MDMA	prop-2-een-1-yl [1-(2H-1,3-benzodioxol-5-yl)propaan-2-yl]methylcarbamaat	N-Alloc-MDMA
MDMA	N-[1-(2H-1,3-benzodioxol-5-yl)propaan-2-yl]-N-methylbenzamide	N-Bz-MDMA, N-benzoyl-MDMA
MDMA	benzyl [1-(2H-1,3-benzodioxol-5-yl)propaan-2-yl]methylcarbamaat	N-Cbz-MDMA
MDMA	N-[1-(2H-1,3-benzodioxol-5-yl)propaan-2-yl]-N,4-dimethylbenzeen-1-sulfonamide	N-Tosyl-MDMA
MDMA	N-[1-(2H-1,3-benzodioxol-5-yl)propaan-2-yl]-N-methyl-4-nitrobenzeen-1-sulfonamide	N-Ns-MDMA
MDMA	N-[1-(2H-1,3-benzodioxol-5-yl)propaan-2-yl]-4-broom-N-methylbenzeen-1-sulfonamide	N-Bs-MDMA
Andere stoffen		
4-fluoramfetamine	1-(4-fluorfenyl)propaan-2-on	459-03-0
4-MMC	(mefedron) 2-broom-1-(4-methylfenyl)propaan-1-on	1451-82-7
2C-H	1,4-dimethoxy-2-(2-nitroethenyl)benzeen	108536-18-1

2. <u>Describing the possible ATS designer precursor as families of derivatives or related chemicals</u>

Designer precursors are chemically tweaked substances. One or a group of atoms are replaced to create a brand-new substance. Such substances are also known as derivatives (substance y derives from substance x). It is therefore possible to describe designer precursors as a family of derivatives of a base molecule. Applying this technique to the substances listed above, an additional 56 substances would be included in the scope of scheduling.

Base molecule	**Designer precursors are following derivatives of the base molecule**	***Explanatory note to the proposed scheduling***
1-(2H-1,3-Benzodioxol-5-yl)propan-2-one or 1-phenyl-propan-2-one	Acetals (aldehydes/ketones + alcohol) with linear or branched alkyl chain up to 6 carbon atoms and the sulfo substituted variants	*This 'generic' derivative scheduling will include 22 substances that are not included in the above list.*
1-phenyl-prop-1-en-2-ol or 2-(2H-1,3-benzodioxol-5-yl)-3-oxobutanoic acid or 3-oxo-2-phenylbutanoic acid	Esters (carboxylic acid + alcohol) with carboxilic up to 6 carbon atoms	*This 'generic' derivative scheduling will include 14 substances that are not included in the above list.*
2-methyl-3-phenyl-2-oxiranecarboxylic acid or 3-(2H-1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylic acid or	Esters with carboxylic up to 7 carbon atoms	*This 'generic' derivative scheduling will include 24 substances that are not included in the above list.*
1-phenylpropan-2-amine or N-methyl-1-phenylpropan-2-amine or N-methyl-1-(3,4-methylenedioxyphenyl)propan-2-amine	Sulfonamides (sulfonic acid + amine) with 4-nitro-, 4-bromo-, 4-methyl substituted benzene-1-sulfonic acid.	*This 'generic' derivative scheduling will include 3 substances that are not included in the above list.*
(1-phenylpropan-2-yl)carbamic acid or Methyl (1-phenylpropan-2-yl)carbamic acid or N-methyl-(1-phenylpropan-2-yl)carbamic acid or N-methyl-(3,4-methylenedioxyphenyl)propan-2-carbamic acid	Carbamates (carbamic acid + alcohol)	*It is not possible to delimit the scope based on the number of carbon atoms because there is no such correlation between the 16 carbamates listed above. On the other hand, carbamates are artificial substances having no known legal use. The risk of scheduling substance with legal use is extremely low.*
1-phenylpropan-2-amine or N-methyl-1-phenylpropan-2-amine or N-methyl-1-(3,4-methylenedioxyphenyl)propan-2-amine	Alkyls, amides, azide, chloro, fluoro, bromo or iodo substituted variant, hydroxylamine (only 1 variant possible), imides with carboxylate substitution with both up to 2 carbon atoms, imines with toluene, methoxy, methansulfonic acid and substituted dioxolane substitutions,	*It is not possible to delimit the scope based on the number of carbon atoms. This generic derivatives scheduling would have a much wider scope than the list above and would inevitably include substances with legal use.*

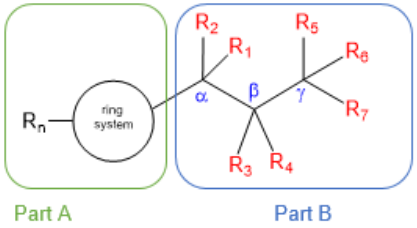
For some type of derivatives, such as carbamates, alkyls, amides, it is difficult to delineate the scope by number of carbon atoms. The variants of these families of derivatives do not vary based on incremental number of carbon atoms. Several parameters may vary while maintaining the characteristics to easily 'eject' the precursor molecule. However, the family of carbamate-precursors have no known legal use at present. The generic derivative scheduling of these families would result in a very wide scope probably including substances with legitimate use.

Derivative scheduling as described here would not cover 18 substances from the above list. Nomenclatures would need to be spelled out sufficiently clearly to provide legal certainty.

3. Describing the possible ATS designer precursor based on a chemical formula

Substances can be identified by their chemical name, common name, registration number, formula or structure. As explained above, designer precursors are derived from a core molecule. Consequently, they all have a similar core structure. It is therefore possible to describe designer precursors as a core structure with one or more variables. For example, the generic structure for the above list of 110 designer precursors is:

Substances and their salts fulfilling following equations are designer precursors:



With

Part A		**Part B**								**Explanatory note to the proposed scheduling)**
Rn*	**Ring system**	**R1**	**R2**	**R3**	**R4**	**R5**	**R6**	**R7**	***With Ra***	
H	Phenyl, or Methylene- dioxyphenyl	H	H	H	-NH(CO)O*Ra* -NC(CO)O*Ra*	H	H	H	9H-fluoren-9-yl-methyl, or Tert-butyl, or Trifluoromethyl, or Prop-2-en-1-yl, or Benzyl (Cbz), or Methyl	This row schedules 24 substances of which 8 are not in the above list.
H	Phenyl, or Methylene- dioxyphenyl	-(CO)O*Ra*	H	=O	-	H	H	H	H, or any linear, branched alkyl chain up to 6 carbon atoms	This row schedules 28 substances of which 12 are not in the above list.
H	Phenyl, or Methylene- dioxyphenyl	-O- on R3	H	-	-(CO)O*Ra*	H	H	H	H, or any linear, branched alkyl chain up to 7 carbon atoms	This row schedules 46 substances of which 34 are not in the above list. For pentyl you need up to 7 carbon atoms which multiply considerably the number of possible combinations.
H	Phenyl or Methylene- dioxyphenyl	H	H	H	-NH(CO)*Ra* -NC(CO)*Ra*	H	H	H	H, or any linear alkyl chain up to 2 carbon atoms, or Trifluoromethyl, or Phenyl	This row schedules 20 substances of which 8 are not in the above list.
H	Phenyl	-ORa	H	H	-NHRa	H	H	H	Any linear alkanoyl up to 2 carbon atoms	This row schedules 2 substances, same as in the above list.
H	Phenyl Methylene- dioxyphenyl	H	H	-	-O*Ra*- on R3	H	H	H	any linear or branched alkyl chain up to 6 carbon atoms	This row schedules 14 substances of which 8 are not in the above list.

Part A		**Part B**								**Explanatory note to the proposed scheduling)**
Rn*	**Ring system**	**R1**	**R2**	**R3**	**R4**	**R5**	**R6**	**R7**	***With Ra***	
H	Phenyl, or Methylene- dioxyphenyl	H	H	-O*Ra*	-O*Ra*	H	H	H	any linear alkyl chain up to 2 carbon atoms	This row schedules 4 substances, same as in the above list
H	Phenyl, or Methylene- dioxyphenyl	H	H	-	-NH*Ra*, or -NCH3*Ra*	H	H	H	4-alkylbenzene-1-sulfonyl, with alkyl any linear alkyl chain up to 1 carbon atoms, or 4-nitrobenzene-1-sulfonyl, or 4-bromobenzene-1-sulfonyl	This row schedules 12 substances of which 3 are not in the above list.
H	Phenyl	H	H	H	N*Ra*	H	H	H	-OH, or benzyl, or Methoxyl, or Sulfomethyl, or 4,4,5,5-tetramethyl-dioxolanyl	This row schedules 5 substances, same as in the above list.
H	Phenyl	H	H		*Ra*	H	H	H	-Br, or -Cl, or -I, or -(CO)NH2, or -N=N^{+}=N^{-}, or -(CO) N=N^{+}=N^{-}, or -N=C=O	This row schedules 7 substances, same as in the above list
F	phenyl	H	H	H	=O	H	H	H		This row schedules 1 substance, same as in the above list.
H	Phenyl	*Ra*	H	H	NH2	H	H	H	-Br, or -Cl, or -I	This row schedules 3 substances, same as in the above list.
-S-benzyl	Phenyl	H	H	H	NH2	H	H	H		This row schedules 1 substance, same as in the above list.
H	Phenyl	H	H	H	=O	H	H	-(CO)OH		This row schedules 1 substance, same as in the above list.
H	Phenyl	-N=O	H	H	NO2	H	H	H		This row schedules 1 substance, same as in the above list.
H	Phenyl	-O(CO)NH on R4	H	H	-	H	H	H		This row schedules 1 substances, same as in the above list.
H	Phenyl	H	H	H	NHP(=O)(O*Ra*)2	H	H	H	any linear aldehyde chain up to 2 carbon atoms, or phenyl	This row schedules 3 substances, same as in the above list.

Part A		**Part B**								**Explanatory note to the proposed scheduling)**
Rn*	**Ring system**	**R1**	**R2**	**R3**	**R4**	**R5**	**R6**	**R7**	***With Ra***	
H	Phenyl, or Methylene- dioxyphenyl	H	H	-OH	$-SO3^-$	H	H	H		This row schedules 2 substances, same as in the above list.
H	Phenyl	H	H	-	-NH*Ra*, or -NCH3*Ra*	H	H	H	triphenylmethyl	This row schedules 2 substances, same as in the above list.
H	Phenyl	-(CO)NH(CO)*Ra*	H	H	H=0	H	H	H	any linear alkyl chain up to 1 carbon atom	This row schedules 1 substance, same as in the above list.

Such chemical equation is unambiguous. Chemical substances have a chemical formula. They either fit the equation or not.

The above proposed ‘simplified’ chemical formula scheduling schedules 173 substances of which 73 are not included in the list described under 1. 6 substances included in the list above cannot be integrated in the formula scheduling. These substances have a structure that is very distinct from the other substances. Adding them in the format of a formula will make the scheduling disproportionately complex.

2. INTERNATIONAL DEVELOPMENTS AND THIRD COUNTRY LEGISLATION

In 2020, the conference room paper on "Options to address the proliferation of non-scheduled chemicals, including designer precursors"[1], the International Narcotics Control Board (INCB) proposed the following: (i) while keeping the substance-by-substance scheduling the **closely related substances could be scheduled together,** (ii) **increase the speed of the scheduling and assessment process**, and (iii) introducing a **category of scheduled substances with no known legitimate uses** within one of the existing tables for which the powers and obligations to seize and interdict are not linked to requirements to monitor (non-existent or severely limited) licit trade.

In March 2022, the Commission of Narcotic Drugs adopted 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" where in its operative paragraph 7 encouraged Member States, **when placing domestic controls on a substance to consider also taking domestic measures, on related chemicals that may readily be converted or substituted for that substance.**

Practical implementation of resolution 65/3 can be seen in countries such as Argentina, Canada, Mexico, USA and more recently China that introduced extended scheduling on drug precursors legislation.

Phenylacetic acid is a key precursor for amphetamine and methamphetamine production. While Argentina scheduled phenylacetic acid and all its salts and esters, Mexico on the other hand, decided to schedule in addition the phenylacetic acid its salts and its derivatives naming all derivatives individually.

USA has also included extended scheduling in its legislation and depending on the key precursor it extended the scope to different derivatives: For amphetamine type stimulants precursors such as APAAN (alpha-acetoacetonitrile) the scheduling includes also its salts, optical isomers, & salts of optical isomers. For fentanyl precursors such as 4-Anilinopiperidine the scheduling includes also: its amides, its carbamates, and its salts.

Canada lists the controlled substance and uses a very broad definition referring to its analogues and derivatives. This can be seen for both amphetamine type stimulants precursors such as BMK (1-Phenyl-2-propanone) and for fentanyl precursors such as norfentanyl. In some cases, the Canadian legislation lists individually some of the substances that are part of the analogues or derivatives of the controlled substance.

China introduced extended scheduling on 1st of September 2024 covering the esters of BMK glycidic acid and PMK glycidic acid. China went further than what was decided at the Commission of Narcotic Drugs in March 2024 that was to schedule seven esters of PMK Glycidic acid and 8 esters of BMK glycidic acid.

In advance of the March 2024 Commission on Narcotics Drugs that would decide the schedule of the seven esters of PMK glycidic acid and 8 esters of BMK glycidic acid, the EU proactively scheduled them in January 2024 ahead of the UN decision.

The March 2024 Commission of Narcotic drugs can be considered as a landmark. For the first time, the INCB recommended scheduling as a direct application on Resolution 65/3 and introduced proactive scheduling, resulting that some of the substances proposed for scheduling were never detected. This is an important change as for the first-time authorities are working on a proactive way instead of working only on a reactive way to the new modus operandi by criminals.

Please see table below with examples of extended scheduling in the countries mentioned above

Country	**Signatory of the 1988 UN Convention**		**Chemical substance**	**Derivatives**	**Legislation**
Argentina	Yes		Phenylacetic acid,	Its salts, and its esters	Decreto 593-2019
Mexico	Yes		Phenylacetic acid,	Salts and derivatives - the state officials, in collaboration with the chemical industry, developed a list naming all esters individually to avoid legal loopholes.	Ley Federal para el Control de Precursores Químicos, Productos Químicos Esenciales y Máquinas para Elaborar Cápsulas, Tabletas y/o Comprimidos (diputados.gob.mx)
Canada	Yes		N-Phenyl-4-piperidinamine	Analogues and derivatives of N-Phenyl-4-piperidinamine and its salts including: (1) 4-anilino-1-boc-piperidine (2) 4-fluoro anilino-1-boc-piperidine (3) N-(4-fluorophenyl)-4-piperidinamine (4) 4-bromo anilino-1-boc-piperidine	Regulations Amending the Narcotic Control Regulations and the Precursor Control Regulations Order Amending Schedule V to the Controlled Drugs and Substances Act
			4-Anilino-N-phenethylpiperidine (ANPP) (N-phenyl-1-(2-phenylethyl)piperidine-4-amine)	its derivatives and analogues and salts of derivatives and analogues	
			1-Phenyl-2-propanone (BMK)	1-Phenyl-2-propanone, its derivatives and analogues and salts of derivatives and analogues Including:	

				(1) methyl 2-methyl-3-phenyloxirane-2-carboxylate (BMK methyl glycidate) (2) 3-oxo-2-phenylbutanamide (α-phenylacetoacetamide-APAA)	
			Methylenedioxyphenyl-2-propanone	3,4-Methylenedioxyphenyl-2- propanone (1-(1,3-benzodioxole)-2-propanone), its derivatives and analogues and salts of derivatives and analogues Including: (1) methyl 3-(1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (MMDMG)	
			Norfentanyl (N-phenyl-N-piperidin- 4-ylpropanamide)	its salts, derivatives and analogues and salts of derivatives and analogues	
			Benzylfentanyl (N-(1-benzylpiperidin-4-yl)-N-phenylpropionamide)	its salts, derivatives and analogues and salts of derivatives and analogues	
China	Yes		BMK glycidic acid	Its esters	https://m.mps.gov.cn/n6935718/n6936579/c9690580/content.html
			PMK glycidic acid	Its esters	
			Ephedrine	Its derivatives	
USA	YES		4-ANILINOPIPERIDINE (N-phenylpiperidin-4-amine; N phenyl-4- piperidinamine; 4–AP)	The scheduling includes also: its amides, its carbamates, and its salts.	Chemical Diversion and Trafficking Act (CDTA) List of monitored drug precursors Other source to find the list of monitored drug precursors USC page on drug precursors
			APAA (Alpha-phenylacetoacetamide)	The scheduling includes also: its optical isomers.	
			APAAN (Alpha-acetoacetonitrile)	The scheduling includes also: salts, optical isomers, & salts of optical isomer.	
			EPHEDRINE	The scheduling includes also: salts, optical isomers, & salts of optical isomers.	
			PHENYLPROPANOLAMINE	The scheduling includes also: salts, optical isomers, & salts of optical isomers.	

[1] *Options to address the proliferation of non-scheduled chemicals, including designer precursors – contribution to a wider policy dialogue*, INCB, 21 February 2020

[3]

ANNEX 8: DIGITALIZATION OF EU DRUG PRECURSORS FORMALITIES AND PROCEDURES.

I. INTERNAL TRADE:

Baseline cost provided by Commission services:

Expected /estimated Volume/traffic/use for the function 3

- Currently there are around 4,000 operators.
- It is assumed that the final number of operators will never exceed 50,000 operators.
- It is expected that the operators will connect to the future system to fill in a form once a year. Therefore, the user will not connect daily but will connect between 2 and 10 times a year.
- The traffic can be estimated as the current one existing (around 100 users) and multiply it by 500 (if 50,000 operators were expected).

Development for Options 2 and 3 (e-licenses and registrations, verification):

While the digital solution goes further than function 3 contained in the baseline, there are still some common aspects that a digital solution for the internal market would need to include. This is notably a database with a role for economic operators, a mechanism to grant access securely and an infrastructure to support many users.

A simple workflow would be set up in which the user applies for a license (registration), and afterwards the authority approves or reject the application, a confirmation e-mail is then sent to the concerned operator. After approval a certificate is generated. This EU license (registration) certificate will contain a QR code with a digital signature to protect it against falsification. When checked, the QR code will be scanned, and the signature verified. The Commission has EU sign tools that can be used for such purposes.

High-level budgetary estimates for e-licensing a verification

The challenge is to ensure that the system can accept thousands of users.

There are some economies of scale to be had from implementing both function 3 and the e-license service, since there are many common grounds/aspects: The Role management, the operators' management and the user access grant, the license/registration recorded information.

Further costs to consider are hosting costs, the evolutive / corrective maintenance (e.g. the first year: EUR 100 000 for after care, the second year EUR 50 000, the third year EUR 25 000, the following years EUR 10 000). Support costs which are at about EUR 25 000/year for 250-500 incident tickets a year.

Some additional budget may be required if the service is required seven days a week, 24h/24.

II. EXTERNAL TRADE

1. BACKGROUND

This analysis supports the Impact Assessment Study on the Revision of the EU Drug Precursors (DP) Regulations. A key problem driver identified during this study pertains to complex implementation rules and procedures, including very limited and partially digitalised procedures and a lack of integration into the customs environment in line with the EU Single Window Environment for Customs (SWE-C) Digital Framework Policy and its legal framework.[31] One specific policy objective is to streamline, modernise, and reduce the burden of the EU control system for legal trade. This involves digitalising paper-based procedures related to the DP policy to be compliant with EU digital strategy and modify provisions that create unnecessary burdens. This approach is compliant with international agreements and supports the EU policy on illicit drugs, while minimising disruptions to legal trade in accordance with the EU internal market and common commercial policy.

The analysis focuses on supporting the core aspects of policy options 2[32] and 3[33] from the list of policy options initially formulated in the Inception Report. These options entail substantial digitalisation of the formalities using different methods for deregulation, facilitation, and simplification of the procedural rules, proposing measures such as customs simplification through connecting the EU database to the customs environment by implementation of EU SWE-C legal framework and streamlining reporting obligations. Conversely, option 3 advocates for an additional simplification for AEOs and possibility to verify electronically the permissions issued for the substances of new Category 2.

The scope of this analysis of digitalisation options is limited to assessing the approach and impacts of digitalising current paper flows, assuming that permissions[34] would be required for licit activity in the DP domain and cross-border trade. The primary objective of this analysis is to evaluate, compare and choose the preferred digitalisation option to facilitate a transformation from the existing paper-based process and minimise the administrative burden for economic operators and competent authorities. The analysis is technology agnostic and not meant to be an assessment of the possible technologic capabilities available for digitalisation.

In considering the optimal option for digitalisation of the EU DP domain, an e-licensing platform is integral for the management and issuance of permissions. It is important to note that the preferred digitalisation option must comply with EU Digital Strategy, the long-term EU

---

[31] EU SWE-C Digital Framework Policy is based on Regulation (EU) 2022/2399 of the European Parliament and of the Council of 23 November 2022 establishing the European Union Single Window Environment for Customs and amending Regulation (EU) No 952/2013.

32 Based on the Interim Report policy option 2 is initially formulated as a set of regulatory changes aimed at tackling illicit trade and facilitating legal trade, with particular emphasis on simplification, modernisation and burden reduction. The concrete measures proposed include a comprehensive digitalisation of the procedures accompanied by a streamlining of the legal text and of non-critical obligations., which would reduce the administrative burden by changing the procedural rules for monitoring international trade to be aligned to those at the UN level in combination with the digital transition.

[33] Policy option 3 addresses both objectives of the intervention, but compared to the previous one is more comprehensive as regards fight against illegal trade, i.e. with a stronger ban on designer precursors and a more extensive 'catch-all clause' for non-scheduled substances. Regarding Option #2, digitalisation and simplification are also envisaged, but some burden-reduction changes envisaged under Option #2 do not apply here as the emphasis is on maintaining control.

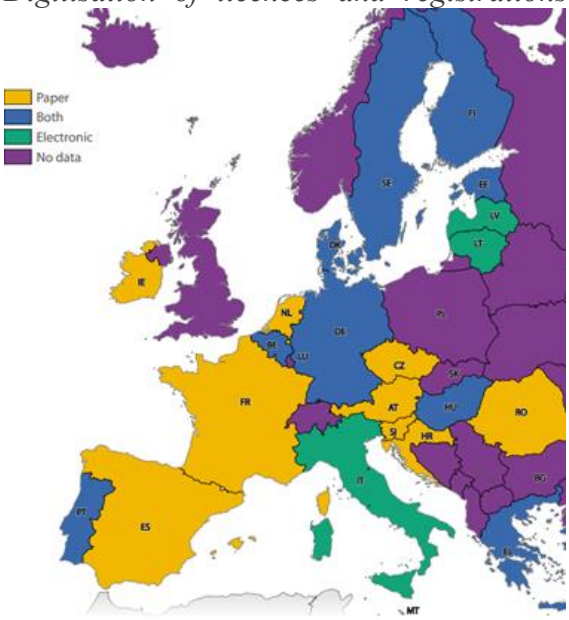
34 Permissions in the context of this analysis refers to the registration/self-registration, licensing and authorisations required by economic operators.

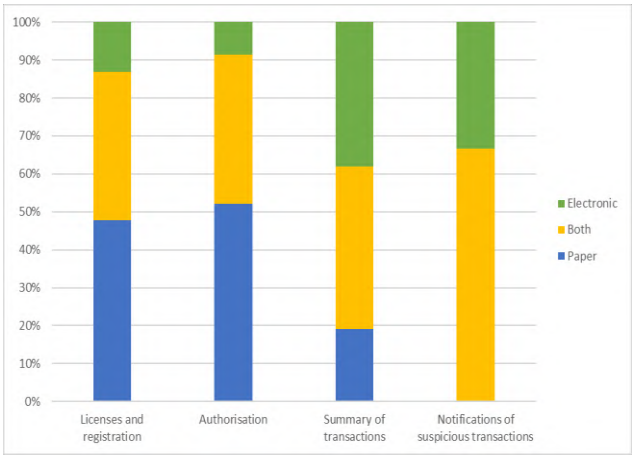
strategy of an EU Customs Data Hub with the Single Window as its backbone and international DP policy, which are reliant on the special permissions required for the cross-border movement of listed drug precursors. This implies that trade involving these goods should be authorised by competent authorities through cross-border permissions, in accordance with the UN Convention 1988[35]. Article 12, paragraph 8(b)(iii) of the UN Convention 1988 mandates competent authorities to implement appropriate measures to monitor the manufacture and distribution of drug precursors carried out in their territory, and may require licensees to obtain permits for conducting their operations.

[35] United Nations Convention Against Illicit Traffic in Narcotics Drugs and Psychotropic Substances, 1988 (UN Convention 1988).

***Figure 1* Level of digitisation in EU Member States**

Digitisation of licences and registrations in the EU Digitisation of various formalities





Source: EU Survey 'Questionnaire on current drug precursors formalities in preparation for digitalisation', run in Q4 2022. 23 Member States responded to the Licenses and registration and authorisation questions, 21 Member States responded to the summary of transactions and notifications of suspicious transactions.

2. DESCRIPTION OF OPTIONS

Three options have been identified and examined in collaboration with the experts of the Project Group for the digitalisation of the EU Drug Precursors (DP) system. The three options are:

a) Decentralised: An option of decentralised system is soft law policy scenario[36] or baseline scenario from digitalisation point of view, which would involve multiple national systems responsible for managing different aspects of the drug precursors e-licensing platform. These national systems would operate independently, with no possibility of implementing the EU SWE-C Digital Framework Policy[37] to streamline the electronic exchange of documents and information with customs. Member States will only be able to integrate and automate customs controls within their own national customs IT systems, and will continue to use a user interface for collaboration with third countries via the Pre-Export Notification (PEN) Online system. Consequently, IT solutions based on common requirements for the management and issuance of permissions will be developed and deployed by Member States themselves.

b) Centralised: A centralised system would consist of a single system responsible for managing all applications in the drug precursors platform. With a fully centralised EU-

[36] Option #1 is soft law approach, which encompasses a series of measures that do not require a revision of the EU Regulations themselves. This option foresees developing the guidance for MS who develop their own digital solutions.

[37] EU SWE-C Digital Framework Policy is based on Regulation (EU) 2022/2399 of the European Parliament and of the Council of 23 November 2022 establishing the European Union Single Window Environment for Customs and amending Regulation (EU) No 952/2013.

wide system, there would be a single user interface for information exchange between economic operators and Member States' competent authorities. This interface will support the necessary permissions required by economic operators. This solution would be consistent with the EU SWE-C Digital Framework Policy and allow automated checks by Member States' customs. Additionally, a functionality could be developed and deployed to facilitate effective integration with the UN system.

c) **Hybrid**: A hybrid system aims to accommodate Member States who have customised IT solutions for end-to-end issuance through a system-to-system interface that is connected to the EU-wide central system. This connection would allow the necessary replication of data from national to central database. Member States who do not have their own IT solutions will be able to use the central system. Under a hybrid system there will be a user interface within the central system available for Member States not having a national solution in place, available to its national competent authorities and economic operators. ´

Both centralised and hybrid approaches for digitalisation would address the measures of digitalisation and rationalisation of procedures under the policy options 2 and 3. The differences of the central and hybrid approaches are reflected in the comparative analysis, in particular the analysis regarding the criteria of effectiveness, coherence and proportionality.

3. ANALYSIS OF OPTIONS

In line with the broader Impact Assessment Study related to the revision of the EU DP framework, this analysis is performed to advance the digital transformation of the EU DP domain. The objective of the analysis is to identify the most preferred option for digitalisation based on the policy options. This analysis is performed through a collaboration effort within the project team together with Project Group experts. It will undergo further evaluation based on the outcome of the study, with a specific focus on the cost-benefits analysis and potential rewards expected from digitalisation to reduce the administrative burden, improve cost-efficiency, and ensure effective enforcement of regulatory requirements.

The ensuing sub-sections provide a summary of the comparative analysis of the three options, based on each of the pre-defined criteria.

3.1. EFFECTIVENESS

This criterion evaluates the extent to which the digitalisation of the option will achieve the business requirements of the EU DP domain. Factors considered under this criterion include: improvements in the enforcement of regulatory requirements; the potential to facilitate licit trade by reducing the administrative burden for competent authorities and economic operators (EOs); and the impact on international cooperation.

a) **Decentralised:** A decentralised system will give flexibility to Member States to operate independently. To reduce the administrative burden, Form D can be incorporated into national systems to enable the capture of EO data for reporting, but submission of consolidated data of Member States to COM would still be a manual process. The absence

of a central database raises the concern about cross-border validation between up to 27 different national systems. Possible difficulties are foreseen in streamlining processes with customs if national IT systems are not interconnected. There is no possibility to ensure implementation of the G2G schema of EU SWE-C Digital Framework Policy, which allows proper monitoring and control of the quantities of goods imported or exported at the EU level. It will thus maintain high risks of fraud and gaps in the enforcement of DP requirements. This option also creates a risk of the current paper-based system persisting for certain customs controls, maintaining an administrative burden on customs authorities and EOs involved in cross-border trade - customs authorities at points of exit would still require EOs to present a paper-based document if permissions were issued by other Member States. Member States are accountable for complying with international reporting requirements. In the case of 27 national solutions, streamlining the process by building a system-to system interface with the PEN Online system would require very close collaboration between Member States to define common requirements and ensure consistency across national systems. Possible differences in the technology that is accessible to Member States is a risk that might have to be addressed in the development of the interface with the PEN Online system. Therefore, it would be very challenging to avoid duplication and reduce the administrative burden. Under the decentralised option each Member State would retain responsibility to send Pre-Export Notifications via the PEN Online system[38] to third countries' competent authorities. There is a very low likelihood that the decentralised approach would be more effective than the current baseline paper-based approach.

b) **Centralised:** Under a fully centralised system, EOs and competent authorities will have the capability to use a unified platform. This system will feature harmonised functionalities for all Member States, providing a streamlined and consistent approach. EOs will benefit from direct access to the front-end solution, enabling them to submit applications directly in the system. Implementation of a centralised option will enhance and streamline information-sharing between customs and partner competent authorities by enabling them to automatically exchange and verify the information that is required by the EU SWE-C Digital Framework Policy. The integration of synchronised online communication with Customs IT systems and the utilisation of EORI numbers for quantity management enhance the efficiency of the centralised option. The system will support a multi-lingual operability with 23 languages. The harmonised interface and a single data repository will reduce the administrative burden, especially for multinational companies. Furthermore, this option will facilitate the collection of information by competent authorities for regulatory enforcement to potentially reduce this administrative burden too. With a centralised system, competent authorities would also be relieved from the administrative burden of having to develop a national system. The central system could facilitate peer-to-peer verification for intra-EU and extra-EU trade, however, competent authorities and EOs would have to be trained on usage of the system. Form D can be incorporated into the

[38] The Pre-Export Notification (PEN) Online System launched in 2005 by INCB enables easy on-line exchange of information between competent national authorities on planned exports of precursor chemicals, United Nations Office on Drugs and Crime, 2024, https://www.unodc.org/unodc/en/global-it-products/pen.html.

central system to facilitate a streamlined process starting from the collection and consolidation of information, subsequently making such data available in the central database, up until reporting to the International Narcotics Control Board (INCB). The full centralisation option advocates for a single gateway for communication with third countries to ensure coherence with the UN Convention. The design would incorporate functionalities that guide compliance with international initiatives, such as facilitating the sending of pre-export notifications by leveraging the PEN Online system for efficient communication of notifications. There is a very high likelihood that the centralised approach would be more effective than the current baseline paper-based approach.

c) **Hybrid:** The hybrid option provides a flexible approach to accommodate the preference of Member States that wish to create their own national solution or maintain the existing one. For those Member States who opt to create their own national solution, data will have to be replicated to the central database. This will allow a streamlined approach within the customs environment. Developing national solutions require harmonisation of data elements and compliance with future legislative requirements for national solutions. For Member States without a dedicated national system, EOs will be able to use the graphic user interface (GUI) of the EU-wide solution. Form D can be incorporated into the system to capture the EO data for reporting and facilitate a similar end-to-end process from collection of information up until reporting to the INCB, as mentioned above under the centralised option.

3.2. COHERENCE

This criterion assesses whether the option is aligned with international policies and standards, including the EU policy related to digitalisation of government services and interoperability, EU customs policy, as well as international initiatives such as the exchange of information on pre-export notification with third countries via the IT solution developed by the INCB in line with the UN Convention.

a) **Decentralised:** The decentralised option does not support the quantity management objectives of the EU SWE-C Digital Framework Policy, nor is it aligned with the long-term customs policy related to the establishment of the EU Customs Data Hub. It also does not improve information-sharing between customs and partner competent authorities across Member States. It fails to fully implement the EU policy related to digitalisation of government services and interoperability. In order to be aligned with international reporting obligations Member States would have to send Pre-Export Notifications via the PEN Online system manually.

b) **Centralised:** Overall, this option is aligned with the EU digital strategy to increase the efficiency of public services by reducing the administrative and improving the quality of communication with EOs. The centralised solution would be in adherence to the EU SWE-C Digital Framework Policy and in line with the long-term strategy on the establishment of the EU Customs Data Hub. Moreover, it would be easily accessible to candidate EU countries, suggesting a smoother adoption process for countries seeking alignment with the

EU policy on digitalisation. The centralised option will align with international obligations and following consultation with the INCB it would potentially make it possible to implement a system-to-system interface for proceedings with PEN notifications automatically.

c) **Hybrid:** The hybrid option would firstly need the system-to-system interface to allow connection of national solutions with the central database. This option supports the EU digital strategy and EU SWE-C Digital Framework Policy by ensuring quantity management and streamlining the exchange of information between customs and non-customs authorities, however, in the long-term it is not in line with the customs union strategy related to the establishment of the EU Customs Data Hub. Implementation of international obligations could be standardised via a single system-to-system interface implemented for PEN notifications to align with the INCB.

3.3. PROPORTIONALITY

This criterion assesses to what extent the future digitalisation can leverage existing IT solutions and infrastructure.

a) **Decentralised:** For some Member States the obligation to develop an IT solution is disproportionate due to the low number of permissions that its competent authority has per year[39] and the responsibility to keep systems fully functional at all times. In addition to development of the solution, the possibility to check authenticity and validity of issued permissions via the national system should be developed by Member States. A decentralised option will put pressure on national authorities to collaborate for development purposes in an attempt to alleviate the disproportionate burden.

b) **Centralised:** This option will centralise the entire e-licensing platform and make use of the existing EU SWE-C environment architecture and infrastructure, thereby reassuring the EU policy objectives related to interoperability. It is also considered to be optimal because of the potential reuse of existing IT solutions with similar functionalities to the licence management that exists in the EU today. This option is geared towards eliminating the burden of paper-based processes and reducing the workload on Member States in terms of development, implementation, and maintenance responsibilities. An element of concern is the vulnerability to cyber-attacks or system collapse, which could compromise data protection. Consideration should be given to the risk of system redundancy by 2030, attributed to the rapid speed of digital innovation and emergence of new technologies.

c) **Hybrid:** Some Member States (e.g. Portugal, Netherland, Belgium) have already developed national systems. The hybrid option offers flexibility to those Member States who prefer to continue using their existing national systems, however, those Member States would have to create a new interface for replication of data to the central database and upgrade national solutions. At the same time, the disproportionate burden for Member States who still work on a paper-based approach will be eliminated by the availability of

[39] For additional information please see the outcome of survey on current drug precursors formalities in preparation for digitalisation of Oct 2022.

the centralised user interface. COM will leverage the existing infrastructure, including infrastructure related to EU SWE-C Digital Framework Policy, with the exception to build an interface for connection with Member States using national IT solutions.

3.4. FEASIBILITY

This criterion assesses the complexity to implement the digitalisation option relative to the relevance of the option to Member States and EOs.

a) **Decentralised:** The relevance of implementing this option is low for Member States who have very low volumetrics[40]. For such Member States the resource allocation to develop a national IT solution and streamline processes with other Member States renders the feasibility of a decentralised option as very low.

b) **Centralised:** The centralised option is highly relevant for both competent authorities and EOs, providing a streamlined process through a single interface to support the management and issuance of permissions required by EOs. The B2G[41] initiatives foreseen in the Single Window Regulation related to the single submission of data elements necessary for permissions and customs declarations, the so-called principle of once only submission through a single interface of National Single Window, make the centralised solution optimal for EOs.

c) **Hybrid:** Given that the fully centralised solution will be available to all Member States, this option is more relevant and moderately feasible to those individual Member States who wish to continue using their national IT solutions.

3.5. CONCLUSION

This analysis of the options for digitalisation of the EU Drug Precursors formalities focused on three options, decentralised, fully centralised, and hybrid. Each option was considered in collaboration with experts from the Project Group based on the identified policy options.

The decentralised option under Policy Option #1 offers for Member States flexibility, however, it introduces disproportionate complexities in cross-border validation and does not align with the EU digital policies or long-term customs policy related to the establishment of the EU Customs Data Hub. For implementation of measures 8 of Policy Option #2 and #3 the centralised option appears to be the most optimal solution, aligning with the EU policies and reducing administrative burdens for EOs and competent authorities. Full centralisation would allow the implementation of G2G and B2G schemes of the EU SWE-C Digital Framework Policy. It would also accommodate the long-term strategy of customs policy and be consistent with the EU digital policy. The hybrid option gives 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. In comparison with the preferred full centralisation

[40] For additional information please see the information provided by MSs to question 6 of the Survey on current drug precursors formalities in preparation for digitalisation of Oct 2022.

[41] Regulation (EU) 2022/2399 of the European Parliament and of the Council of 23 November 2022 establishing the European Union Single Window Environment for Customs and amending Regulation (EU) 295/2013.

option, the hybrid option would have difficulties being consistent with the long-term strategy on customs union establishing Customs Data Hub as a centralised solution.

From a cost-efficiency perspective, a decentralised option bears by design higher costs on Member States overall. Due to a potential 27 duplications, the cost and effort to develop the decentralised option will become disproportionate in comparison with other options. When considering the financial implications, the centralised option appears to be the most cost-efficient for the Union. The hybrid option would hold by design higher implementation costs for both COM and Member States.

4. COSTING

In the remainder of the current MFF period (2026-2027), the Commission has estimated a total cost of about EUR 0.9 million to be spent on this initiative to cover for its pre-inception activities, business analysis, digitalisation policy and business architecture input during the impact assessment, coordination and work with external stakeholders (notably the Project Group with MS), digitalisation legal input during the preparation of internal COM legal proposals, cooperation during the co-legislation phase and preparation for the next phases to build the solutions (e.g. COM IT Governance). The core digitalisation work will occur under the next MFF period (from 2028), as the updated Regulation(s) on Drug Precursors are expected to come into force by mid to late 2027 (Impact Assessment presented at the Regulatory Scrutiny Board in Jan. 2025, possible adoption by the College by Q2 2025, followed by at least 18 months of co-legislation). Based on experience from other e-licensing platforms and their linkage to national customs via the EU Customs Single Window, the Commission assesses the COM costs for such approach under the next MFF period (from 2028 until entry into operations of the solution by early 2033) to be in range from EUR 17 to 25 million. The costs are based on the range of costs for the future digital solution from lower cost based on re-use to full scratch development. The recurring yearly maintenance and operational costs from 2033 onwards would total EUR 2.3 million. The maintenance covers corrective maintenance, whilst evolutions should be costed in due time based on scope. This would include the link to the international UN relevant system. This approach would build on the Government-to-Government features of the EU Customs Single Window, meaning the Business-to-Government facilitation if deemed feasible is not factored in these costs for the moment. 1 Form D: report from EU and EU MS to UN on transactions on Drug Precursors 3 The costs will differ depending on the alternative for building the electronic system for digitalisation of Drug Precursors domain, delivery model and solution provider, which will be discussed and decided by Commission services Digital Steering Committee (previously ITSC), based on Business Case to be composed at the later stage. This decision will be supported by approval of Business Case describing the developing alternative by IT Commission Board (ITCB). The exact cost will depend on the reusability of the features and functionalities and the alternative approved by ITCB, where the representatives of IT Units of Directorates are participating. At this stage we cannot provide more costing elements. We cannot go lower than 70 % of most expensive scenario as we have no assurance of the future delivery model. At the moment there is no certainty that the Partner DGs having the component suitable for reuse will accept the suggestion to be solution provider and there is a possibility that the above-mentioned DG can push back on use of their platforms for new e-licensing domains.

5. BREAKDOWN OF THE COST ESTIMATE FOR A CENTRALISED SOLUTION

A. Scenario when building a new central drug precursors database from scratch.

TCO from scratch EUR 25 million	**Period/EUR**					
	Current MFF (2024-2027)	**2028**	**2029**	**2030**	**2031**	**Total**
pre-inception, impact assessment, legislation	1 100 000					
Inception, business analysis		1 500 000	1 500 000	500 000	500 000	
Technical specifications, IT construction			6 000 000	6 000 000	1 900 000	
Infrastructure, deployment, testing and operations			3 000 000	2 000 000	1 000 000	
	1 100 000	1 500 000	10 500 000	8 500 000	3 400 000	25 000 000

B. Scenario when upgrading the current European drug precursors database or extending an existing e-Licensing system.

TCO with re-use EUR 17 million	**Period/EUR**					
	Current MFF (2024-2027)	**2028**	**2029**	**2030**	**2031**	**Total**
pre-inception, impact assessment, legislation	1 100 000					
Inception, business analysis		1 050 000	1 050 000	350 000	350 000	
Technical specifications, IT construction			4 200 000	4 200 000	1 330 000	
Infrastructure, deployment, testing and operations			2 100 000	1 400 000	700 000	
Total	1 100 000	1 050 000	7 350 000	5 950 000	2 380 000	17 830 000

6. FALL-BACK SOLUTION – INTEGRATION OF THE DRUG PRECURSORS FORMALITIES IN THE EU CUSTOMS DATA HUB

Taking into account the budgetary constraints and the interplay with the EU Customs Reform establishing a new EU Customs Authority (EUCA) that will run an EU Customs Data Hub, following fall-back scenario may be envisaged subject to the adoption of the EU Customs Reform.

The proposed EU Customs Data Hub has three main legal milestones (applicable EU-wide):

1. 2028: eCommerce operational with partial Hub capabilities – all business-to-consumer flows for IOSS-registered platforms will be reported to the Hub,
2. 2032: Full Hub capabilities – mandatory use of the Hub for Trust and Check traders, voluntary use of the Hub for other traders.
3. 2038: Mandatory Hub fully operational for all traders

The digitalisation may be postponed until the EUCA and the EU Customs Data Hub are sufficiently operational. The EUCA would develop drug precursors digitalisation features as part of the EU Customs Data Hub for 2032 deployment.

An advantage of the Hub deployment is that the drugs precursors data can be integrated in **Union-wide risk analysis.** Information on legitimate supplies, and on detections of illicit supplies, can be used in supporting co-operative targeting at EU level. This should improve the capacity of the Union to detect complex drugs precursors supply chains which are difficult to detect in purely national-level data analysis.

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 foresee at this time 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.

It is not yet possible to assess the overall costs for this option, but it is assumed that it will be lower than for option 1 as there would be no costs to connect from the national customs declaration systems to the central services (in this case, the Hub).

This option is however subject to some political choices, including by the Member States:

- It would arguably create a precedent by widening the scope of the EU Customs Data Hub to internal market requirements. Although the Commission proposal for the customs reform provides the possibility of assigning EUCA any tasks related to free movement, import or export of goods, the MS have reduced this scope to tasks related to the customs authorities' mission, thereby refusing the idea of expanding the tasks of EUCA beyond international trade. The final regulation and potential tasks of EUCA are therefore uncertain in this moment.
- Given that the Data Hub has not yet been built, assessing the human and financial costs of incorporating in it the licencing system for drug precursors becomes more challenging. It would be premature in practice to do so now as it would involve an isolated analysis which could prejudge the broader development work that would be done on building the Hub as such.
- It must be accepted as a priority use case and legally or otherwise effectively obliging all drug precursors operators to use the EU Customs Data Hub as of 2032 instead of 2037, to avoid a requirement to connect national systems transitionally.
- Non-customs authorities dealing with drug precursors and with seizures of drugs, and even EUDA, must be willing to use the EU Customs Data Hub.

Assuming there would be a political agreement on the Hub taking the drug precursors requirements as a priority use case, the Member States could take the view that the customs aspects should be considered as already covered in the EU Customs Data Hub budget – in particular, the aspects of EU risk management, and the development of co-operation and interoperability with competent authorities on external trade. To the extent that the Member States take this view and treat drugs precursors functionality as one of the priority use cases for the Hub, the digitalisation of the drug precursors formalities would not entail additional budgetary costs. The purely internal market aspects might need a (smaller) funding allocation both from the technical and human resource side (EUCA staff); this resourcing may need to come from outside the customs budget lines.

ANNEX 9: CURRENT REGULATORY FRAMEWORK AND COMPARISON

1. OVERVIEW OF THE CURRENT REGULATORY REQUIREMENT

	Category 1	*Category 2*	*Category 3*	*Category 4*
General obligations	Operators (and users) hold a license	Operators and (Category 2A users) are registered	Operators are registered (for export only)	
	Operators secure premises against unauthorised removal			
	Report suspicious transactions. Ensure that the labels and commercial documents contain the name of the scheduled substances, as included in the Regulations. Keep documentation of each transaction for 3 years, readily available for inspection			
	Designate a responsible officer			
External trade	Obtain an export authorisation (including pre-export notification)	Obtain an export authorisation (including pre-export notification towards certain countries)	Obtain an export authorisation (including pre-export notification) towards certain countries	Obtain an export authorisation (including pre-export notification)
	Obtain an import authorisation			
	Demonstrate licit purpose for special customs procedure and temporary storage.			
Internal trade	Trade only with operators or users holding a license	Trade only with registered users for Category 2A		
	Special licenses may be granted	Special registration may be done		
	Obtain a customer declaration			

2. COMPARISON BETWEEN INTERNAL MARKET AND EXTERNAL TRADE REGULATION

This Annex sets out the correlation between the internal market Regulation and the external trade Regulation. In the 'comments' column it is marked in green whenever common provisions are drafted in slightly different ways. This shows how merging the two Regulations could lead to more coherent rules, where such situations would no longer exist.

Ref.	Internal Market Regulation	External trade Regulation	Comments
		1. Material scope	
1	Article 1 – rules on monitoring and control of possession and placing on the market of substances most frequently used in the illicit production of drugs	Article 1 – import, export and intermediary activities of the same substances	Complementary provisions
		2. Definitions	
2	Article 2 defines scheduled substances, non-scheduled substances, natural product, INCB	Article 2 sets out the same definitions	Common provisions with similar drafting
3	Article 2 also defines placing on the market, operator, user, special license etc.	Article 2 defines import, export, intermediary activities, importer, exporter, etc.	Complementary provisions
		3. Licences and registrations	
4	Article 3(2)-(5) – operators and users involved in transactions with Category 1 substances or possessing such substances have to hold a license. Rules are set out on the conditions for granting, suspending or revoking it, as well as on the possibility to grant special licences. Operators holding a licence can trade only with operators also holding a licence.	Article 6 – operators involved in transactions with Category 1 substances have to hold a license. Rules are set out on the conditions for granting, suspending or revoking it.	Common provisions with slightly different drafting. There are no rules on special licenses in the external trade Regulation.
5	Article 3(6)-(6c) – operators and users involved in transactions with Category 2 and, respectively 2A substances or possessing such substances have to hold a registration. Rules are set out on the conditions for granting, suspending or revoking it, as well as on the possibility to grant special registrations. Operators holding a registration for Category 2A can trade only with operators also holding a registration.	Article 7 – operators involved in transactions with Category 2 substances or exporting Category 3 substances have to hold a registration. Rules are set out on the conditions for granting, suspending or revoking it.	Common provisions with slightly different drafting. There are no rules on special registrations in the external trade Regulation.

		4. Documentation of transactions	
7	Articles 4 and 5 – documentation including customer declaration for all transactions with Category 1 and Category 2 substances, except in case of special licenses and special registrations, are to be kept for 3 years and kept available for inspection. There are also rules on the content of the information to be provided. The customer declarations is to be filled in per transaction. In specific conditions, one customer declaration can cover several transactions. A certified copy of the declaration has to accompany all transactions of Category 1 substances	Articles 3 and 4 Documentation of all imports, exports or intermediary activities of Category 1, Category 2 and Category 3 substances are to be kept for 3 years, ready for inspections; rules regarding the elements to be included in those documents (including the mention 'drug precursor') and their availability for inspection.	Rules common in part, with similar drafting. The scheduled substances concerned are different, with the external trade Regulation having a broader scope.
		5. Labelling	
8	Article 7 – obligation to include the name of the substance as in Annex I on the label of substances of Category 1 and Category 2.	Article 5 – obligation to include the name of the substance as included in the Annex on the label of substances of Category 1, Category 2 and Category 3	Common provision, different drafting – for internal market trade it does not concern Category 3 substances.
		6. Import and export requirements	
9		Article 11 – pre-export notifications are needed for transactions with Category 1 and Category 4 substances, as well as with Category 2 and Category 3 substances if the export is toward certain third countries.	Specific to external trade.
10		Articles 12 to 19 export authorisations – rules on the obligation to obtain an export authorisation for all scheduled substances (Category 3 substances only when subject to a pre-export notification), the content of the request, the deadline for granting the authorisation, the conditions for refusing, suspending or revoking it, as well as the maximum period of validity, as well as simplified procedures.	Specific to external trade.
11		Articles 20 to 25 Import authorisations – rules on the obligation to obtain an import authorisation for Category 1 substances, the content of the request, the deadline for granting the authorisation, the conditions for refusing, suspending or revoking it, as well as the maximum period of validity.	Specific to external trade.

	7. Other provisions concerning economic operators		
12	Article 3(1) obligation to designate a responsible officer for operators involved in transactions with Category 1 and Category 2 substances.		Not included in the external trade Regulation.
13	Article 6 sets out the possibility to exempt operators from the obligations to hold a license or a registration, to keep the documentation for Category 2 substances if the transactions performed in one year to not meet the maximum quantities set out in an Annex.		The corresponding provisions for external trade are set out in secondary Regulation, not in the basic one.
14		Article 8 – obligation to demonstrate licit purpose for all transactions with scheduled substances	Specific to external trade
	8. Notification of suspicious transactions		
15	Article 8(1) obligation of operators for transaction with any scheduled substance.	Article 9(1) obligation of operators for transaction with any scheduled substance; a list of details to be provided is set out.	Common provision with slightly different drafting.
	9. Notification of the annual summary of transactions		
16	Article 8(2) obligations of operators concerning transactions and use of all scheduled substances	Article 9(2) obligation of operators concerning their imports, exports and intermediary activities, without any reference to scheduled substances	Common provisions with different drafting.
	10. Guidelines and the EU Voluntary Monitoring List		
17	Article 9 – obligation of the Commission to develop Guidelines to support operators to identify suspicious transactions, in particular with non-scheduled substances; the Guidelines include the EU Voluntary Monitoring List	Article 10 – in addition to the similar rules in internal market Regulation, details are laid out as regards amendments to the EU VML	Common issue with slightly different drafting.
	11. Powers of the competent authorities – catch-all clauses		
18	Article 10 obligation of Member States to adopt national rules to empower their competent authorities to fight against the diversion of scheduled substances, and possibility to do so for non-scheduled substances	Article 26 similar provisions as for internal trade and specific powers for external trade authorities, such as stopping shipments	Common provisions with similar drafting and complementary provisions specific to external trade

		12. Administrative cooperation	
19	Article 11 sets out obligations for Member States to ensure a good cooperation between them, as well as with the Commission	Article 27 – communication of competent authorities to the Commission and the other Member States	Common provision with slightly different drafting
20	Article 16(1) and (2): Member States have the obligation to communicate to the Commission measures adopted in the implementation of the Regulation		Specific to internal market.
		13. European Database on Drug Precursors	
21	Article 13(1) sets out the data to be communicated via the database, both illegal uses and legitimate trade Article 13a sets pit the three functions of the database: to support the statistical analysis and communication of data to the UN, to set out a registry of operators holding licences and registrations and to implement the annual reporting obligations of operators. Obligation of public authorities to ensure the security of the data collected.	Article 32(1) – data to be communicated by Member States via the database cover both illegal use and legitimate trade Article 32a – similar three functions	Common provisions with slightly different drafting
		14. Implementing powers	
22	Article 14: implementing acts on: rules on how to provide customer declarations in electronic form rules on how to provide the annual summary of transactions, including, where appropriate, in electronic form to a European database and for listing operators and users in the European database	Article 28 implementing acts on 'measures to ensure the effective monitoring of trade between the Union and third countries in drug precursors, in particular with regard to the design and use of export and import authorisation form'	Complementary provisions – specific to each Regulation
23	Article 14: procedural rules for granting licences and registrations and	Article 6(3) – model of license	Common issues, with slightly different drafting
24	Article 8(2) communication of annual summary, including via the database	Article 9(2) communication of annual summary, including via the database	Common issues with similar drafting
25		Article 11 – list of third countries for which a pre-export notification is needed for Category 2 and Category 3 substances.	Specific to external trade

26	Article 14a	Article 30	Common provisions with similar drafting – same committee and same comitology procedure
		15. Delegation of powers	
27	Article 15 'in order to adapt Annexes I, II and III to new trends in diversion of drug precursors and to follow any amendment to the tables in the Annex to the United Nations Convention.'	Article 30a 'n order to adapt the Annex hereto to new trends in diversion of drug precursors, in particular substances which can be easily transformed into scheduled substances, and to follow any amendment to the tables in the Annex to the United Nations Convention.'	Common provisions with slightly different drafting.
28	Article 13(2)	Article 32(2) – conditions for communication of data via the European database	Common issue with similar drafting
29	Article 4(4) – rules on customer declarations		Specific to internal trade
30	Article 5 – rules on documentation for mixtures		Common issue not included in the external trade Regulation
31	Article 7 – rules on labelling of mixtures		Common issue not included in the external trade Regulation
32	Article 3(8) conditions for granting a licence or a registration, including data in the European database on the licences or registrations issued	Article 6(1) conditions for granting a license Article 7(1) conditions for granting a registration	Common issue with slightly different drafting
33	Article 8(2) information to be provided by operators in the annual summary of transactions	Article 9(2) information to be provided by operators in the annual summary of transactions	Common issue with similar drafting
34		Article 8(2) conditions for demonstrating the licit purpose	Specific to external trade
35		Article 11 – simplified pre-export notifications	Specific to external trade
36		Article 19 – rules on simplified procedures for export authorisations	Specific to external trade
37	Article 15a	Article 30b	Conditions for exercising the empowerment – common provisions with similar drafting

	16. Protection of personal data		
38	Article 13a(3) – with reference to the European database on drug precursors Article 13b	Article 33	Common provision with similar drafting.
	17. Penalties		
39	Article 12	Article 31	Common issue with similar drafting
	18. Evaluation – Commission reports		
40	Article 13(3) summary of the information received in the database is communicated by the Commission to UN each year	Article 32(3): Annual report to the UN based on the information provided in the European database	Common issue with slightly different drafting
41	Article 16(3)evaluation report 6 years after the 2013 revision, with focus on non-scheduled substances	Article 32(4):	Common provision with similar drafting
	19. Repeal and transition		
42	Article 17	Article 34	The validity of documents issues under the repealed acts relevant for internal market is maintained.
	20. Entry into force		
43	Article 18	Article 35	Application of the basic Regulations was aligned and postponed with 18 months from the entry into force of the internal market Regulation and 12 more months were set out for the application of the implementing measures.

3. CORRELATION BETWEEN ARTICLE 12 OF THE UN CONVENTION AND THE TWO REGULATIONS

This Annex shows how the UN Convention has been implemented by the Regulations, by indicating the corresponding provisions. In the 'Comments column', it is mentioned, among others, whenever the Regulations go beyond the requirements in the UN Convention.

Ref.	*Article 12* **SUBSTANCES FREQUENTLY USED IN THE ILLICIT MANUFACTURE OF NARCOTIC DRUGS OR PSYCHOTROPIC SUBSTANCES**	The Regulations	Comments
	1. The Parties shall take the measures they deem appropriate to prevent diversion of substances in Table I and Table II used for the purpose of illicit manufacture of narcotic drugs or psychotropic substances, and shall co-operate with one another to this end.	By adopting Regulations (EC) Nos 273/2004 and 111/2005	
	2. If a Party or the Board has information which in its opinion may require the inclusion of a substance in Table I or Table II, it shall notify the Secretary-General and furnish him with the information in support of that notification. The procedure described in paragraphs 2 to 7 of this article shall also apply when a Party or the Board has information justifying the deletion of a substance from Table I or Table II, or the transfer of a substance from one Table to the other.	-	Paragraphs 2 to 8 include procedural provision, specific to the legal order of each entity. **At UN level**, the position of the EU is set out in Decisions of the Council, typically based on proposals from the Commission in accordance with Article 218(9) of the Treaty on the functioning of the European Union. **At EU level**, updates to the Annexes to the Regulations are introduced by Commission delegated regulations.
	3. The Secretary-General shall transmit such notification, and any information which he considers relevant, to the Parties, to the Commission, and, where notification is made by a Party, to the Board. The Parties shall communicate their comments concerning the notification to the Secretary-General, together with all supplementary information which may assist the Board in establishing an assessment and the Commission in reaching a decision.	-	
	4. If the Board, taking into account the extent, importance and diversity of the licit use of the substance, and the possibility and ease of using alternate substances both for licit purposes and for the illicit manufacture of narcotic drugs or psychotropic substances, finds: (a) that the substance is frequently used in the illicit manufacture of a narcotic drug or psychotropic substance; (b) that the volume and extent of the illicit manufacture of a narcotic drug or psychotropic substance creates serious public health or social problems, so as to warrant international action, it shall communicate to the Commission an assessment of the substance, including the likely effect of adding the substance to either Table I or Table II on both licit use and illicit manufacture, together with recommendations of monitoring measures, if any, that would be appropriate in the light of its assessment.	-	

	5. The Commission, taking into account the comments submitted by the Parties and the comments and recommendations of the Board, whose assessment shall be determinative as to scientific matters, and also taking into due consideration any other relevant factors, may decide by a two-thirds majority of its members to place a substance in Table I or Table II.	--	
	6. Any decision of the Commission taken pursuant to this article shall be communicated by the Secretary-General to all States and other entities which are, or which are entitled to become, Parties to this Convention, and to the Board. Such decision shall become fully effective with respect to each Party one hundred and eighty days after the date of such communication.	-	
	7. (a) The decisions of the Commission taken under this article shall be subject to review by the Council upon the request of any Party filed within one hundred and eighty days after the date of notification of the decision. The request for review shall be sent to the Secretary-General, together with all relevant information upon which the request for review is based. (b) The Secretary-General shall transmit copies of the request for review and the relevant information to the Commission, to the Board and to all the Parties, inviting them to submit their comments within ninety days. All comments received shall be submitted to the Council for consideration. (c) The Council may confirm or reverse the decision of the Commission. Notification of the Council's decision shall be transmitted to all States and other entities which are, or which are entitled to become, Parties to this Convention, to the Commission and to the Board	-	
	8. (a) Without prejudice to the generality of the provisions contained in paragraph 1 of this article and the provisions of the 1961 Convention, the 1961 Convention as amended and the 1971 Convention, the Parties shall take the measures they deem appropriate to monitor the manufacture and distribution of substances in Table I and Table II which are carried out within their territory. (b) To this end, the Parties may: (i) control all persons and enterprises engaged in the manufacture and distribution of such substances; (ii) control under licence the establishment and premises in which such manufacture or distribution may take place; (iii) require that licensees obtain a permit for conducting the aforesaid operations (iv) prevent the accumulation of such substances in the possession of manufacturers and distributors, in excess of the quantities required for the normal conduct of business and the prevailing market conditions.	Internal market Regulation – Articles 3, 4, 5 and 8(1) in particular	The Regulation sets out rules for licences and registrations. Contrary to the UN Convention, the substances are divided into 3 categories, instead of 2. The obligations of Category 3 substances (which includes some Table II substances are lighter than the possibilities in the UN Convention). There are no rules to prevent the accumulation of substances. However, additional obligations are set out, such as keeping documents and labelling, informing about suspicious transactions.

	9. Each Party shall, with respect to substances in Table I and Table II, take the following measures: (a) Establish and maintain a system to monitor international trade in substances in Table I and Table II in order to facilitate the identification of suspicious transactions. Such monitoring systems shall be applied in close co-operation with manufacturers, importers, exporters, wholesalers and retailers, who shall inform the competent authorities of suspicious orders and transactions.	External trade Regulation, Article 9(1)	
	(b) Provide for the seizure of any substance in Table I or Table II if there is sufficient evidence that it is for use in the illicit manufacture of a narcotic drug or psychotropic substance.	External trade Regulation, Article 10(1)	Rules are also set out for non-scheduled substances in the external trade Regulation.
	(c) Notify, as soon as possible, the competent authorities and services of the Parties concerned if there is reason to believe that the import, export or transit of a substance in Table I or Table II is destined for the illicit manufacture of narcotic drugs or psychotropic substances, including in particular information about the means of payment and any other essential elements which led to that belief.	External trade Regulation, Article 9(1)	
	(d) Require that imports and exports be properly labelled and documented. Commercial documents such as invoices, cargo manifests, customs, transport and other shipping documents shall include the names, as stated in Table I or Table II, of the substances being imported or exported, the quantity being imported or exported, and the name and address of the exporter, the importer and, when available, the consignee. (e) Ensure that documents referred to in subparagraph (d) of this paragraph are maintained for a period of not less than two years and may be made available for inspection by the competent authorities.	External trade Regulation, Articles 3 and 4	Documents are to be kept for a longer period than the one set out in the UN Convention.
	10. (a) In addition to the provisions of paragraph 9, and upon request to the Secretary-General by the interested Party, each Party from whose territory a substance in Table I is to be exported shall ensure that, prior to such export, the following information is supplied by its competent authorities of the competent authorities of the importing country: (i) Name and address of the exporter and importer and, when available, the consignee; (ii) name of the substance in Table I; (iii) quantity of the substance to be exported; (iv) expected point of entry and expected date of dispatch; (v) any other information which is mutually agreed upon by the Parties. (b) A Party may adopt more strict or severe measures of control than those provided by this paragraph if, in its opinion, such measures are desirable or necessary.	External trade Regulation, Article 11	

	11. Where a Party furnishes information to another Party in accordance with paragraphs 9 and 10 of this Article, the Party furnishing such information may require that the Party receiving it keep confidential any trade, business, commercial or professional secret or trade process.	External trade Regulation, Article 11	
	12. Each Party shall furnish annually to the Board, in the form and manner provided for by it and on forms made available by it, information on: (a) The amounts seized of substances in Table I and Table II and, when known, their origin; (b) Any substance not included in Table I or Table II which is identified as having been used in illicit manufacture of narcotic drugs or psychotropic substances, and which is deemed by the Party to be sufficiently significant to be brought to the attention of the Board; (c) Methods of diversion and illicit manufacture.	Internal market Regulation, Article 13 External trade Regulation, Article 32	In addition to the UN requirements, information on legitimate trade is to be collected from operators and transferred by Member States to the Commission.
	13. The Board shall report annually to the Commission on the implementation of this article and the Commission shall periodically review the adequacy and propriety of Table I and Table II.		
	14. The provisions of this article shall not apply to pharmaceutical preparations, nor to other preparations containing substances in Table I or Table II that are compounded in such a way that such substances cannot be easily used or recovered by	Both Regulations, Article 2	

ANNEX 10: SCHEDULED SUBSTANCES, AND THEIR CONTEXT

1. LIST OF SCHEDULED SUBSTANCES, THEIR LICIT AND ILLICIT USE

The following table provides the ***list of substances that are under control*** in the EU (the EU schedule) and at the international level (UN Tables), with summary indications on their ***licit and illicit uses***. The table allows to identify the correspondences and the differences between the EU and the UN list.

A relevant aspect that emerged from the comparison is the different nomenclature used in the identification of substances. To facilitate correspondences internationally accepted coding system are used in both list (e.g. the CAS number, the HS/CN code). However, for new substances – and especially designer precursors – ***identification and classification are a non-trivial issue*** as these substances lack a unique identifier and can be trade with non-standardised names and under customs codes that designates large families of chemicals. For background, the following text box provides an overview of the relevant nomenclatures and code systems of chemicals used in the existing control system.

Summary of relevant nomenclatures and code systems of chemicals

The name and reference codes of chemical substances may vary depending on the context in which they are used. For what concerns drug precursors, there are several nomenclatures and codes used for substances.

The chemical name of one substance, based on its molecular structure, is established at the international level by the International Union of Pure and Applied Chemistry (**IUPAC**). However, at the international level the scheduling process of precursors follows a reference dictionary, i.e., the **UNODC Multilingual Dictionary of Narcotic Drugs and Psychotropic Substances under International Control.** It contains also information on name variants, including synonyms, common, generic and trade names. UNODC assigns most "principal names" to scheduled precursors, following the **International Non-proprietary Names (INN) System for Pharmaceutical Substances** developed by WHO. In cases where INN are not available, other non-proprietary, generic or trivial names may be used. In the UN scheduling, each name is then linked to a HS code and a CAS code, which are the two main coding systems used for identifying substances in trade and statistics, globally:

- **HS (Harmonised Commodity Description and Coding System).** It is the international system to classify goods developed by the World Customs Organisation (WCO). It is a classification system of around 5.000 six-digit product categories. More than 200 countries use the HS system as a basis for customs tariffs and the collection of statistical data. It is updated every 5 years (latest update in 2022).
- **CAS RN (Chemical Abstracts Service Registry Number).** It is a unique and unambiguous identifier assigned by the American Chemical Society to every chemical substance described in the scientific literature. The Register is updated daily, and the registration of substances are not dependent upon any system of chemical nomenclature. No specific information other than the identifier are linked to the substances, however, the CAS number is the one referenced at the UN level for identifying scheduled substances. On top of the CAS number, the INCB assigns to scheduled substances another specific code, the **IDS code**, which has mostly an internal use.

At the European level, names of scheduled substances follow the "principal names" assigned in the UN scheduling lists. When a substance is scheduled at the EU level, but not at the international level, **it is given a name following the IUPAC nomenclature (**e.g., *diethyl (phenylacetyl) propanedioate*, or the *Methyl 2-methyl-3-phenyloxirane-2-carboxylate*).

The HS code is used in the European context in an extended version, the CN (Combined Nomenclature) Code, which extends the former to an eight-digit code. This EU coding system, managed by DG TAXUD and Eurostat serves the common customs tariff and provides statistics for trade within the EU and between the EU and

the rest of the world. The list of CN codes is updated once a year through a specific legal act, taking into account both changes at WCO level (in the HS system) and specific changes needed at EU level. Changes to CN codes should be approved by *DG TAXUD and Eurostat* together with all the interested parties: (i) the *Customs Code Committee*, Tariff and Statistical Nomenclature Section, and the (ii) *European Federations* acting in their capacity as representatives of economic operators using the CN and as representatives for providers and users of trade statistics based on the CN.

Moreover, DG TAXUD manages a comprehensive inventory called **ECICS** (**European Customs Inventory of Chemical Substances)** which allows anyone to (i) identify chemicals according to their IUPAC name (ii) classify them according to the CN code, and (iii) translate them in all EU languages. For each chemical the inventory provides also:

- the CAS RN,
- INN names as well as known other common names and synonyms,
- if available, the **EC number** used by ECHA in the EINECS (European Inventory of Existing Commercial chemical Substances),
- if available, the **UN code** given to hazardous chemicals by the United Nations Committee of Experts on the Transport of Dangerous Goods.

EU Schedules						UN Tables			Uses			2022[42] (tons)		
Cat	**Substance**	**TARIC**	**CAS No**	**Added on**	**Notes**	**Tab**	**Added on**	**Notes**	**Illicit**	**Licit**	**DDP**	**Import**	**Export**	**Usage**
I	1-phenyl-2-propanone (BMK)	2914 31 00 00	103-79-7			I			Amph / meth	Used in the chemical and pharmaceutical industries		6.2	2.0	8.5
I	2-methyl-3-phenyloxirane-2-carboxylic acid (BMK glycidic acid)	2918 99 90 63	25547-51-7	2020-07	Expanded by DelReg 2024/1331: its ethyl, methyl (CAS No 80532-66-7), propyl, isopropyl, butyl, isobutyl, sec-butyl and tert-butyl esters, with the same CN code as BMK glycidic acid.	I	2024-03	Including of methyl, butyl, ethyl, propyl, isopropyl, isobutyl, sec-butyl, tert-butyl ester	Amph / meth	no known licit production, trade or use	x	-	-	-
I	Methyl 2-methyl-3-phenyloxirane-2-carboxylate (BMK methyl glycidate)	*2918 99 90 90*	80532-66-7	2020-07	Deleted under DelReg 2024/1331 (moved under BMK Glycidic Acid)				Amph / meth	no known licit production, trade or use	x	-	-	-
I	Alpha-phenylacetoacetamide (APAA)	2924 29 70 07	4433-77-6	2020-07		I	2019-03		Amph / meth	None, except R&D	x	0	0	0
I	Alpha-phenylacetoacetonitrile (APAAN)	2926 40 00 00	4468-48-8	2013-11		I	2014-03		Amph / meth	None, except R&D	x	0	0	0
I	Methyl alpha-phenylacetoacetate (MAPA)	2918 30 00 37	16648-44-5	2020-07		I	2020-03		Amph / meth	None, except R&D	x	0	0	0

[42] Source: EU Drug Precursors database, Form D reporting

EU Schedules						UN Tables			Uses			2022[42] (tons)		
Cat	Substance	TARIC	CAS No	Added on	Notes	Tab	Added on	Notes	Illicit	Licit	DDP	Import	Export	Usage
I	Diethyl (phenylacetyl) propanedioate (DEPAPD)	2918 30 00 27	20320-59-6	2022-11					Amph / meth	no known licit production, trade or use	x	0	0	0
I	Ethyl alpha-phenylacetoacetate (EAPA)	2918 30 00 17	5413 05 8	2022-03					Amph / meth	no known licit production, trade or use	x	-	-	-
I	Norephedrine	2939 44 00 00	14838-15-4			I			Amph	Used in the manufacture of nasal decongestants and appetite suppressants		3.8	0 01	3.4
I	Ephedrine	2939 41 00 00	299-42-3			I			Meth	Used in the manufacture of bronchodilators (cough medicines)		4.9	24.7	13.2
I	Pseudoephedrine	2939 42 00 00	90-82-4			I			Meth	Used in the manufacture of bronchodilators and nasal decongestants		65	175	46 6
I	(1R,2R)-(-)-chloropseudoephedrine	2939 79 90 40	771434-80-1	2016-06					Meth	no known licit production, trade or use	x	0	0	0
I	(1R,2S)-(-)-chloroephedrine	2939 79 90 10	110925-64-9	2016-06					Meth	no known licit production, trade or use	x	0	0	0
I	(1S,2R)-(+)-chloroephedrine	2939 79 90 20	1384199-95-4	2016-06					Meth	no known licit production, trade or use	x	0	0	0
I	(1S,2S)-(+)-chloropseudoephedrine	2939 79 90 30	73393-61-0	2016-06					Meth	no known licit production, trade or use	x	0	0	0

EU Schedules						UN Tables			Uses			2022[42] (tons)		
Cat	**Substance**	**TARIC**	**CAS No**	**Added on**	**Notes**	**Tab**	**Added on**	**Notes**	**Illicit**	**Licit**	**DDP**	**Import**	**Export**	**Usage**
I	3,4-methylenedioxyphenylpropan-2-one (PMK)	2932 92 00 00	4676-39-5			I			MDMA	It has a known use in the production of Talampanel (prescription drug)		0	0	0
I	3-(1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylic acid (PMK glycidic acid)	2932 99 00 07	2167189-50-4	2020-07	Expanded by DelReg 2024/1331: its ethyl (CAS No 28578-16-7), methyl (CAS No 13605-48-6), propyl, isopropyl, butyl, isobutyl, sec-butyl and tert-butyl esters, with the same CN code as PMK glycidic acid.'	I	2019-03	Expanded: CND 2024. Inclusion of ethyl, propyl, sec-butyl, isopropyl, isobutyl, butyl, tert-butyl ester	MDMA	no known licit production, trade or use	x	0	0	0
I	Ethyl 3-(2H-1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (PMK ethyl glycidate)	*2932 99 00 90*	28578-16-7	2022-11	Deleted under DelReg 2024/1331 (moved under PMK Glycidic Acid)				MDMA	no known licit production, trade or use	x	0	0	0
I	Methyl 3-(1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (PMK methyl glycidate)	*2932 99 00 90*	13605-48-6	2020-07	Deleted under DelReg 2024/1331 (moved under PMK Glycidic Acid)	I	2019-03		MDMA	no known licit production, trade or use	x	0	0	0
I	Piperonal	2932 93 00 00	120-57-0			I			MDMA	Used in perfumery, in cherry and vanilla flavours, in organic synthesis and as a		441.5	100	288

EU Schedules						UN Tables			Uses			2022[42] (tons)		
Cat	Substance	TARIC	CAS No	Added on	Notes	Tab	Added on	Notes	Illicit	Licit	DDP	Import	Export	Usage
										component for mosquito repellent				
I	Methyl 3-oxo-2-(3,4-methylenedioxyphenyl)butanoate (MAMDPA)	2932 99 00 87	1369021-80-6	2022-03					MDMA	no known licit production, trade or use	x	-	-	-
I	Isopropylidene (2-(3,4-methylenedioxyphenyl)acetyl)malonate (IMDPAM)	2932 99 00 61		2024-02					MDMA	no known licit production, trade or use	x	-	-	-
I	Safrole	2932 94 00 00	94-59-7			I			MDMA	Used in perfumery, and for denaturing fats in soap manufacture		0	0	0
I	Isosafrol (cis + trans)	2932 91 00 00	120-58-1			I			MDMA	Used in the manufacture of piperonal; to modify “oriental perfumes”; to strengthen soap perfumes; and as a pesticide		-	-	-
I	Lysergic acid	2939 63 00 00	82-58-6			I			LSD	Used in organic synthesis		0	0	3.9
I	Ergometrine	2939 61 00 00	60-79-7			I			LSD	Used in the treatment of migraine and as an oxytocic in obstetrics		0	0	0
I	Ergotamine	2939 62 00 00	113-15-5			I			LSD	Used in the treatment of migraine and as an oxytocic in obstetrics		0	1	0

EU Schedules						UN Tables			Uses			2022[42] (tons)		
Cat	Substance	TARIC	CAS No	Added on	Notes	Tab	Added on	Notes	Illicit	Licit	DDP	Import	Export	Usage
I	N-acetylanthranilic acid	2924 23 00 00	89-52-1			I			Methaqualone	Used in the manufacture of pharmaceuticals, plastics and fine chemicals		0	0	0
I	N-phenyl-1-(2-phenylethyl)piperidin-4-amine (ANPP)	2933 36 00 00	21409-26-7	2018-02		I	2017-03		Fentanyl etc	Used in the pharmaceutical industry for the manufacture of fentanyl		-	-	-
I	1-(2-phenylethyl)piperidin-4-one (NPP)	2933 37 00 00	39742-60-4	2018-02		I	2017-03		Fentanyl etc	Used in the pharmaceutical industry for the manufacture of fentanyl and carfentanil		-	-	-
I	N-phenylpiperidin-4-amine (4-AP)	2933 39 99 01	23056-29-3	2022-11		I	2022-03		Fentanyl etc	May be used as pharma building block (including fentanyl) but extent of legal use is unknown	x	0	0	0
I	N-phenyl-N-(piperidin-4-yl)propanamide (norfentanyl)	2933 39 99 03	1609-66-1	2022-11		I	2022-03		Fentanyl etc	None, except research and lab analysis (intermediate in the production of fentanyl)	x	0	0	0
I	Tert-butyl 4-anilinopiperidine-1-carboxylate (1-boc-4-AP)	2933 39 99 02	125541-22-2	2022-11		I	2022-03		Fentanyl etc	None, except R&D	x	0	0	0
II a	Acetic anhydride	2915 24 00 10	108-24-7			I			Heroine	Acetylating and dehydrating agent used in the chemical and pharmaceutical industries for the manufacture of cellulose acetate, for		126.5 m	175.2 m	31.7 m

EU Schedules						UN Tables			Uses			2022[42] (tons)		
Cat	Substance	TARIC	CAS No	Added on	Notes	Tab	Added on	Notes	Illicit	Licit	DDP	Import	Export	Usage
										textile sizing agents and cold bleaching activators, for polishing metals and for the production of brake fluids, dyes and explosives				
II a	Red phosphorus	2804 70 10 00	7723-14-0	2020-07					Meth	Production of semiconductors, pyrotechnics, fertilizers, safety matches, pesticides, smoke bombs, incendiary shells in organic synthesis reactions and certain flame retardants				
II b	Phenylacetic acid	2916 34 00 00	103-82-2			I		From table II to table I in 2010	Amph / meth	Used in the chemical and pharmaceutical industries for the manufacture of phenylacetate esters, amphetamine and some derivatives; also used for the synthesis of penicillins and in fragrance applications and cleaning solutions				
II b	Anthranilic acid	2922 43 00 10	118-92-3			II			Methaqu alone	Chemical intermediate used in the manufacture of dyes, pharmaceuticals and perfumes; also used in the preparation of bird and insect repellents		760	0	0

EU Schedules						UN Tables			Uses			2022[42] (tons)		
Cat	Substance	TARIC	CAS No	Added on	Notes	Tab	Added on	Notes	Illicit	Licit	DDP	Import	Export	Usage
II b	Piperidine	2933 32 00 00	110-89-4			II			Phencyclidine	Commonly used solvent and reagent in chemical laboratories and in the chemical and pharmaceutical industries; also used in the manufacture of rubber products and plastics		452	81	43
II b	Potassium permanganate	2841 61 00 00	7722-64-7			I			Cocaine	Important reagent in analytical and synthetic organic chemistry; used in bleaching applications, disinfectants, anti-bacterials and anti-fungal agents and in water purification		1.3 m	515	1 m
III	Acetone	2914 11 00 00	67-64-1			II				Variety of substances in the chemical and pharmaceutical industries, including plastics, paints, lubricants, varnishes and cosmetics; explosives		8.9 m	118.3 m	41 m
III	Ethyl ether	2909 11 00 00	60-29-7			II				chemical and pharmaceutical industries; mainly used as an extractant for fats, oils, waxes and resins; also used for the manufacture of munitions, plastics and perfumes and, in		241.7	618.8	256.7

EU Schedules						UN Tables			Uses			2022[42] (tons)		
Cat	Substance	TARIC	CAS No	Added on	Notes	Tab	Added on	Notes	Illicit	Licit	DDP	Import	Export	Usage
										medicine, as a general anaesthetic				
III	Hydrochloric acid	2806 10 00 00	7647-01-0			II				Used in the production of chlorides and hydrochlorides, for the neutralization of basic systems and as a catalyst and solvent in organic synthesis		35.5 m	148.0 m	436.3 m
III	Methylethylketone (MEK)	2914 12 00 00	78-93-3			II				Common solvent; used in the manufacture of coatings, solvents, degreasing agents, lacquers, resins and smokeless powders		36 026	5 311	4 680
III	Sulphuric acid	2807 00 00 00	7664-93-9			II				Used in the production of sulphates; as an acidic oxidizer; as a dehydrating and purifying agent; for the neutralization of alkaline solutions; as a catalyst in organic synthesis; in the manufacture of fertilizers, explosives, dyestuffs and paper; and as a component of drain and metal cleaners, anti-rust compounds and automobile battery fluids		77 269	3 m	7.6 m

EU Schedules						UN Tables			Uses			2022[42] (tons)		
Cat	Substance	TARIC	CAS No	Added on	Notes	Tab	Added on	Notes	Illicit	Licit	DDP	Import	Export	Usage
III	Toluene	2902 30 00 00	108-88-3			II				Industrial solvent; used in the manufacture of explosives, dyes, coatings and other organic substances and as a gasoline additive		12 960	137 497	39 628
IV	Medicinal products and veterinary medicinal products containing ephedrine or its salts	3003 41 00 00							Meth	Medicinal products and veterinary medicinal products		0.5	0.6	2.1
IV	Medicinal products and veterinary medicinal products containing pseudoephedrine or its salts	3003 42 00 00							Meth	Medicinal products and veterinary medicinal products		5	24.8	21.7
NO	1-boc-4-piperidone	*2932 39 99 90*	79099-07-3			I	2024-03		Fentanyl etc	Limited known legitimate manufacture of and trade (only R&D)	x			
NO	4-piperidone	*2933 39 99 90*	41661-47-6			II	2024-03		Fentanyl etc	Limited known legitimate manufacture of and trade (only R&D)	x			

2. COMPETITIVE POSITION OF THE MOST AFFECTED SECTORS

Drug precursors are critical components of various industrial supply chains, 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. To define the sector for the purpose of competitiveness analysis, the table below aims to place scheduled substances into larger, yet relevant, product categories for which more economic information exists. [43]

This table highlights that some of the substances scheduled have only a weak link with the chemical industry. This is the case of the last 6 lines, for which the original precursor is to be found in the mining industry, in oil and gas, or in bioprocesses.

Finally, two indications are needed for an understanding of the content of the table:
a) the scheduled substances are presented according to a colour code that indicates to which of the 3 categories devised by the Regulation they belong, i.e.: Category 1, Category 2 and Category 3.
b) because several possible production routes exist for some of the drug precursors listed, the chosen links of the respective value chain belong to the production process that is the most extensively employed.

The vast majority (well over 90 %) of chemical production in general rests on so-called "building blocks". There are some discrepancies in specialised literature as to which these are, but the largest body of evidence points to 9 of them, as listed below:
- petrochemicals, i.e., **methanol**; olefins (**ethylene**, **propylene**, **butadiene**); and aromatics (**benzene**, **toluene**, **xylenes**);
- inorganics, i.e., **ammonia** and **chlorine**.

Schedules substances and their link to a chemical 'building block' (for certain substances, more than one critical intermediate or "building block" is used, for reasons of simplicity only one is mentioned in the list)

Scheduled substance	CN code	Closest precursor	Critical intermediate	Originating chemical "building block"
1-phenyl-2-propanone (Phenylacetone)	*2914 31 00*	Phenylacetic acid	Acetic acid	Methanol
Alpha-phenylacetoacetamide (APAA)	*2924 29 70*	Acetoacetamide		
Acetic anhydride	*2915 24 00*	Acetic acid		
Piperidine	*2933 32 00*	Pyridine	Formaldehyde	
Ethyl ether, Diethyl ether	*2909 11 00*	Ethanol	Ethanol	Ethylene
Alpha-phenylacetoacetonitrile (APAAN)	*2926 40 00*	Acetonitrile	Acrylonitrile	Propylene
MAPA & EAPA	*2918 30 00*	Acetonitrile		
BMK glycidic acid	*2918 99 90*	APAAN		
PMK glycidic acid	*2932 99 00*		Acrylic acid	
IMDPAM	*2932 99 00*	Acetone	Isopropyl alcohol	
MAMDPA	*2932 99 00*		Butyric acid	
Methylethylketone, Butanone	*2914 12 00*	2-butanol	2-butanol	

[43] This exercise did not include 5 fentanyl precursors scheduled in 2022. Apart from not having any legal uses, they originate from production processes that are neither widely known, nor are they in need of being advertised.

Acetone	*2914 11 00*	Cumene	Cumene****	
Isosafrol	*2932 91 00*	Allylbenzene	Allylbenzene	Benzene
Piperonal	*2932 93 00*	Isosafrol		
Safrole	*2932 94 00*	Catechol	Phenol	Benzene*
3,4-Methylenedioxyphenylpropan-2-one	*2932 92 00*	Safrole		
N-acetylanthranilic acid 2-acetamidobenzoic acid	*2924 23 00*	Benzoic acid	Benzoic acid	Toluene
Ephedrine	*2939 41 00*	Benzaldehyde	Benzaldehyde	
- 2 chloroephedrines	*2939 79 90*	Ephedrine		
Pseudoephedrine	*2939 42 00*	Benzaldehyde		
- 2 chloropseudoephedrines	*2939 79 90*	Pseudoephedrine		
Norephedrine	*2939 44 00*	Benzaldehyde		
Phenylacetic acid	*2916 34 00*	Benzyl cyanide	Benzyl chloride	
Toluene	*2902 30 00*	Toluene	Toluene	
Anthranilic acid	*2922 43 00*	Phtalic anhydride	Phtalic anhydride	Xylenes (orto-~)
Hydrochloric acid	*2806 10 00*	Chlorine	Chlorine	Chlorine
Sulphuric acid	*2807 00 00*	Sulphur dioxide	Elemental sulphur	Oil & natural gas**
Red phosphorus	*2804 70 10*	White phosphorus	White phosphorus	Phosphate rock***
Potassium permanganate	*2841 61 00*	Manganese dioxide	Manganese dioxide	Manganese ore***
Ergometrine	*2939 61 00*	Lysergic acid	Specific fungi	*No exclusively synthetic production route exists*
Ergotamine	*2939 62 00*	Lysergic acid	Specific fungi	
Lysergic acid	*2939 63 00*	Tryptophan	Specific fungi	

* Production process also involves propylene, but the molar ratio benzene-to-propylene is >1

** By removing sulphur-containing contaminants

*** These are minerals, not chemicals

**** These synthesis process requires also benzene and yields acetone as well as phenol

The table shows that 7 of the above-mentioned 9 building blocks are at the origin of 28 of the 34 drug precursors listed in the table (out of the currently 60 scheduled substances). In addition, another building block (ammonia) also intervenes in the production process of some of them. On this basis we can conclude that **drug precursors are chemical substances that, taking into account their production process, have links with the quasi-entirety of the basic chemical industry**, albeit their presence is more frequent in some value chains than in others. In particular, value chains that begin with toluene (from which 8 drug precursors ultimately originate) are the most frequent occurrence, followed by propylene (7 drug precursors), benzene (5) and methanol (4).

Moreover, the table shows that the chemical intermediates used for producing drug precursors are so diverse that:

- many of them are very marginal in the chemical industry, hence there is no way to find any relevant economic information on them;
- for those where such information may be extracted, there is no possible underlying logic that allows them to be grouped.

The following table shows the share of precursor chemicals within the chemical industry:

:	Import (EUR billion)	Export (EUR billion)	Total EU Sales (EUR billion)
EU Chemical[44] industry	189	224	655
Drug Precursors[45]	0.462	0.766	-
Drug Precursors, category 1[46]	0.015	0.033	-
Designer precursors[47]	0.0004	None	-
Drug Precursors, category 2[48]	0.204	0.029	-
Drug Precursors, category 3[49]	0.221	0.613	-

The only unifying approach that allows to (partially) overcome this problem is one centred on the chemical building blocks, meaning that, indeed, <u>the whole chemical sector is the object of the analysis</u>.

EU chemical industry – importance and competitiveness challenges

Within the EU, the chemical industry is one of the most important sectors of manufacturing, as it:[50]

- represents about 7 % of total EU manufacturing by turnover (2018);
- provides 1.2 million direct jobs, displaying a labour productivity 77 % higher than EU's manufacturing average (2020) and paying wages 48 % higher than EU's manufacturing average (2022);
- displays the 2nd-largest capital spending in the global chemical industry, which has constantly represented over 15 % of the EU chemical industry's value added during the last two decades (19.5 % in 2023);
- is currently (since 2021) spending about EUR 10 billion annually on R&I, which amounts to 6 % of the sector's value added;
- generates trade surpluses of over EUR 40 billion annually (EUR 50 billion in 2024), ranking 4th among all EU industrial sectors.

While there are 29 000 companies operating in the EU chemical industry, meaning that the number of SMEs runs in the tens of thousands, their relevance for this exercise is tenuous and strictly theoretical. In fact, none of the building blocks and of the critical intermediates required for manufacturing the scheduled drug precursors are produced in small companies.

Besides, one of the most (if not squarely the most) important contribution the SMEs are reputedly making to the economy overall is in terms of employment. Yet, over 2/3 of people employed in the EU chemical industry work in large companies:

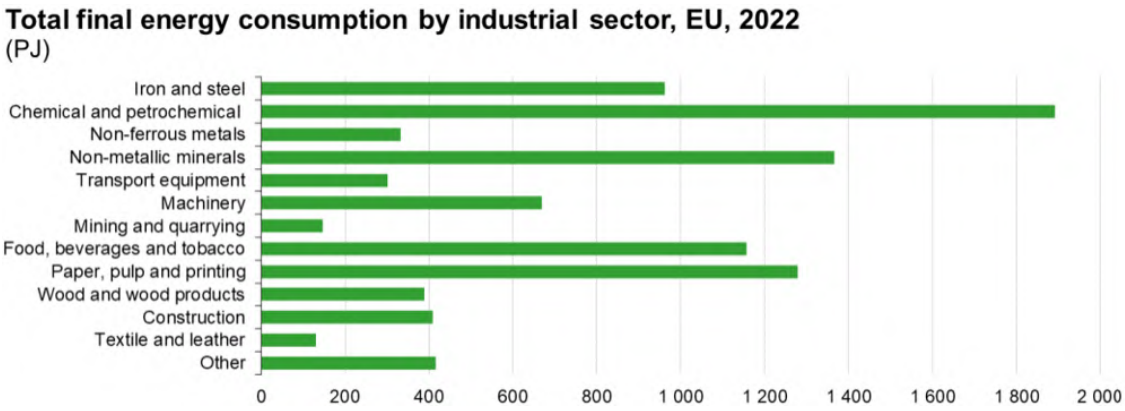
[44] Source : Cefic data (2023)
[45] Source : EU Customs Surveillance (2023)
[46] Ibid.
[47] Ibid.
[48] Ibid.
[49] Ibid.
[50] Based on Eurostat and Cefic

Source: Eurostat

Finally, as already mentioned above, the burdens imposed by the regulation of drug precursors are not dependent on the size of a company (in terms of turnover and/or production volume), but on its product mix. There are therefore no conclusions to be sought and derived from the size of the companies on which these regulations are imposed.

A distinct characteristic of the chemical industry is that it requires energy, which can also be in the form of fossil fuels, not just in order to power its production processes, but in fact mainly as feedstock for obtaining all of its building blocks. This makes it:

- the highest industrial final energy consumer in the EU

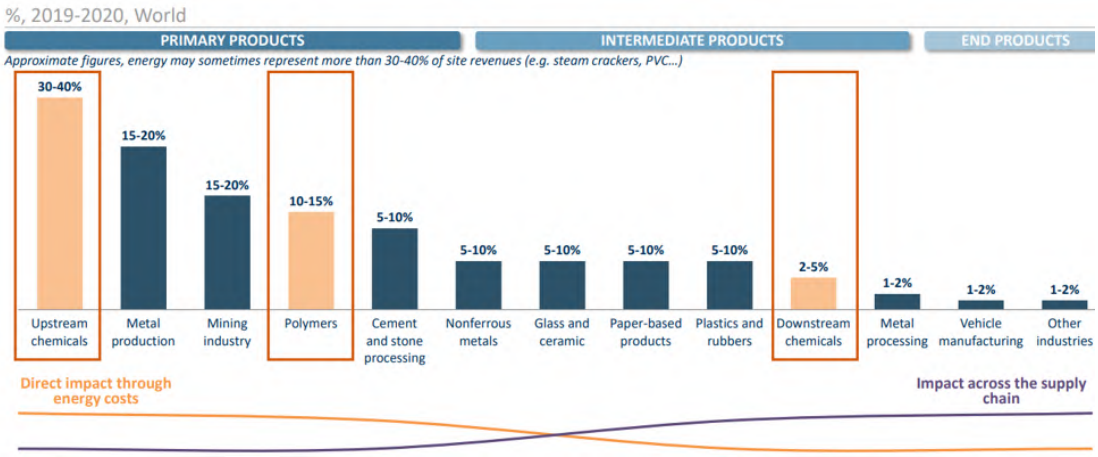


Source: Eurostat

…

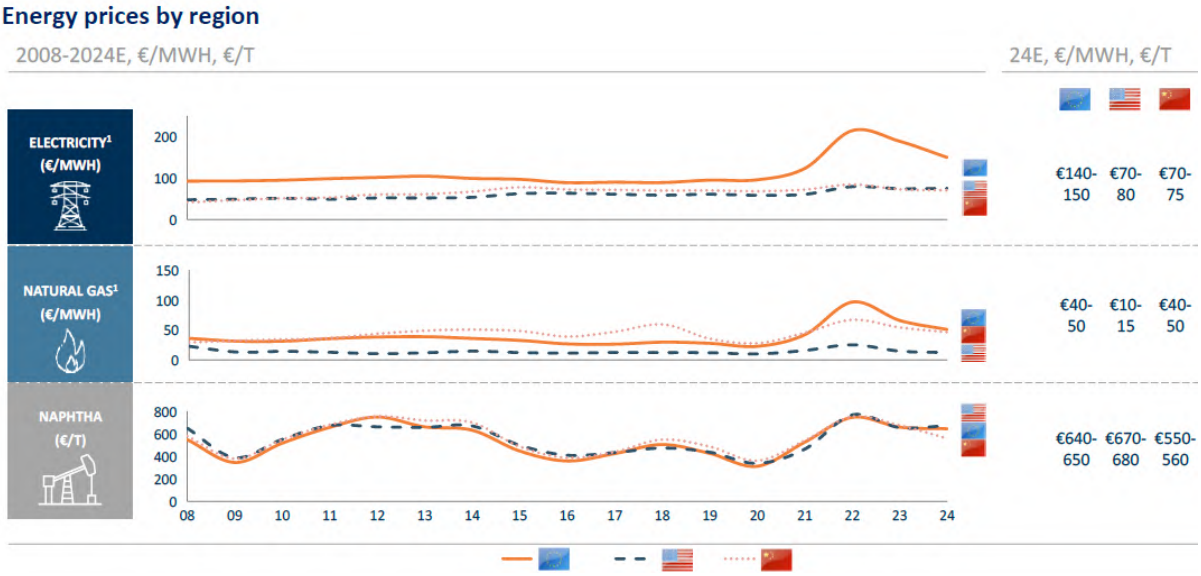
as well as

- the industrial sector displaying the highest energy intensity (in terms of % of revenues):



Source: Cefic and Advancy, January 2025

This has become an invalidating feature for the EU chemical industry in the context of the significantly higher energy prices triggered by the Russian unprovoked aggression of Ukraine launched in February 2022.



Source: Cefic and Advancy, January 2025

Indeed, the competitive position of the EU on the global cost curves for the chemical industry's main building blocks has massively deteriorated.

As chemical products are intensively traded internationally, the EU chemical industry's important erosion of international competitiveness translated itself in a corresponding deterioration of all its main indicators.

a) Production

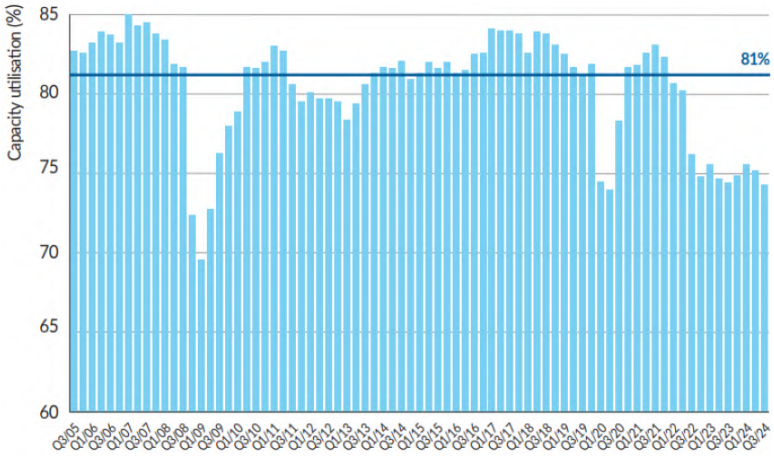
Evolution of production in real terms

	2022	2023	2024
EU, of which:	-6.1 %	-8.2 %	+1.6 %
- Germany*	-10.3 %	-12.1 %	+3.1 %

* Germany is the EU's most important chemical producer. It accounts for one third of the EU chemical industry's sales, equivalent to the combined share of the next three EU producers (France, Italy and the Netherlands)

Sources: Cefic; VCI; BASF

b) Production capacity and capacity utilisation



Source: Cefic

Over the last two years, the EU chemical industry's capacity utilisation rate was 6 percentage points lower than its long-term (20 years) average. In some chemical subsectors the situation is even worse. Such is in particular the case of the chlor-alkali subsector (where chlorine is being produced), whose 12-month rolling average utilisation rate stood at 67.2 % in January 2025, far below the 82 % average recorded over 2019-21 and of the ammonia subsector, where a pickup of gas prices since the last quarter of 2024 led to capacity curtailments that have pushed down the EU ammonia plants average utilisation rate below 70 % currently.

In fact, the state of capacity utilisation in the EU chemical industry is so morose that the most realistic prospect of seeing it improving consists of closures of existing capacities. And these are unfortunately occurring, as illustrated below for the most important chemical building blocks.

OLEFINS

Company	*Location*	*Capacity ('000 t/year)*		*Timing*
		Ethylene	Propylene	
ENI/Versalis	Porto Marghera, IT	490	245	May 2022
Exxon Mobil	Gravenchon, FR	425	290	May 2024
Sabic	Geleen, NL	530	260	May 2024
ENI/Versalis	Brindisi, IT	410	220	April 2025
Dow Chemical	Terneuzen, NL	600	300	April-May 2025
Cumulated capacity closed down = 2.5 million tonnes of ethylene (11.7 % of initial EU capacity)				

METHANOL

Company	*Location*	*Capacity ('000 t/year)*	*Timing*
OCI NV	Delfzijl, NL	200*	2023
BP	Gelsenkirchen, DE	285	2023
Shell	Wesseling, DE	400	Early-2025
Cumulated capacity closed down = ~0.9 million tonnes (ca. 40 % of initial EU capacity)			

***** The closure might not be permanent. It was decided because of the cost of natural gas, but it is idle since almost 2 years.

CHLORINE

Company	*Location*	*Capacity ('000 t/year)*	*Timing*
Kem One	Lavera, FR	333	November 2023
Vencorex	Pont de Claix, FR	118	September 2024
Arkema	Jarrie, FR	73	January 2025
Cumulated capacity closed down = 0.5 million tonnes (4.7 % of initial EU capacity)			

c) Financial situation

No aggregate data exists for the financial performance of the chemical industry as a whole and, *a fortiori*, it cannot exist for a selected part of the chemical industry, i.e., the one that has drug precursors featuring in its product slate.

Given these objective limitations, but to nevertheless provide indications that have at least some relevance, the following table captures the recent financial performance of the largest EU-incorporated companies whose outputs include intermediates *derived from petrochemicals* involved in the production of drug precursors.

EUR million	Net income, after tax (profit/loss)			Proportion of European sales
	2022	2023	2024	(%)
BASF	4 070*	225	1 298	37 %
Evonik	1 054	(465)	222	49 %
Covestro	(272)	(198)	(266)	41 %
Arkema	965	418	354	33 %
Lanxess**	250	(113)	(266)	47 %

***** The figure does not reflect the EUR 4.7 billion impairment recorded in 2022 on account of BASF's stake in Wintershall which it can no longer control given the latter's extensive operations in Russia (as a result, BASF formally reported a net loss of EUR 627 million in 2022)

****** In the case of Lanxess, whose annual report will only be released on 20 March, the 2024 figures refer only to the period January-September.

Source: Fourth quarter and full year 2024 reports of the companies concerned

While the trends conveyed by the figures above are not fully coincident, there is an obvious general deterioration of the financial performance of all companies considered. The main highlight is represented by the losses recorded for 3 years in a row by Covestro, as a result of which its shareholders acquiesced to the takeover bid made by ADNOC (Abu Dhabi National Oil Company), which became the company's majority shareholder at the beginning of 2025. Lanxess also appears to be following a similar path and its postponement of the release of the 2024 results comes as a corroboration.

Although it may look counter-intuitive, all companies considered recorded their best recent financial results in 2022, when energy prices were at all-time highs (which also pushed

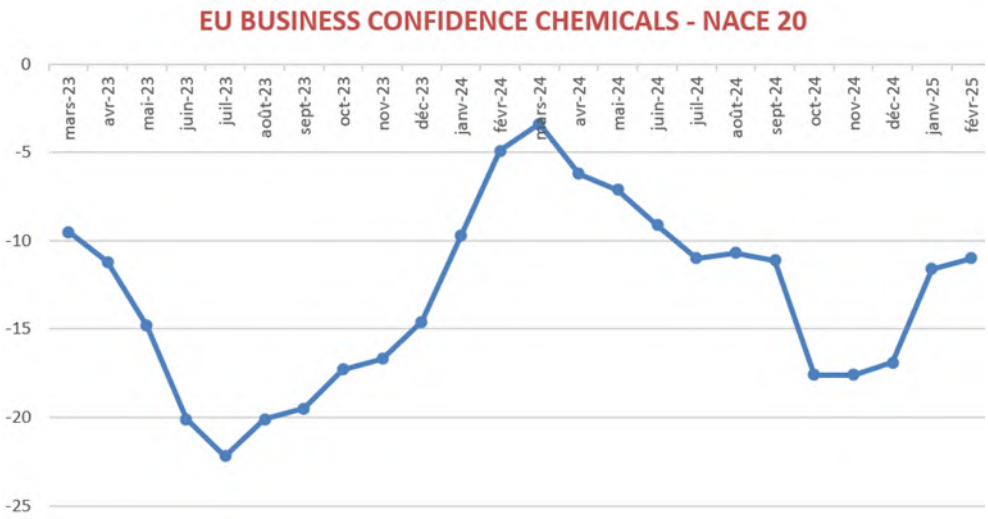
chemical prices to unprecedented records). This does not mean that the high prices of petrochemical feedstock and of energy in Europe do not matter a lot, but quite the opposite: while a market characterised by high prices may validate high (and otherwise uncompetitive) production costs, this is no longer possible in a market characterised by weak demand, where the same suppliers are chasing a depressed volume of potential sales.

d) Business confidence

Following a deterioration of the business confidence sentiment in the EU chemical industry over the last quarter of 2024, a recovery can be noticed since January 2025. This, however, needs sobering qualifications:

- the last time this indicator was in positive territory is May 2022;
- even if significantly better than in all of the previous three months, the indicator displays a considerably worse level than last spring and even last summer.

At most, this is indicative of the fact that what may have looked like a sentiment of panic getting installed has been dispelled.



Source: DG ECFIN business and consumer survey data

3. THE EU DRUG AND DRUG PRECURSORS MARKET

This section summarizes the data that were made available by the EUDA throughout its Annual Reports and Drug Market Reports. Precursor seizures are complex and vary year to year.

3.1. SUMMARY PER DRUG

Cannabis

- Cannabis is the largest illicit drug market in Europe, with around **84 million adults having tried it** and **22.6 million using it in the last year**. Most herbal cannabis is grown within the EU, while cannabis resin mainly comes from Morocco.
- The illicit market now includes a **diverse range of products** like high-potency concentrates, oils, edibles, and vaping products, with increasing potency posing greater health risks.
- In 2021, **seizures of herbal cannabis and resin hit their highest levels in a decade**, mainly in Spain, France, and Italy, reflecting active trafficking routes and domestic cultivation in the Western Balkans.
- Criminal networks from Belgium, the Netherlands, Spain, Albania, and Morocco dominate the market, often cooperating but also driving violence and corruption.
- The market is valued at around **€11.4 billion**, with potency rising sharply over the past decade while prices remained stable. Stronger monitoring, enforcement, and international cooperation are needed to address health, security, and environmental challenges.
- Seizures: 98,000 seizures of cannabis plants, totalling 3.5 million plants and 6.5 tonnes (down from 4.3 million plants and 32.5 tonnes in 2021).
- Cultivation sites dismantled: Nearly 5,700 illicit cannabis grow operations dismantled in 14 Member States.

Heroin

- The heroin market in Europe is worth around **€5.2 billion (2021)**, with about **1 million high-risk opioid users**; opioids were involved in **74% of drug-related deaths** that year.
- Heroin supply remains stable with increasing purity and declining prices; **Afghanistan is still the main source**, though political instability may impact supply routes, which include the Balkan and Southern maritime routes.
- Criminal networks are highly adaptive and use legal businesses, money laundering, and corruption to facilitate heroin trafficking across complex international routes.
- Around **1 million** Europeans used heroin or other illicit opioids in 2020.
- Production sites: Two heroin production sites dismantled in the Netherlands (down from three in 2021).
- Precursor seizures: Only 141 litres of acetic anhydride (heroin precursor) seized in Germany, Spain, and Poland, a significant decrease from 5,730 litres in 2021.
- Trend: Declining global seizures of acetic anhydride may indicate fewer diversion attempts or shifts in trafficking routes.

Cocaine

- Approximately **3.5 million** adults used cocaine in the past year.

- The EU cocaine retail market was valued at a minimum of **€10.5 billion in 2020**, making it the second-largest illicit drug market after cannabis. This estimate likely **understates the true market size**.
- **High-risk criminal networks** dominate cocaine trafficking, profiting billions and operating through complex, fluid networks involving brokers and intermediaries.
- Cocaine seizures in Europe have hit **record highs since 2017**, with **214.6 tonnes seized in 2020** and preliminary 2021 data showing an increase to **240 tonnes**.
- The largest seizures occur at **Belgian, Dutch, and Spanish ports**, but growing amounts are now intercepted at other European ports, indicating expanding trafficking routes.
- Chemical analyses confirm **Colombia remains the main cocaine source**, though Peruvian-origin samples have increased recently.
- Evidence shows **cocaine production is happening within Europe**, especially in the Netherlands, Spain, and Belgium, involving sophisticated operations and new production methods (e.g., using ethyl acetate).
- Cocaine production and trafficking cause **serious environmental harm**, including deforestation linked to coca cultivation and pollution from toxic chemicals used during manufacturing.
- Production sites: At least 39 cocaine production sites dismantled in the EU (up from 34 in 2021).
- Precursor seizures: 173 kg of potassium permanganate seized (down from 1,100 kg in 2021).
- Processing: Large-scale cocaine processing from imported intermediates continues; example includes a Spanish lab with 200 kg daily output.
- Concealed shipments: Notable seizures of chemically concealed cocaine, such as 22 tonnes hidden in sugar (France) and 100 kg in coal (Croatia).

Amphetamine

- Amphetamine is the most common synthetic stimulant in Europe, competing with cocaine and new psychoactive substances. The retail market is valued at approximately **€1.1 billion annually**, with amphetamine powder and paste being the main forms consumed. Use is higher than methamphetamine in most EU countries except for places like Czechia and Slovakia.
- Production is mainly concentrated in **the Netherlands and Belgium**, using the precursor BMK (often derived from chemicals imported from China). Amphetamine oil produced is sometimes trafficked for conversion into amphetamine sulfate elsewhere in the EU. Captagon tablet production, mainly trafficked to the Middle East, occurs occasionally within the EU, especially the Netherlands.
- Amphetamine trafficking within the EU is complex and mainly occurs overland and via postal services, with consignments originating from key production hubs in the Netherlands, Belgium, and Germany. Large seizures of captagon tablets have been made in Greece and Italy, highlighting the EU's role as a transhipment zone for Middle Eastern markets.
- Dutch criminal groups dominate synthetic drug production and trafficking in Europe, working with distributors worldwide. Baltic criminal groups are active in regional amphetamine production and distribution to Nordic countries. Networks use legal businesses, corruption, money laundering, and cooperative strategies to facilitate operations.
- Amphetamine is relatively inexpensive and of variable purity across Europe, with higher purities in Belgium and the Netherlands due to local production. Use is

associated with significant health risks, including cardiovascular effects and risks from injection (such as HIV). Around 5 000 people entered specialized treatment in 2021 citing amphetamine as their primary drug.

- Globally, amphetamine use is smaller compared to methamphetamine but has grown sixfold in seizures from 2010 to 2021. Most amphetamine seizures occur in the Near and Middle East (mainly as captagon) and Europe (mainly powder/paste).
- Approximately **2 million** adults used amphetamines in the past year.
- Labs dismantled: 108 amphetamine labs dismantled in 7 Member States, mainly in the Netherlands (39), Belgium (35), and Poland (22).

Methamphetamine

- Methamphetamine plays a relatively small role in European stimulant markets compared to the global situation, but its threat is increasing as the drug spreads to new markets across Europe. Europe not only produces methamphetamine for its own markets but also acts as a significant source for external markets, with major production hubs in the Netherlands, Belgium, Czechia, and neighbouring countries. Between 2010 and 2020, methamphetamine seizures in the EU increased by 477%, reflecting the rapid expansion of the market. Europe also serves as a transit zone for methamphetamine produced in Iran, Nigeria, Mexico, and increasingly Afghanistan.
- Methamphetamine use remains concentrated mainly in central Europe (notably Czechia and Slovakia), but recent years have seen growth elsewhere. The drug is commonly found as methamphetamine hydrochloride powder and increasingly as crystalline 'ice' or 'crystal meth', which carries higher health risks. Prices vary widely, from approximately €13.50 per gram in Hungary to €113 in Cyprus, with darknet prices around €55 per gram.
- Seizures in the EU have increased both in number and quantity, partly due to industrial-scale labs in the Netherlands and Belgium, supported by collaboration between European and Mexican criminal networks. In 2020, several large-scale labs were dismantled, underscoring the growing sophistication of production.
- Globally, methamphetamine accounts for over 70% of all amphetamine seizures (325 tonnes in 2019), with Asia, North America, and Australia as the largest markets. While Europe's market is smaller, it is an emerging global producer and distributor, with production capacity expanding rapidly.
- About **2.6 million** adults used MDMA/ecstasy in the past year.
- Labs dismantled: 242 methamphetamine labs dismantled in 9 Member States, primarily Czechia (202).
- Precursor seizures: 352 kg of ephedrine and pseudoephedrine seized (down from 723 kg in 2021).
- BMK-related precursors: 1,329 litres of BMK and 26.6 tonnes of related substances seized, including new alternative chemicals DEPAPD and DEPAPD enolate detected for the first time.
- Tartaric acid seizures: 2.6 tonnes seized, indicating ongoing large-scale production of d-methamphetamine ('crystal meth').

MDMA

- MDMA (commonly known as ecstasy) is a synthetic illicit drug prevalent in Europe mainly as tablets, powder, or crystals. The European market, largely supplied by illicit labs in the Netherlands and Belgium, is estimated to have an annual retail value of around **€594 million**, corresponding to about **72 million tablets** consumed yearly.

Despite being smaller in value than other stimulants, MDMA production is highly profitable and increasingly sophisticated, with Dutch criminal networks playing a major role both within Europe and internationally.

- Europe is a prominent global supplier, accounting for approximately **43% of global MDMA seizures** and about half of all dismantled illicit MDMA labs worldwide. Production mainly uses the 'high-pressure' method, though shortages of equipment and precursor chemicals have led to shifts in production techniques and precursor sources, often involving designer chemicals from China.
- MDMA produced in Europe is trafficked worldwide, particularly to Oceania, Asia, and Latin America, with emerging markets in Latin America linked to barter deals exchanging MDMA for cocaine. Within Europe, Germany, Bulgaria, and Belgium are growing distribution hubs, while the Netherlands remains the primary origin of ecstasy trafficking globally.
- Demand is met largely by large-scale EU production, with retail prices and purity varying by region. MDMA distribution relies on diverse channels including land transport, air cargo, maritime shipping, and increasingly, online markets such as darknet and social media platforms.
- Around **12.3 million adults in the EU** have used MDMA at least once, with frequent users responsible for most consumption. While MDMA content per tablet peaked before 2019 and has since slightly declined—partly due to COVID-19 impacts—high-strength ecstasy tablets and novel products like MDMA edibles remain on the market, posing health risks including acute toxicity.
- Labs dismantled: 48 labs dismantled in 6 Member States (27 in Belgium, 13 in the Netherlands).
- Precursor seizures: MDMA precursor seizures increased to 20.5 tonnes (up from 7.1 tonnes in 2021), with PMK and derivatives accounting for 19.9 tonnes.
- Production trends: Increased precursor seizures and exports suggest a rebound in MDMA production post-COVID-19.

Synthetic Cathinones

- Production sites dismantled: 29 sites (mostly in Poland and the Netherlands), nearly double from 15 in 2021.
- Precursor seizures: 558 kg seized, mainly in Poland.
- Notable interception: 1 tonne shipment of 4-CMC precursor stopped in France en route from China to Poland.

Synthetic Opioids (see heroine)

- Synthetic opioids, often from **China, India, and Russia**, are increasingly present in Europe, posing significant public health risks due to high potency and detection challenges.
- Around **1 million** Europeans used heroin or other illicit opioids in 2020.
- Notable seizures (2023): Latvian police dismantled a fentanyl production site, seizing nearly 2 kg of fentanyl and 2.7 kg of precursor NPP, as well as an illicit methadone lab.

Environmental Impact: Dumping Sites

- Drug production waste: 194 dumping sites reported, mostly in Belgium (41) and the Netherlands (153), down from 234 in 2021.

3.2. Overview table per Member State and drug

The figures are approximate and reflect aggregated seizures of key precursors like PMK for MDMA, ephedrine/pseudoephedrine for amphetamines, acetic anhydride for heroin.

Country	Drug	Quantity Seized (Year)	Estimated Quantity Used (Year)	Estimated Number of Users (millions)	Quantity of Precursor Seized	Criminal Threat	Health Issues	Environmental Issues
Austria	Cannabis	10 tons (2021)	Moderate use (2021)	1.9	No data	Organized crime involvement	Increased hospital admissions for cannabis-related issues	None reported
	Cocaine	2 tons (2021)	Low use (2021)	0.5	Limited data	Transnational trafficking	Occasional overdoses	None reported
	Heroin	0.5 tons (2021)	Low use (2021)	0.1	Limited data	Heroin trafficking groups	Opioid overdose deaths	Production waste concerns
	MDMA	0.8 tons (2021)	Low use (2021)	0.3	No data	Small scale production	Ecstasy-related emergencies	None reported
	Amphetamines	1.2 tons (2021)	Low use (2021)	0.2	No data	Street-level dealing	Occasional acute toxicity	None reported
	Methamphetamine	0.3 tons (2021)	Very low use (2021)	No data	No data	Limited	Very low	Minimal
	Synthetic Opioids	0.2 tons (2021)	Low use (2021)	No data	No data	Rising threat	Overdose deaths	None reported
	Cathinones	No data	Very low use (2021)	No data	No data	Limited	No data	No data
Belgium	Cannabis	15 tons (2021)	Moderate use (2021)	1.8	Limited	Organized crime	Hospitalizations for cannabis use	No data

Country	Drug	Quantity Seized (Year)	Estimated Quantity Used (Year)	Estimated Number of Users (millions)	Quantity of Precursor Seized	Criminal Threat	Health Issues	Environmental Issues
	Cocaine	3 tons (2021)	Moderate use (2021)	0.5	Limited	Large trafficking networks	Overdoses	Production waste reported
	Heroin	0.7 tons (2021)	Low use (2021)	0.1	No data	Organized trafficking	Opioid deaths	Some environmental concerns
	MDMA	2 tons (2021)	High use (2021)	0.3	Large precursor seizures	Industrial production	Emergency visits	Chemical waste issues
	Amphetamines	1.5 tons (2021)	Moderate use (2021)	0.2	Moderate precursor seizures	Street dealing	Acute toxicity	No data
	Methamphetamine	1 ton (2021)	Low use (2021)	No data	No data	Industrial scale production	Risks related to 'ice'	Chemical dumping
	Synthetic Opioids	0.4 tons (2021)	Moderate use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	0.2 tons (2021)	Low use (2021)	No data	No data	Street level dealing	Acute toxicity	No data
Bulgaria	Cannabis	5 tons (2021)	Low use (2021)	0.5	No data	Organized crime	Occasional hospitalizations	No data
	Cocaine	1 ton (2021)	Very low use (2021)	0.1	No data	Limited trafficking	Very low	No data
	Heroin	0.3 tons (2021)	Moderate use (2021)	0.05	No data	Heroin trafficking groups	Opioid deaths	Production waste concerns
	MDMA	No data	Very low use (2021)	0.1	No data	Limited	No data	No data
	Amphetamines	0.5 tons (2021)	Low use (2021)	0.1	No data	Street dealing	Occasional toxicity	No data
	Methamphetamine	0.4 tons (2021)	Very low use (2021)	No data	No data	Limited	No data	No data

Country	Drug	Quantity Seized (Year)	Estimated Quantity Used (Year)	Estimated Number of Users (millions)	Quantity of Precursor Seized	Criminal Threat	Health Issues	Environmental Issues
	Synthetic Opioids	No data	Low use (2021)	No data	No data	Emerging threat	Overdose deaths	No data
	Cathinones	No data	Low use (2021)	No data	No data	Limited	No data	No data
Croatia	Cannabis	3 tons (2021)	Moderate use (2021)	0.6	No data	Organized crime	Hospital admissions	No data
	Cocaine	0.5 tons (2021)	Low use (2021)	0.2	No data	Limited trafficking	Low	No data
	Heroin	0.2 tons (2021)	Moderate use (2021)	0.05	No data	Organized crime	Overdose deaths	No data
	MDMA	No data	Low use (2021)	0.1	No data	Limited	No data	No data
	Amphetamines	0.3 tons (2021)	Low use (2021)	0.1	No data	Street dealing	Occasional toxicity	No data
	Methamphetamine	No data	Very low use (2021)	No data	No data	Limited	No data	No data
	Synthetic Opioids	No data	Low use (2021)	No data	No data	Emerging threat	Overdose deaths	No data
	Cathinones	No data	Very low use (2021)	No data	No data	Limited	No data	No data
Cyprus	Cannabis	No data	Moderate use (2021)	0.2	No data	Limited	Hospital admissions	No data
	Cocaine	No data	Low use (2021)	0.05	No data	Limited	No data	No data
	Heroin	No data	Very low use (2021)	0.01	No data	Limited	No data	No data
	MDMA	No data	Low use (2021)	0.03	No data	Limited	No data	No data
	Amphetamines	No data	Low use (2021)	0.02	No data	Limited	No data	No data
	Methamphetamine	No data	Very low use (2021)	No data	No data	Limited	No data	No data
	Synthetic Opioids	No data	Very low use (2021)	No data	No data	Limited	No data	No data

Country	Drug	Quantity Seized (Year)	Estimated Quantity Used (Year)	Estimated Number of Users (millions)	Quantity of Precursor Seized	Criminal Threat	Health Issues	Environmental Issues
	Cathinones	No data	Very low use (2021)	No data	No data	Limited	No data	No data
Czechia	Cannabis	6 tons (2021)	High use (2021)	1.8	No data	Organized crime	Hospital admissions	No data
	Cocaine	1.5 tons (2021)	Moderate use (2021)	0.3	Limited	Trafficking groups	Overdose cases	No data
	Heroin	0.7 tons (2021)	Moderate use (2021)	0.05	No data	Heroin trafficking	Opioid deaths	No data
	MDMA	1 ton (2021)	High use (2021)	0.2	Moderate precursor seizures	Industrial production	Emergency visits	Chemical waste reported
	Amphetamines	2 tons (2021)	High use (2021)	0.1	Large precursor seizures	Street dealing	Acute toxicity	No data
	Methamphetamine	1.8 tons (2021)	High use (2021)	No data	Limited	Industrial scale production	Risks related to ‘ice’	Chemical dumping
	Synthetic Opioids	0.3 tons (2021)	Moderate use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	0.1 tons (2021)	Low use (2021)	No data	No data	Street level dealing	Acute toxicity	No data
Denmark	Cannabis	8 tons (2021)	Moderate use (2021)	1.5	No data	Organized crime	Hospital admissions	No data
	Cocaine	2.5 tons (2021)	Moderate use (2021)	0.3	Limited	Trafficking groups	Overdose deaths	No data
	Heroin	0.6 tons (2021)	Moderate use (2021)	0.05	No data	Heroin trafficking	Opioid overdoses	No data
	MDMA	1.2 tons (2021)	Moderate use (2021)	0.2	Moderate precursor seizures	Industrial production	Emergency visits	Chemical waste concerns

Country	Drug	Quantity Seized (Year)	Estimated Quantity Used (Year)	Estimated Number of Users (millions)	Quantity of Precursor Seized	Criminal Threat	Health Issues	Environmental Issues
	Amphetamines	1.6 tons (2021)	Moderate use (2021)	0.1	Moderate precursor seizures	Street dealing	Acute toxicity	No data
	Methamphetamine	0.9 tons (2021)	Low use (2021)	No data	No data	Industrial scale production	Risks related to 'ice'	Chemical dumping
	Synthetic Opioids	0.4 tons (2021)	Moderate use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	0.3 tons (2021)	Low use (2021)	No data	No data	Street level dealing	Acute toxicity	No data
Estonia	Cannabis	1 ton (2021)	Moderate use (2021)	0.6	No data	Organized crime	Hospital admissions	No data
	Cocaine	0.4 tons (2021)	Low use (2021)	0.1	No data	Limited trafficking	Low	No data
	Heroin	0.2 tons (2021)	Moderate use (2021)	0.02	No data	Organized crime	Opioid overdoses	No data
	MDMA	No data	Low use (2021)	0.07	No data	Limited	No data	No data
	Amphetamines	0.5 tons (2021)	Low use (2021)	0.05	No data	Street dealing	Acute toxicity	No data
	Methamphetamine	No data	Very low use (2021)	No data	No data	Limited	No data	No data
	Synthetic Opioids	No data	Low use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	No data	Very low use (2021)	No data	No data	Limited	No data	No data
Finland	Cannabis	2 tons (2021)	Moderate use (2021)	1.0	No data	Organized crime	Hospital admissions	No data
	Cocaine	0.7 tons (2021)	Low use (2021)	0.2	No data	Limited trafficking	Low	No data
	Heroin	0.3 tons (2021)	Low use (2021)	0.1	No data	Limited	Opioid overdoses	No data
	MDMA	No data	Low use (2021)	0.1	No data	Limited	No data	No data

Country	Drug	Quantity Seized (Year)	Estimated Quantity Used (Year)	Estimated Number of Users (millions)	Quantity of Precursor Seized	Criminal Threat	Health Issues	Environmental Issues
	Amphetamines	0.8 tons (2021)	Moderate use (2021)	0.2	No data	Street dealing	Acute toxicity	No data
	Methamphetamine	No data	Very low use (2021)	No data	No data	Limited	No data	No data
	Synthetic Opioids	0.1 tons (2021)	Low use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	No data	Very low use (2021)	No data	No data	Limited	No data	No data
France	Cannabis	60 tons (2021)	High use (2021)	7.5	Limited precursor seizures	Organized crime	High hospitalizations	No data
	Cocaine	15 tons (2021)	High use (2021)	1.5	Limited precursor seizures	Large trafficking networks	Overdose deaths	Production waste concerns
	Heroin	4 tons (2021)	Moderate use (2021)	0.2	Limited	Organized trafficking	Opioid overdose deaths	Production waste
	MDMA	5 tons (2021)	Moderate use (2021)	1.0	Moderate precursor seizures	Industrial scale production	Emergency visits	Chemical waste
	Amphetamines	7 tons (2021)	High use (2021)	0.5	Moderate precursor seizures	Street dealing	Acute toxicity	No data
	Methamphetamine	2 tons (2021)	Moderate use (2021)	No data	No data	Industrial production	Risks related to ‘ice’	Chemical dumping
	Synthetic Opioids	1 ton (2021)	Moderate use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	0.5 tons (2021)	Low use (2021)	No data	No data	Street dealing	Acute toxicity	No data
Germany	Cannabis	70 tons (2021)	High use (2021)	6.0	Limited precursor seizures	Organized crime	High hospital admissions	No data

Country	Drug	Quantity Seized (Year)	Estimated Quantity Used (Year)	Estimated Number of Users (millions)	Quantity of Precursor Seized	Criminal Threat	Health Issues	Environmental Issues
	Cocaine	20 tons (2021)	High use (2021)	1.0	Moderate precursor seizures	Large trafficking groups	Overdose deaths	Production waste concerns
	Heroin	5 tons (2021)	Moderate use (2021)	0.2	No data	Organized trafficking	Opioid deaths	Production waste concerns
	MDMA	6 tons (2021)	High use (2021)	0.8	Large precursor seizures	Industrial production	Emergency visits	Chemical waste issues
	Amphetamines	8 tons (2021)	High use (2021)	0.4	Large precursor seizures	Street dealing	Acute toxicity	No data
	Methamphetamine	3 tons (2021)	Moderate use (2021)	No data	No data	Industrial scale production	Risks related to ‘ice’	Chemical dumping
	Synthetic Opioids	1.5 tons (2021)	Moderate use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	0.7 tons (2021)	Low use (2021)	No data	No data	Street dealing	Acute toxicity	No data
Greece	Cannabis	10 tons (2021)	Moderate use (2021)	1.0	No data	Organized crime	Hospital admissions	No data
	Cocaine	3 tons (2021)	Moderate use (2021)	0.2	No data	Trafficking groups	Overdose deaths	No data
	Heroin	2 tons (2021)	Moderate use (2021)	0.05	No data	Organized trafficking	Opioid deaths	Production waste concerns
	MDMA	0.5 tons (2021)	Low use (2021)	0.1	No data	Limited	No data	No data
	Amphetamines	1 ton (2021)	Low use (2021)	0.1	No data	Street dealing	Acute toxicity	No data
	Methamphetamine	No data	Very low use (2021)	No data	No data	Limited	No data	No data
	Synthetic Opioids	No data	Low use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	No data	Low use (2021)	No data	No data	Limited	No data	No data
Hungary	Cannabis	3 tons (2021)	Moderate use (2021)	0.3	No data	Organized crime	Hospital admissions	No data

Country	Drug	Quantity Seized (Year)	Estimated Quantity Used (Year)	Estimated Number of Users (millions)	Quantity of Precursor Seized	Criminal Threat	Health Issues	Environmental Issues
	Cocaine	0.7 tons (2021)	Low use (2021)	0.05	No data	Limited trafficking	Low	No data
	Heroin	0.5 tons (2021)	Moderate use (2021)	0.01	No data	Organized trafficking	Opioid deaths	No data
	MDMA	No data	Low use (2021)	0.03	No data	Limited	No data	No data
	Amphetamines	1 ton (2021)	Moderate use (2021)	0.02	No data	Street dealing	Acute toxicity	No data
	Methamphetamine	0.8 tons (2021)	Low use (2021)	No data	No data	Limited	No data	No data
	Synthetic Opioids	No data	Low use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	No data	Low use (2021)	No data	No data	Limited	No data	No data
Ireland	Cannabis	12 tons (2021)	High use (2021)	1.0	No data	Organized crime	Hospital admissions	No data
	Cocaine	4 tons (2021)	High use (2021)	0.3	Limited precursor seizures	Trafficking groups	Overdose deaths	No data
	Heroin	1 ton (2021)	Moderate use (2021)	0.05	No data	Organized trafficking	Opioid deaths	No data
	MDMA	1.5 tons (2021)	Moderate use (2021)	0.2	Moderate precursor seizures	Industrial scale	Emergency visits	Chemical waste concerns
	Amphetamines	2 tons (2021)	Moderate use (2021)	0.1	Limited precursor seizures	Street dealing	Acute toxicity	No data
	Methamphetamine	0.5 tons (2021)	Low use (2021)	No data	No data	Limited	No data	No data
	Synthetic Opioids	0.6 tons (2021)	Moderate use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	0.4 tons (2021)	Low use (2021)	No data	No data	Street dealing	Acute toxicity	No data

Country	Drug	Quantity Seized (Year)	Estimated Quantity Used (Year)	Estimated Number of Users (millions)	Quantity of Precursor Seized	Criminal Threat	Health Issues	Environmental Issues
Italy	Cannabis	40 tons (2021)	High use (2021)	4.0	Limited precursor seizures	Organized crime	Hospital admissions	No data
	Cocaine	12 tons (2021)	High use (2021)	0.8	Limited precursor seizures	Large trafficking networks	Overdose deaths	Production waste
	Heroin	5 tons (2021)	Moderate use (2021)	0.1	No data	Organized trafficking	Opioid deaths	Production waste concerns
	MDMA	3 tons (2021)	Moderate use (2021)	0.5	Moderate precursor seizures	Industrial scale	Emergency visits	Chemical waste
	Amphetamines	5 tons (2021)	Moderate use (2021)	0.3	Limited precursor seizures	Street dealing	Acute toxicity	No data
	Methamphetamine	2 tons (2021)	Low use (2021)	No data	No data	Limited	Risks related to ‘ice’	Chemical dumping
	Synthetic Opioids	1 ton (2021)	Moderate use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	0.5 tons (2021)	Low use (2021)	No data	No data	Street dealing	Acute toxicity	No data
Latvia	Cannabis	2 tons (2021)	Moderate use (2021)	0.3	No data	Organized crime	Hospital admissions	No data
	Cocaine	0.3 tons (2021)	Low use (2021)	0.05	No data	Limited trafficking	Low	No data
	Heroin	0.1 tons (2021)	Low use (2021)	0.01	No data	Organized trafficking	Opioid overdoses	No data
	MDMA	No data	Low use (2021)	0.03	No data	Limited	No data	No data
	Amphetamines	0.4 tons (2021)	Low use (2021)	0.02	No data	Street dealing	Acute toxicity	No data

Country	Drug	Quantity Seized (Year)	Estimated Quantity Used (Year)	Estimated Number of Users (millions)	Quantity of Precursor Seized	Criminal Threat	Health Issues	Environmental Issues
	Methamphetamine	No data	Very low use (2021)	No data	No data	Limited	No data	No data
	Synthetic Opioids	No data	Low use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	No data	Very low use (2021)	No data	No data	Limited	No data	No data
Lithuania	Cannabis	3 tons (2021)	Moderate use (2021)	0.3	No data	Organized crime	Hospital admissions	No data
	Cocaine	0.2 tons (2021)	Low use (2021)	0.05	No data	Limited trafficking	Low	No data
	Heroin	0.1 tons (2021)	Low use (2021)	0.01	No data	Organized trafficking	Opioid overdoses	No data
	MDMA	No data	Low use (2021)	0.03	No data	Limited	No data	No data
	Amphetamines	0.6 tons (2021)	Low use (2021)	0.02	No data	Street dealing	Acute toxicity	No data
	Methamphetamine	No data	Very low use (2021)	No data	No data	Limited	No data	No data
	Synthetic Opioids	No data	Low use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	No data	Very low use (2021)	No data	No data	Limited	No data	No data
Luxembourg	Cannabis	1.5 tons (2021)	Moderate use (2021)	0.2	No data	Organized crime	Hospital admissions	No data
	Cocaine	0.8 tons (2021)	Moderate use (2021)	0.05	No data	Limited trafficking	Low	No data
	Heroin	0.1 tons (2021)	Low use (2021)	0.01	No data	Organized trafficking	Opioid overdoses	No data
	MDMA	No data	Low use (2021)	0.03	No data	Limited	No data	No data
	Amphetamines	0.7 tons (2021)	Low use (2021)	0.02	No data	Street dealing	Acute toxicity	No data
	Methamphetamine	No data	Very low use (2021)	No data	No data	Limited	No data	No data

Country	Drug	Quantity Seized (Year)	Estimated Quantity Used (Year)	Estimated Number of Users (millions)	Quantity of Precursor Seized	Criminal Threat	Health Issues	Environmental Issues
	Synthetic Opioids	No data	Low use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	No data	Very low use (2021)	No data	No data	Limited	No data	No data
Malta	Cannabis	1 ton (2021)	Moderate use (2021)	0.1	No data	Organized crime	Hospital admissions	No data
	Cocaine	0.3 tons (2021)	Low use (2021)	0.02	No data	Limited trafficking	Low	No data
	Heroin	No data	Low use (2021)	0.005	No data	Organized trafficking	Opioid overdoses	No data
	MDMA	No data	Low use (2021)	0.01	No data	Limited	No data	No data
	Amphetamines	No data	Low use (2021)	0.01	No data	Street dealing	Acute toxicity	No data
	Methamphetamine	No data	Very low use (2021)	No data	No data	Limited	No data	No data
	Synthetic Opioids	No data	Low use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	No data	Very low use (2021)	No data	No data	Limited	No data	No data
The Netherlands	Cannabis	150 tons (2021)	High use (2021)	3.0	Significant precursor seizures	Major production hub	Hospital admissions	Production waste concerns
	Cocaine	20 tons (2021)	High use (2021)	0.5	Moderate precursor seizures	Major trafficking hub	Overdose deaths	Production waste
	Heroin	3 tons (2021)	Moderate use (2021)	0.1	No data	Organized trafficking	Opioid overdoses	Production waste
	MDMA	10 tons (2021)	High use (2021)	0.3	Large precursor seizures	Global production center	Emergency visits	Chemical waste

Country	Drug	Quantity Seized (Year)	Estimated Quantity Used (Year)	Estimated Number of Users (millions)	Quantity of Precursor Seized	Criminal Threat	Health Issues	Environmental Issues
	Amphetamines	12 tons (2021)	High use (2021)	0.2	Large precursor seizures	Industrial scale	Acute toxicity	No data
	Methamphetamine	1 ton (2021)	Moderate use (2021)	No data	No data	Industrial production	Risks related to ‘ice’	Chemical dumping
	Synthetic Opioids	1.2 tons (2021)	Moderate use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	0.8 tons (2021)	Low use (2021)	No data	No data	Street dealing	Acute toxicity	No data
Poland	Cannabis	15 tons (2021)	Moderate use (2021)	1.0	Limited precursor seizures	Organized crime	Hospital admissions	No data
	Cocaine	5 tons (2021)	Low use (2021)	0.2	No data	Limited trafficking	Low	No data
	Heroin	2 tons (2021)	Moderate use (2021)	0.05	No data	Organized trafficking	Opioid overdoses	No data
	MDMA	1 ton (2021)	Low use (2021)	0.1	No data	Limited	No data	No data
	Amphetamines	3 tons (2021)	Moderate use (2021)	0.1	Limited precursor seizures	Street dealing	Acute toxicity	No data
	Methamphetamine	2 tons (2021)	Moderate use (2021)	No data	No data	Industrial production	Risks related to ‘ice’	Chemical dumping
	Synthetic Opioids	No data	Low use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	0.4 tons (2021)	Low use (2021)	No data	No data	Street dealing	Acute toxicity	No data
Portugal	Cannabis	10 tons (2021)	High use (2021)	1.0	No data	Organized crime	Hospital admissions	No data
	Cocaine	8 tons (2021)	High use (2021)	0.2	No data	Trafficking networks	Overdose deaths	No data
	Heroin	1.5 tons (2021)	Moderate use (2021)	0.05	No data	Organized trafficking	Opioid overdoses	No data

Country	Drug	Quantity Seized (Year)	Estimated Quantity Used (Year)	Estimated Number of Users (millions)	Quantity of Precursor Seized	Criminal Threat	Health Issues	Environmental Issues
	MDMA	1 ton (2021)	Moderate use (2021)	0.1	No data	Limited	No data	No data
	Amphetamines	2 tons (2021)	Moderate use (2021)	0.1	No data	Street dealing	Acute toxicity	No data
	Methamphetamine	No data	Low use (2021)	No data	No data	Limited	No data	No data
	Synthetic Opioids	No data	Low use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	No data	Low use (2021)	No data	No data	Limited	No data	No data
Romania	Cannabis	4 tons (2021)	Low use (2021)	0.3	No data	Organized crime	Hospital admissions	No data
	Cocaine	0.5 tons (2021)	Low use (2021)	0.05	No data	Limited trafficking	Low	No data
	Heroin	0.2 tons (2021)	Low use (2021)	0.01	No data	Organized trafficking	Opioid overdoses	No data
	MDMA	No data	Low use (2021)	0.03	No data	Limited	No data	No data
	Amphetamines	0.6 tons (2021)	Low use (2021)	0.02	No data	Street dealing	Acute toxicity	No data
	Methamphetamine	No data	Very low use (2021)	No data	No data	Limited	No data	No data
	Synthetic Opioids	No data	Low use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	No data	Very low use (2021)	No data	No data	Limited	No data	No data
Slovakia	Cannabis	3 tons (2021)	Moderate use (2021)	0.5	No data	Organized crime	Hospital admissions	No data
	Cocaine	0.4 tons (2021)	Low use (2021)	0.1	No data	Limited trafficking	Low	No data
	Heroin	0.3 tons (2021)	Moderate use (2021)	0.02	No data	Organized trafficking	Opioid overdoses	No data
	MDMA	No data	Low use (2021)	0.07	No data	Limited	No data	No data

Country	Drug	Quantity Seized (Year)	Estimated Quantity Used (Year)	Estimated Number of Users (millions)	Quantity of Precursor Seized	Criminal Threat	Health Issues	Environmental Issues
	Amphetamines	1 ton (2021)	Moderate use (2021)	0.05	No data	Street dealing	Acute toxicity	No data
	Methamphetamine	No data	Low use (2021)	No data	No data	Limited	No data	No data
	Synthetic Opioids	No data	Low use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	No data	Low use (2021)	No data	No data	Limited	No data	No data
Slovenia	Cannabis	2 tons (2021)	Moderate use (2021)	0.3	No data	Organized crime	Hospital admissions	No data
	Cocaine	0.5 tons (2021)	Low use (2021)	0.05	No data	Limited trafficking	Low	No data
	Heroin	0.3 tons (2021)	Moderate use (2021)	0.01	No data	Organized trafficking	Opioid overdoses	No data
	MDMA	No data	Low use (2021)	0.03	No data	Limited	No data	No data
	Amphetamines	0.8 tons (2021)	Moderate use (2021)	0.02	No data	Street dealing	Acute toxicity	No data
	Methamphetamine	No data	Low use (2021)	No data	No data	Limited	No data	No data
	Synthetic Opioids	No data	Low use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	No data	Low use (2021)	No data	No data	Limited	No data	No data
Spain	Cannabis	50 tons (2021)	High use (2021)	4.0	Limited precursor seizures	Organized crime	Hospital admissions	No data
	Cocaine	18 tons (2021)	High use (2021)	1.0	Limited precursor seizures	Large trafficking groups	Overdose deaths	Production waste concerns
	Heroin	4 tons (2021)	Moderate use (2021)	0.1	No data	Organized trafficking	Opioid overdoses	Production waste
	MDMA	3 tons (2021)	Moderate use (2021)	0.6	Moderate precursor seizures	Industrial scale	Emergency visits	Chemical waste

Country	Drug	Quantity Seized (Year)	Estimated Quantity Used (Year)	Estimated Number of Users (millions)	Quantity of Precursor Seized	Criminal Threat	Health Issues	Environmental Issues
	Amphetamines	5 tons (2021)	Moderate use (2021)	0.3	Limited precursor seizures	Street dealing	Acute toxicity	No data
	Methamphetamine	1.5 tons (2021)	Low use (2021)	No data	No data	Limited	Risks related to 'ice'	Chemical dumping
	Synthetic Opioids	1 ton (2021)	Moderate use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	0.5 tons (2021)	Low use (2021)	No data	No data	Street dealing	Acute toxicity	No data
Sweden	Cannabis	8 tons (2021)	Moderate use (2021)	1.5	No data	Organized crime	Hospital admissions	No data
	Cocaine	2 tons (2021)	Low use (2021)	0.2	No data	Limited trafficking	Low	No data
	Heroin	0.8 tons (2021)	Low use (2021)	0.05	No data	Organized trafficking	Opioid overdoses	No data
	MDMA	0.7 tons (2021)	Low use (2021)	0.1	No data	Limited	No data	No data
	Amphetamines	1.5 tons (2021)	Moderate use (2021)	0.1	No data	Street dealing	Acute toxicity	No data
	Methamphetamine	No data	Low use (2021)	No data	No data	Limited	No data	No data
	Synthetic Opioids	No data	Low use (2021)	No data	No data	Rising threat	Overdose deaths	No data
	Cathinones	No data	Very low use (2021)	No data	No data	Limited	No data	No data

3.3. UNEVEN IMPLEMENTATION ACROSS MEMBER STATES – STUDY FINDINGS

The study reaffirmed a key finding from the 2020 Evaluation: inconsistent implementation and enforcement of EU drug precursor regulations across Member States (MS) undermines the system's effectiveness. Specifically, 15 out of 27 MS authorities indicated that uneven enforcement creates "paths of least resistance," exploited by organised criminal groups (OCGs) to traffic drug precursors into and across the EU. This aligns with the European Union Drugs Agency (EUDA)'s 2024 report, which highlights OCGs' use of commercial transportation infrastructure—particularly EU ports—as a major driver of drug availability. Around 70% of drug seizures occur in EU ports, especially in large intermodal container hubs in Belgium and the Netherlands. However, smaller ports are increasingly being targeted, and although systematic data on precursors are lacking, interviews suggest similar trafficking patterns.

Differences among MS emerge across three main dimensions:

Legal frameworks:

Several MS have adopted national legislation that complements or extends EU rules. Examples include the Dutch ban on certain designer precursors not yet scheduled at the EU level; Denmark's special licensing requirements for substances with no known legitimate use; Czech restrictions on the quantity of certain Category 4 substances available for purchase in pharmacies; and Italy's obligation to notify its anti-drug authority immediately about commercial transactions involving specific precursors. In addition, some MS (e.g. Italy, Hungary, Czech Republic) have gone further by treating unscheduled substances such as GBL and BDO as illicit drugs. Legal systems also diverge in terms of penalties and prosecutorial priority: some countries impose harsher sanctions for precursor-related offences, while others may deprioritise such cases, creating enforcement loopholes.

Discretionary implementation of EU measures

Several EU drug precursor regulations leave room for national discretion, which has led to inconsistent application across MS. This includes voluntary monitoring of non-scheduled substances and the "catch-all" clause, which allows authorities to intervene in cases not explicitly covered by the legislation. Some countries, like Belgium and Hungary, impose stricter requirements by obliging operators to prove the licit use of such substances. France has recently enhanced its customs authority's capacity to investigate unclassified substances. Other disparities concern the scope and format of reporting obligations, the interpretation of subjective provisions (particularly concerning mixtures), and the adoption of technological tools to support implementation. These inconsistencies not only complicate enforcement but also increase legal uncertainty for operators.

Enforcement capacity and awareness

Control and detection capabilities differ not only between MS but also within them—particularly at various entry points. Familiarity with drug precursor issues varies widely, depending on how acutely each MS is affected. Nevertheless, enforcement gaps are broadly acknowledged: 24 out of 29 MS authorities surveyed agreed that stronger implementation and enforcement support should be a key objective of future policy reform. As echoed in public consultation feedback, this support should include improved information-sharing, scientific and technical guidance, international cooperation, and training. The lack of uniform enforcement creates an uneven risk environment, where some

jurisdictions become preferred entry points for traffickers due to weaker oversight or lower institutional awareness.

In summary, the consultation findings highlight that divergence in legal structures, discretionary practices, and enforcement capacity continues to undermine the EU drug precursors framework. Harmonisation—both in legal interpretation and operational practice—is broadly seen as essential to reduce vulnerabilities, ensure fair treatment of legitimate operators, and strengthen the EU's collective ability to prevent precursor diversion.